

**8th Annual Controversies in Dialysis Access - Washington, USA - October 10-11, 2011**

## ESRD Update: What's new?

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The major access issues continue to be: increasing fistula use in hemodialysis patients; understanding the mechanisms of and preventing fistula and graft failures; and prevention of dialysis catheter-related thrombosis and infection. This lecture will highlight key publications from 2011 addressing these issues.

A recent study provided an update on the Fistula First Initiative (1). From 2007 to 2010 the proportion of U.S. hemodialysis patients with fistulas increased from 45.3 to 55.5%, whereas catheter use decreased from 28.2 to 24.0%. There was substantial variability among dialysis networks. Unfortunately, fewer than 20% of patients initiated dialysis with a usable fistula, suggesting a need for substantial improvement in pre-dialysis access planning.

Early fistula failure due to non-maturation remains a major hurdle to increasing fistula use. Fistula non-maturation is frequently associated with remediable anatomic problems, such as perianastomotic stenosis, large accessory veins, or excessive fistula depth. Percutaneous or surgical interventions to correct the underlying anatomic problems can successfully convert many immature fistulas to ones suitable for dialysis. A recent multi-center study pointed out that there is a price to pay for multiple salvage procedures in immature fistulas (2). As compared with fistulas that matured without intervention, those requiring 2 or more interventions had shorter cumulative access survival (68 vs 92% at 1 year, 57 vs 85% at 2 years, and 42 vs 75% at 3 years). In addition, the number of interventions required to maintain fistula patency after maturation was 3.51 vs 0.76 per year in patients with  $\geq 2$  vs zero interventions before maturation. The cellular mechanism of fistula non-maturation remains poorly understood. There is controversy about whether intimal hyperplasia pre-exists in the veins used for fistula creation or whether it develops as a consequence of fistula creation. A recent study obtained vascular specimens at the time of fistula creation, and again at the time of surgical revision of immature fistulas several months later (3). There was no venous intimal hyperplasia at the time of fistula creation, and intense intimal hyperplasia at the time of revision, suggesting *de novo* intimal hyperplasia as a mechanism of fistula non-maturation.

When a pre-dialysis patient is deemed more suitable for a graft than a fistula, there is controversy over whether the graft should be placed before or after initiation of dialysis. A recent single-center study compared outcomes in the two patient groups (4). Patients with graft placement post-dialysis had a median catheter dependence of 48 days and a mean of 0.63 episodes of catheter-dependent bacteremia. In contrast, 86% of patients receiving grafts pre-dialysis had no catheter-dependence at initiation of dialysis. Cumulative graft survival was similar in both groups. This study concluded that graft placement should not be delayed in CKD patients.

Finally, two randomized studies evaluated lock solutions for prophylaxis of catheter complications. The Pre-CLOT study randomized 225 patients to receive prophylactic tPA locks once weekly and heparin twice weekly or standard heparin locks thrice weekly (5). Weekly prophylactic tPA was associated with lower catheter dysfunction (35 vs 20% at 6 months) and fewer episodes of catheter-related bacteremia (0.4 vs 1.4 episodes per 1000 catheter-days). The second study randomized 407 patients to methylene blue or heparin locks (6). The former group had a lower frequency of catheter-related bacteremia (0.24 vs 0.82 per 1000 catheter-days).

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## Access Selection: Is there a Method to the Madness?

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Controversy surrounds the establishment of proper planning, placement and management of dialysis access. These include how to select the dialysis modality i.e. Hemodialysis (HD) vs. Peritoneal Dialysis (PD), type and site of HD access, timing of access placement and who places the access. The lack of and the difficulty of performing randomized studies with many confounding factors, in a heterogeneous and rapidly changing demographics in the end stage renal disease explains the dialysis access conundrum. Add to this the rapidly developing and competing technologies, the wide spectrum of professional experience, bias and socio-economic forces, making the dialysis access multivariate and complex (1).

The overzealous creation of arteriovenous fistulae (AVF) may have resulted in the astounding failure to mature rate of 60% (2), and likely contributed to the high NA central venous catheter initiation and prevalent rate of 81 % and 25-50% respectively. Newer vascular graft designs and proper re-evaluation of data have shown graft survival rates exceeding that of native AVF (2, Lok: Unpublished data). Newer designs that show this benefit include the luminal surface bonded Heparin expanded PolyTetraFluoroEthylene (e-PTFE) grafts (3). Improved outcomes depend not only on new access designs but also on the proper patient selection (1). Many factors play into proper patient selection for the most suitable mode of dialysis and type of access (including vascular grafts) (5). These include patient characteristics i.e. age, co-morbidity severity, vessel quality based on preoperative ultrasound (US) and patient life expectancy (1,4). For instance if we consider 25 access surgical site possible in four extremities including PD sites and then consider 20 patient variables that influence the site decision; then there are more than 300 surgical options! An example of a specific scenario where a vascular graft should be considered or preferred include a forearm loop e-PTFE versus upper arm vein transposition AVF in the obese or in the elderly with predicted short longevity. Also, this approach will mature upper arm veins, enabling a future native transposition vein AVF.

Conclusion: Access type, site and location must be chosen to serve the specific short and long-term needs of the patient. A simple validated AVF failure risk score may assist with selecting the best access for the patient (4). It must be stressed that PD remains the best option in the majority of patients for first time dialysis access (5).

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## Simulation in AV Access Surgery

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Medical simulation is an emerging and rapidly evolving field. Simulation can take many forms, ranging from devices designed to train individuals on specific techniques or tasks, to team training where groups of individuals practice healthcare delivery in a simulated environment. While anecdotal information exists regarding effectiveness, large-scale evidence of cost-effectiveness in healthcare is lacking.

Other industries, including the military, have demonstrated that the optimal use of simulation reproduces realistic situations by placing teams of people who normally work together within simulated environments that represent reality. Technologically advanced simulators may be used when necessary, however an essential component of

any simulation is that the participants interact with each other, with their environment and with technology in a manner consistent "real life".

Vascular access training is particularly suited to simulation. Optimizing ESRD patient outcomes, safety, and cost-effectiveness requires that teams of people caring for the patient have common treatment goals, objectives, and protocols. In addition, it is essential that ESRD healthcare provider teams understand the risks and benefits of the various methods of providing access and of treating complications. The future of healthcare economics will emphasize cost-effectiveness as a measure of outcomes.

Vascular access simulation training can improve patient care by enhancing communication between team members, increasing technical skills proficiency, and establishing criteria and testing for competence. The CIDA simulation skills sessions provide an opportunity to experience team training and technical procedure learning that can be reproduced locally to improve patient care, outcomes, and cost effectiveness.

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## Don't Stick without Ultrasound

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Ultrasound guided central venipuncture is gaining wide acceptance in the world of vascular access as the new 'standard of care' for central venous cannulation. It is a safe and cost-effective clinical practice supported by clear and definitive *evidence*. Though, there are still some restraints to its widespread adoption, mostly because of concerns related more to *psycho-anthropological issues* than to scientific issues. On the other hand, the main aspect which may really become an obstacle to the adoption of ultrasound guidance is the need for a specific *training*. This is a critical factor, since self training or poor training is associated with suboptimal results and even with some complications. Therefore, our current efforts should be directed to standardize the training for ultrasound guided central venipuncture, focusing on (a) appropriate training curriculum (which should include theory, lab practice and clinical practice), (b) adequate use of simulation training devices, (c) knowledge of *central venous anatomy*, and (d) knowledge of the appropriate *techniques* of ultrasound guided venipuncture.

*Evidence* - There is a wide and compelling evidence that US guided venipuncture (by real time ultrasonography) is overall associated with a significantly lower incidence of complications and a higher rate of success if compared to 'blind' venipuncture. Ultrasound support is strongly recommended for all CVC insertions. The advantages of US guidance for placement of CVC have been demonstrated in many RCTs and confirmed by all meta-analyses on this subject: in 1996, in a meta-analysis of eight RCTs, US guidance was characterized by a lower rate of failure and complications and by a higher rate of success at the first attempt if compared to the landmark technique (Randolph, 1996). Few years later, in 2001, the Stanford Evidence Based Practice Center at the UCSF published the results of the project 'Making Health Care Safer: A critical analysis of patient safety practices', identifying US guidance for CVC placement as one of eleven evidence-based clinical tools which should be enforced in clinical practice (Rothschild, 2001). In 2002, the National Institute for Clinical Excellence (NICE guidelines, 2002) made the following recommendations: 'imaging US guidance should be the preferred method when inserting a CVC into the internal jugular vein in adults and children in elective situations'. Also, 'imaging US guidance should be considered in most clinical situations where CVC insertion is necessary, whether the situation is elective or an emergency'. An other meta-analysis of 18 RCT showed that US guidance is highly effective in reducing the rate of failure, the rate of complications, the rate of accidental arterial puncture, thus 'clearly improving patient's safety' (Keenan, 2002). Similar results are shown in a 2003 meta-analysis (Hind, 2003), which also showed that US guided venipuncture takes less time to perform than blind venipuncture; the same Authors concluded that 'economic modelling indicates that US is likely to save NHS resources as well as improve failure and complication rates,' and that 'for every 1000 procedures, a resource saving of 2000 pounds is suggested' (Calvert, 2004). More recently, many randomized studies have confirmed - with no exception - the

superiority of US guided venipuncture, not only as an elective procedure, but also in the emergency department (Leung, 2006). A wide, randomized study on US guided vs. blind catheterization of the internal jugular vein has also shown that in critical patients US guidance is associated also with a decrease of CR BSI (Karakitsos, 2006). According to the BCSH guidelines (BCSH 2006), to the position statements of the American College of Surgeons (ACS 2008) and of the Association for Vascular Access (AVA 2008), as well as to ESPEN guidelines (ESPEN, 2009), ultrasound guided insertion is today recommended for all routes of central venous catheterisation.

As brilliantly stated during the 2007 Congress of the Association for Vascular Access in 2007, 'there is now strong statistical evidence that US is more effective than the landmark method for CVA in both adults and children. It may be considered unethical or lacking in common sense to withhold the use of available machines that will certainly help operators determine the location and patency of target vessels. The evidence is extensive, randomized, controlled and compelling in favor of ultrasound guidance' (LeDonne, 2007).

*Psycho-anthropological issues* – Though the scientific evidence is beyond discussion, still a significant percentage of physicians (in particular, surgeons and anesthesiologists) is reluctant to learn and adopt ultrasound guidance. This has become a very interesting psychological-anthropological issue, which must be faced and solved before this clinical practice may achieve universal consent. Physicians and institutions which deal with the quality and safety of health care delivery should try to understand the mechanisms which stops physicians to use ultrasound guidance, as well as to define strategies to overcome such psychological barriers. Why does an expert and dedicated physician refuse to adopt a technique which – according to common sense and overwhelming scientific evidence – clearly increase the patient's safety, the cost-effectiveness of the procedure and the overall efficiency of his/her practice? There are 'surface' motivations, sometimes related to the clinician's ego ('I do not need it, I am already expert ...'), sometimes characterized by a shifting of responsibility ('We do not possess ultrasound machines ...') or by a superficial knowledge of the literature ('The procedure becomes long and difficult ...', 'I doubt this is going to make the procedure safer ...'). Though, much more important is to recognize that there are deep, hard-to-confess motivations behind this aptitude: ignorance of the medical literature, difficulty in changing long standing habits, mental idleness, instinctive protection of one's own behavior, lack of interest for patient's safety, and – ultimately – lack of trust and motivation in one's own cultural and professional progress.

*Training* – As clearly stated by Bodenham in a very important paper about ultrasound guided cannulation, "operators are ethically and legally vulnerable if they have not been adequately trained, or use inappropriate equipment" (Bodenham, 2006). Two of the scientific associations most focused on the issue of ultrasound guided central venous cannulation, GAVeCeLT (the Italian Group for Central Venous Access) and WINFOCUS (The World Interactive Network Focused on Critical Ultrasound), are currently developing a standardized training pattern consisting of a clearly defined teaching protocol inspired by the international recommendations. This teaching protocol includes formal didactic lessons, laboratory training, a practical proctored phase and a self training phase. A post-instructional assessment is also recommended, so to improve the quality of performance during the learning curve.

*Theory* - Our training model includes a total amount of at least 4 hours of theory, i.e. formal didactic lessons on (1) the basic physics and principles of ultrasound; (2) "knobology" - in other words the function and control of ultrasound devices, (3) correct image acquisition, (4) knowledge of ultrasound artifacts, (5) examination of normal vascular anatomy and (6) identification of arterial and venous vessels, (7) knowledge of anatomic variation, (8) technique of USG puncture of internal jugular vein, brachiocephalic vein, subclavian vein and axillary vein both in adults and in children, (9) technique of USG puncture of arm veins (basilic vein, brachial veins, cephalic vein) for peripheral insertion of central catheters (PICC lines).

*Lab* - A total amount of at least 4 hours of laboratory training is also required, divided as follows: 2 hours of ultrasound examination of veins on healthy volunteers and 2 hours of a hands-on simulation of USG venipuncture on a biological simulator. During the ultrasound examination phase on healthy volunteers, the trainee must gain familiarity with 'knobology' and to become proficient in correct image acquisition, identification and interpretation of ultrasound artifacts, identification of the venous and the arterial vessels and other relevant anatomic structures such as muscles, nerves, thyroid and pleural line, detection of anatomic variation and ability to perform CUS (Compressive UltraSound) to detect eventually thrombosed veins. Each trainee, by using B-mode ultrasound, has to provide a transversal scan of the internal jugular vein and common carotid artery, and obtain a visualization of the confluence between subclavian and internal jugular veins and of the brachiocephalic vein. Moreover, the trainee has to provide a longitudinal scan of the subclavian vein, by the supraclavicular approach, and transversal and longitudinal scans of the infraclavicular vessels (axillary vein and cephalic vein). During the visualization of the brachiocephalic vein and the subclavian vein by supraclavicular approach, the trainee should also become competent in identifying the pleural line that appears as a hyper-echoic line characterized by the sliding sign. Afterwards, the trainee must perform transversal scans of the brachial vessels above the fold of the elbow. Each trainee must become able to visualize the brachial artery and veins, the basilic vein, moving the probe medially, and then, moving the probe laterally to the brachial artery, the cephalic vein. The hands-on simulation with our

biological vascular access model consists in performing different kind of ultrasound-guided venipuncture. The objectives of these phase are the acquisition of manual skills, in particular: (1) correct and continuous display of the needle during its introduction into the simulator: index of visual coordination between the probe and the needle; (2) ability to reach a goal (curtains, rubber tube) at a depth of 1-2 cm: index of precision guidance of the needle. Firstly, obtaining a transversal scan of the vessel, each trainee should become competent to achieve the 'in plane' and the 'out of plane' puncture techniques. The 'in plane' technique is performed by advancing the needle in a plane aligned with the long axis of the transducer which should center over the vessel in its short axis. Using this technique the needle tip and shaft will be completely visualized along their course so that the operator will have total control of its trajectory. The 'out of plane' technique is achieved by centering the target vessel in the middle of the screen in its short axis so that the midpoint of the transducer becomes a reference point for the puncture site. The needle is directed perpendicular to the probe plane. Tissue motion during ultrasound-guided puncture can help to direct the advancing needle prior to visualization of the needle itself. Performing this technique, the needle will be detectable only when enters the vein as a hyper-echoic track. Finally, the trainees should become able to perform the 'in plane' technique by using a longitudinal ultrasound imaging of the vessel.

Practice - The proctoring training phase is divided in two steps. Firstly, direct observation of a minimum of 4 procedures performed by an experienced operator. During this observation phase, the trainee has to follow the teacher during a central venous cannulation procedure and learn the different steps that are necessary for a correct procedure (sterile draping, ultrasound examination of the site of cannulation, preparation of the central venous catheter, etc.). A second phase follows, in which each trainee must perform a minimum of 4 ultrasound-guided central venous access procedures on real patients, proctored by an experienced physician present during the procedure and who can intervene if necessary. After the 4 proctored procedures, the independent practice phase may start. This phase consists in a minimum of 25 documented procedures. Skill maintenance is also crucial: we recommend at least 5 insertions a week, for a total of 5 weeks. The main factor in determining the final competence of the trainee in ultrasound vascular cannulation should be the evaluation of the proctor. Different methods have been suggested for a proper evaluation of the trainee during and at the end of his learning curve. Consecutive cases with a one-on-one proctored assistance do not guarantee to protect from complications, which are expected to occur randomly. The only way to improve the quality of the learning curve is to review the complications during the learning curve through assistance of the proctor. All ultrasound guided maneuvers should be registered in digital archives (DICOM, MOV, AVI, etc) in order to create a computer-based curriculum ideally containing patient's characteristics, US findings (including location and adequate compressibility of the vessel), video-recording of the procedure, complications and comments. This computer-based documentation provides not only a method for reviewing vascular anatomy but also a legal documentation that may be included in the medical records of the patients. Computer-based curricula should be revised during the learning curve by proctors in order to assess if the trainee is achieving competence, to correct errors and to answer to questions about abnormalities detected during ultrasound examinations. Finally, this documentation provide a certificate of competence in ultrasound vascular access. The post-instructional assessment phase is a verification of assets of one year. This should include reviewing the stored static picture or videotape and outcome such as success, 'wrong target' complications (pneumothorax or accidental arterial puncture) and 'missed target' complications (repeated puncture attempts, procedure failure), and discussion about factors that may have influenced the outcome. We also recommend continuing education courses to maintain proficiency. Moreover, it is of paramount importance to maintain continuous quality improvement measures by reviewing all difficult cases occurred during the learning period.

*Central venous anatomy* – One critical aspect of training is the appropriate teaching of those features of central venous anatomy that have most clinical relevance in terms of ultrasound guided puncture. The first concept to deliver is that while standard central venous cannulation according to the 'blind' technique was based exclusively on the puncture of two central veins, subclavian vein and internal jugular vein, ultrasound guidance has expanded the spectrum to at least four main central veins (and two minor ones): the internal jugular vein, the brachio-cephalic (or 'innominate') vein, the subclavian vein and the axillary vein. In some patients, two additional 'minor' central veins can be cannulated, the external jugular (in its final tract, close to the junction to the subclavian vein) and the cephalic vein (in its final, infra-clavicular tract, close to the junction to the axillary). This list is limited to the veins available for central cannulation in the neck/thoracic area, since other peripheral veins are available for ultrasound cannulation at the arm (the cephalic vein, the brachial veins, the basilic vein and the axillary vein in its first portion), all of which can be used for the positioning of a peripherally inserted central catheter; also, other veins are available at the groin, such as the femoral vein and the saphenous vein, which can be cannulated for positioning venous catheter which can be utilized, to some extent, as central catheter. The shift from a 'heads-or-tails' choice (subclavian vs. jugular) to a wide spectrum of choices (int.jugular, brachio-cephalic, subclavian, axillary, etc.) is the real 'Copernican' revolution of the Ultrasound era. Whereas in the last century the physician was prone to choose between subclavian and jugular on the basis of personal preference or

instinct or experience, the choice of the most appropriate vein to cannulate can be done today on a rational basis, by using the ultrasound itself. The protocol proposed by the GAVeCeLT suggest the following complete scan of the central veins, before deciding the most adequate approach: (a) probe at midneck: evaluation of internal jugular vein and carotid artery (in short axis); (b) probe sliding down the neck towards the sternum: evaluation of the internal jugular vein (in short axis) in its lower tract and visualization of the subclavian artery (in long axis); (c) tilting the probe so to get an almost frontal plane: evaluation of the brachio-cephalic vein (in long axis); (d) sliding the probe laterally, behind the clavicle: evaluation of the subclavian vein and of the external jugular vein (in long axis), plus visualization of the subclavian artery (in short axis); (e) probe below the lateral 1/3 of the clavicle: visualization of axillary vein and axillary artery (in short axis) and cephalic vein (in long axis); (f) rotating the probe anti-clockwise: visualization of axillary vein in long axis. After this scan of the neck and of the supra/infra clavicular area (which may be rapidly performed, in expert hands, in half a minute), it will be possible to decide rationally the vein to be cannulated, using six criteria: (1) the caliber of the vein (usually, the largest vein in this area is the brachio-cephalic; the other three major veins are variable in their caliber; the cephalic vein and the external jugular vein are small, but may have relevant caliber particularly in neonates and children); (2) its depth (the axillary vein, for example may be very easy or very difficult to cannulate, depending on its depth below the skin surface); (3) the possible collapse during breathing (which is typically an issue of internal jugular and axillary vein); (4) the compression by arterial pulsation (such as the carotid compression over the internal jugular vein); (5) the closeness to 'dangerous' structures (pleura, constantly adherent to the inferior wall of the subclavian vein); (6) easy management of the exit site (for example, when dealing with non-tunneled catheters, an exit site in the infra-clavicular area is highly preferable because associated with an easier nursing care of the exit site and decreased risk of dislocation and infection, if compared to an exit site locate at mid-neck).

*Techniques* – The role of ultrasound during central venous cannulation is not limited to the act of venipuncture; as a matter of fact, ultrasound plays a major role also before the puncture, as an important tool in choosing the best venous approach, as well as after the puncture, as an aid in reducing the risk of malposition and assess the presence/absence of puncture related complications (hematomas, pleura-pulmonary damage, etc.). The techniques which should be taught and learnt during any training course focused on ultrasound guided central venous access can be grouped in four different subsets: (1) Ultrasound evaluation of available veins and subsequent choice of the vein on the basis of rational, common-sense criteria; (2) Real-time US guided venipuncture; (3) US-based control of guidewire/catheter direction; (4) US-based control of pleura-pulmonary integrity.

1. the first aspect has been discussed above. Ultrasound plays a very important role (maybe even more important than its role during the venipuncture!) in choosing the best vein to puncture (i.e., the easiest for the operator, which usually is also the safest for the patient). Of course, ultrasound evaluation of the vein (caliber, depth, collapse during breathing, etc.) should be paired with an adequate clinical knowledge of the features of and of the performance expected from the central venous access device. For example, when dealing with dialysis catheter, the choice will be restricted on internal jugular vein and brachio-cephalic vein: the US features of the vein will help the operator to make the best choice (the internal jugular vein may be sometimes small and/or easily compressed by the carotid artery or collapsed during breathing; the brachio-cephalic vein, though always very large – which is a highly positive characteristic, considering the caliber of dialysis catheters – may be sometimes too deep and/or difficult to visualize and cannulate; etc.).
2. Real time US guided venipuncture can be performed either 'in plane' (when the needle trajectory is in the same plane of the probe) or 'out of plane' (when the needle does not move in the plane of the probe); also, it can be performed 'in short axis' when the vein to be punctured is visualized transversally, or 'in long axis' when the vein is visualized longitudinally. Though any vein can be theoretically punctured in short or long axis, and in plane or out of plane (which would account for four different techniques for each vein), each vein is associated with one or two specific techniques of puncture, which should be known and performed – if needed - by each expert operator. Limiting our discussion to the direct central venous access only (by cannulation of veins of the neck and the thorax), we can list eight different techniques: (a) US guided venipuncture of the internal jugular vein, in short axis, out of plane; this is the most popular US approach to the jugular vein, but it is not to be recommended, for several reasons (it is associated with a potential risk of accidental puncture of the subclavian artery, which passes just behind the posterior wall of the internal jugular vein; if used for non-tunneled central venous catheters, it is characterized by an exit site at mid-neck, very uncomfortable for the nurse and for the patient; it carries the risk of pinching the catheter – specially if made of silicon – in between the fibers of the sterno-clavicular muscle); (b) US guided venipuncture of the internal jugular vein, in short axis, in plane (no risk of accidental arterial puncture, since there is a complete visual control of the needle; the exit site is in the supraclavicular area, not at mid-neck; the catheter does not cross the muscle fibers); this is one of the ideal approaches for positioning a tunneled or non-tunneled dialysis catheter; (c) US guided venipuncture of the brachiocephalic vein, in long axis, in plane: this is

- maybe the easiest and the safest technique of central venipuncture, ideal for large-bore catheters in adults and for any central catheter in neonates; (d) US guided venipuncture of the external jugular vein, in long axis, in plane: very rare, since the vein is quite small – may be helpful in some selected cases, specially in children; (e) US guided venipuncture of the subclavian vein, in long axis, in plane; not a first option, since the subclavian vein has direct contact with the pleura (it is important to stress that US guided puncture of the subclavian vein can be performed only in the supraclavicular area, since the subclavian vein is not visible at US in the infra-clavicular area); (f) US guided venipuncture of the axillary vein, in short axis, out of plane; axillary venipuncture should be the first option for positioning non-tunneled, short term central venous catheter, since the position of the exit site (in the infra-clavicular area) is ideal in terms of maintenance and risk of dislocation and infection; (g) US guided venipuncture of the axillary vein, in long axis, in plane (a slightly more difficult variant of the previous technique); (h) US guided venipuncture of the cephalic vein (in its deeper tract, soon before the junction with the axillary vein), in long axis, in plane; same advantages of axillary puncture: safe, but not always feasible because the caliber is sometimes small.
3. After the venipuncture, US can be helpful in avoiding errors in directing the catheter and/or of the guidewire. After an axillary vein cannulation, US is useful to rule out a possible misdirection of the guidewire towards the ipsilateral internal jugular vein. During the positioning of a peripherally inserted central catheter, US can be helpful in ruling out a malposition of the catheter in the internal jugular vein. In neonates, US can be used to check whether the guide wire has entered correctly the superior vena cava and not the contra-lateral brachio-cephalic vein.
  4. US is also useful for the immediate diagnosis of puncture-related complications: hematoma can be immediately diagnosed by ultrasound. Also, a rapid US scan of the second/third intercostal space can assess the presence or absence of pneumothorax (checking out the 'sliding sign' of the pleura).

### **Guidelines on ultrasound guided venous access**

ACS 2008 - American College of Surgeons. Statement on recommendations for uniform use of real-time ultrasound guidance for placement of central venous catheters. 2008. [http://www.facs.org/fellows\\_info/statements/st-60.html](http://www.facs.org/fellows_info/statements/st-60.html)

AVA 2008 - Association for Vascular Access. Position Statement on the Use of Real-Time Imaging Modalities for Placement of Central Venous Access Devices. 2008. [www.avainfo.org](http://www.avainfo.org)

BCSH 2006 - British Committee for Standards in Haematology : Guidelines on the insertion and management of central venous access devices in adults. Published in 2006 and diffused by the British Society for Haematology, 100 White Lion Street, London. Available on [www.evanetwork.info](http://www.evanetwork.info)

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## Controversial Debate Position: FFBI: The “Good”

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**Background:** The A-V Fistula First Breakthrough Initiative (FFBI), known as “Fistula First”(FF) was initially developed in 2003 and rolled out nationwide in 2004. The purpose was to optimize vascular access for hemodialysis (HD) patients, and specifically to promote autogenous arterio-venous fistula (AVF) use in suitable patients, generally accepted as the ideal type of hemodialysis access--associated with the lowest morbidity, mortality, hospitalizations, and costs, when compared with other access types. A specific AVF prevalence goal of 66% was chosen. The 66% target also takes into account the many patients who are not going to be considered suitable candidates for an AVF. As the ESRD community responded to this call-for-action and began to adopt the FF Change Concepts into practice, a statistically significant trend of increased AVF use in prevalent patients ensued.

Although the primary goal of Fistula First was to increase *functioning* AVFs, an additional objective of reduction of central venous catheter (CVC) use was recently added. High rates of CVC use throughout the U.S. represent a serious problem and risk related to the high rates of infection, sepsis, morbidity, hospitalizations, costs and mortality. Currently, in addition to developing and disseminating CVC-reduction strategies through the 18 ESRD Networks, the FFBI is preparing a comprehensive white paper on CVCs, with the purpose of educating the ESRD community, with a focus on CVC-reduction strategies.

**Outcomes/The “Good”:** In the eight years since its inception, the FFBI has been extremely successful in that AVF use in prevalent patients in 2003 of 32% has increased to almost 60% as of mid-2011. The use of A-V grafts (AVG) has declined in the same period, from 42% to 19%. An increasing number of centers throughout the U.S. have already achieved the AVF goal of 66% and higher, proving that the 66% target is feasible and reasonable. These centers report a reduction in catheter use as well as morbidity and costs and missed dialysis treatments, as a result of their high AVF rates and adoption of the FF Change Concepts. Further, there are currently centers which consistently have AVF rates of greater than 90%, with the lowest CVC prevalence. In spite of the concern and articles alleging that the aggressive promotion of AVF use would lead to an unacceptable increase in CVC use, there has not been any National increase in CVCs in any category of use. In fact, there has been a statistically significant reduction in CVC use. Use of chronic CVC (>90d.) declined from a high of 28.3% almost 18 months following the FF rollout, to just over 21% in mid-2011. Temporary (<90d.) catheter use declined from a high of 7.0% to 5.1% during the same period. This decline in CVC use associated with an almost doubling of AVF use, was consistent with the original expectation of the FFBI Work Group that, although CVC use may actually increase short-term as a “bridge” access during new AVF constructions, as AVFs continued to increase, and the early non-maturing AVFs are salvaged and made useful, there will be a long-term decrease in CVC need and use as a result of the lower morbidity and events associated with matured, well-functioning AVFs. Finally, in addition to the measured improvement in outcomes related to the FFBI, the Initiative can be expected to have lasting, immeasurable benefits as a result of the focus and attention directed to improving vascular access for hemodialysis.

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## FFBI: The Bad and the Ugly

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The Fistula First Breakthrough Initiative is dedicated to improving care for people with chronic kidney disease by increasing AV fistula placement and use in suitable hemodialysis patients. It started in earnest in 2008 and now reports proudly a national rate of 58.9% of AVF nationally in June 2011. This seems very exciting and commendable; unfortunately the reality is very different. The DAC study compared the rate of thrombosis and maturation of upper limb native fistulae in two groups of patients equivalent with regards to their characteristics to whom Clopidogrel or placebo were given after fistula creation in a double blind randomized fashion. The population was relatively young (mean age just above 50 yrs old in both groups) had a low percentage of obese



patients (around 8% in both groups) and had an incidence of diabetes around 45% in both groups. Despite these very favourable conditions the maturation rate (suitability for dialysis) reported was at a very low 40%!

Many went on to criticize the stringent criteria used to define a suitable fistula but the core of the matter is elsewhere: it is surgical knowledge and experience. Nine centers were involved to enroll and randomize patients, but the surgeries were performed in 27 different hospitals by 71 different surgeons. One center enrolled 25% of the patients and it showed in their results: the 6 week thrombosis rate was only 6% in the best center whereas it was 28% in the worst. There does not appear to be any agreed surgical protocol in the study. Are these surgeons dedicated to vascular access? Vascular surgeons in my institution say that one cannot perform carotid artery endarterectomies if one deals with less than 30 cases a year.

Despite all these shortcomings the DAC study is considered the pinnacle of vascular access studies because multicentric and randomized. The problem is that DAC did not take into account the multidisciplinary dimension of our specialty and the fact that we work with what is available locally; if radiologists are motivated and interested then more endovascular rescues take place if not then it is surgical etc. FFBI and DAC are one dimensional they want to increase native access in sheer numbers but we all know that it could be detrimental to quality.

## Pre-op Vascular Mapping: Can Reduce Early AVF Failure Rates

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When presented with a new ESRD patient in need of a vascular access to initiate hemodialysis, the goal is the creation of a fistula that will mature, be used for dialysis and function for a long period of time. Vascular mapping contributes in a major way to this the attainment of this goal. There are three ways that mapping may be accomplished – physical examination, ultrasound, and angiography. While each of these methods has its proponents, many patients require some type of imaging – either ultrasound or angiography.

Of the two modalities, imaging by ultrasound has gained the widest acceptance. This technique enables assessment of vessel parameters such as patency, diameter, and quality of the vein and arterial wall and measurement of hemodynamic characteristics - flow velocities, calculation of blood flow and resistive index. However, it suffers from an inability to adequately evaluate central veins. Angiography offers certain advantages in its ability to identify clinically occult veins usable for hemodialysis access that might otherwise be missed, identify anatomic variants and visualize the central circulation. Some have advocated using a combination of both.

Multiple studies have assessed vein size as a predictor of fistula outcome, but no standard has emerged. However, all agree that larger vein diameter is associated with improved outcome. The thresholds have ranged from 1.6 to 4.0 mm. Arterial diameters smaller than 1.5 have been associated with increased non-maturation rates of AVFs. One analysis of prospectively collected data found the greatest one year patency of radiocephalic fistulae with preoperative radial artery diameters between 2.1 and 2.5 mm.

Current evidence strongly supports that not only does vascular mapping increase the rate of AVF creation, it also appears to support the concept that it can enhance the rate of achieving a functioning vascular access for long term dialysis. This does not mean that in small studies, institutional statistics will reflect this effect.

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## Pre-Op Vascular Mapping: Can It Reduce Early AVF Failure Rates? No: And This Is Why Not!

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What creates early access failure? Is it only dependent on vascular mapping? Does a good vein and a good artery result in a good or successful access creation? What does create a successful access? Access mapping is not standardized throughout the community. There are 5 basic protocols available that units use both non invasive and invasive procedures to delineate vascular anatomy. However it is not only the vascular anatomy alone that creates a successful access.

I will outline the multiple factors that are involved with access success.

*Experience:* Decision making for correct access placement is operator dependent. Less experienced surgeons or operators have higher incidence of access failures. Most USA physicians out of their training have only an average of 20 access procedures as opposed to our European counterparts that have been exposed to over 130 Access procedures. Less experience results in poorer outcomes.

*Anastomosis:* Miller et al and Glickman et al have demonstrated that an interrupted anastomosis leads to better maturation of the avf access. When compared to a running anastomosis, an interrupted anastomosis allows for lower early fistula thrombosis and higher incidence of fistula maturation.

*Angle of the anastomosis:* Early access failure is often the result of the development of swing segment stenosis. It is not only the size and caliber of the vein and the artery, it is also related to the angle of anastomosis to create less turbulence and therefore decreasing the incidence of swing segment stenosis.

*Cardiac output:* Low cardiac output results in poor access maturation.

*Hypercoagulable states:* This also comes into play with patients who have failed accesses.

Only 20% of fistulas mature without any intervention. Aggressive follow-up and aggressive algorithm to treatment of patients is needed to create access success. Non compliant patients and uninformed units help create access failure. A dedicated team approach, education of the patient for expected need for interventions and an aggressive algorithm for access follow-up is needed to help improve access failure.

## The DAC/NIH Studies: What You May Not Know

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The article by Dember et al (1), is a controlled double blind, randomized study comparing the rate of thrombosis at 6 weeks and suitability for dialysis or maturation of upper arm native fistulae in two equivalent groups of patients to whom Clopidogrel or placebo were given after fistula creation (2). Seventy-one surgeons in nine centers at 27 different hospitals participated. With evidence in favor of Clopidogrel the study was stopped after 877 patients (1036 enrolled and 159 excluded), despite the initial intent to include 1284 patients (2). Basic criteria for fistula creation and maintenance were left to the discretion of the participating surgeons and physicians (2). The thrombosis rates observed were: 12.9% and 24.7% with and without Clopidogrel in the forearm, and 11.3% and 12.8% for brachio-cephalic fistulae with and without Clopidogrel, respectively. The failure to mature (useable for dialysis) did not differ between the two groups and was extremely high at around 60%. The study raises questions about the very high thrombosis rate and suitability failure regardless of the Clopidogrel status. Sharing the same characteristics another study examined the outcome of created radio-cephalic fistulae in 195 patients. The primary success rate was 94.2% (n=195) when the fistula was created by the most experienced surgeon dedicated to vascular access (3). Others report primary success rates well above 90% in newly created brachio-cephalic fistulae with a failure to attain sustainability for dialysis rates between 30% and 40% (4,5).

So how do we explain the vast differences in outcomes between these studies? Is it a "Center Effect" reflecting patient referral pattern, patient selection protocols for mode of dialysis and type and site of access, surgical technique such as the length of anastomosis, type of suture, surgeon dedication and experience including using magnifying glasses? Or is it the way we use and interpret duplex vascular mapping. With 71 different surgeons from 27 different hospitals operated on 877 patients (12.3 cases per surgeons) should we insist on

an agreed surgical protocol? Should a minimum number of access procedures created per year per surgeon be required before reporting series like this one? (1,2). Or is it the skills by which the access is cannulated? Does the positive effect of a study drug such as Clopidogrel offset the lack of surgical protocol? For example, it is now well demonstrated that an early re-referral leads to greater numbers starting dialysis on a fistula; and therefore, a better maturation rate (6,7) and lower mortality rate (8). Although, many questions remain, the Dember study demonstrates that the use of Clopidogrel may be beneficial to vascular access patients. In the light of the shortfalls do we follow suit?

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## Upper Arm Access: What's Best For The Patient?

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An upper arm fistula is usually placed in patients whose vessels are unsuitable for creation of a forearm fistula or in those with a prior failed forearm fistula. The two most common types of upper arm access are the brachiocephalic fistula and the transposed brachiobasilic fistula. There are tradeoffs between an upper arm fistula and graft. The advantages of the graft over a fistula are a lower primary failure rate, fewer revisions to achieve maturation, shorter catheter-dependence and fewer episodes of catheter-related bacteremia until the access is in use. The advantage of the fistula is that, once the access is successfully used for dialysis, fistulas have substantially longer cumulative survival and require far fewer interventions to maintain long-term patency for dialysis.

Less commonly, the surgeon may create a transposed brachiobasilic fistula in patients with an unsuitable cephalic vein. There are few publications comparing the outcomes of the 3 types of upper arm access. A large single-center study compared the clinical outcomes of upper arm access placed in 678 patients, including 322 brachiocephalic fistulas, 67 brachiobasilic fistulas and 289 grafts (1). Primary access failure was 38% for brachiocephalic fistulas, 18% for transposed brachiobasilic fistulas, and 15% for upper arm grafts. When primary failures were excluded, the median cumulative access survival was 1254 days for brachiocephalic fistulas, 1494 days for transposed brachiobasilic fistulas, but only 401 days for upper arm grafts. When primary failures were included, median cumulative access survival was 994 days for transposed brachiobasilic fistulas, 386 days for brachiocephalic fistulas and 401 days for upper arm grafts. Infection was observed in ~10% of grafts, but fewer than 1% of brachiocephalic or brachiobasilic fistulas.

In summary, brachiobasilic fistulas appear to offer the best of both worlds: a low primary failure rate (similar to that of grafts) and a high cumulative access survival (similar to that of brachiocephalic fistulas). Thus, in a subset of patients, brachiobasilic fistulas may be the preferred upper arm access. Similar observations have been reported by other investigators (2, 3). On the other hand, transposed brachiobasilic fistulas are more technically challenging, time consuming, and disfiguring. Ideally, the surgeon should identify those patients who would derive the greatest benefit from having a transposed brachiobasilic fistula.

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## PD: Where It’s Been, Where It’s Going

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When patients with end stage renal disease are provided an informed choice of renal replacement modality, about 40% of patients choose peritoneal dialysis. Indeed, there are multiple factors favoring peritoneal dialysis: initial survival advantage over hemodialysis, better preservation of residual renal function, both better short-term and long-term renal transplant outcomes, and better quality of life. Unfortunately in the US less than 10% prevalent patients are using peritoneal dialysis for their renal replacement therapy.

Only 6% of incident patients started peritoneal dialysis in 2008, the latest USRDS data on incident ESRD patients. The incident number of patients started peritoneal dialysis has been unchanged for the last ten years. The US trails most other countries in number of prevalent patients utilizing peritoneal dialysis. For example, Hong Kong has over 80% of prevalent patients on peritoneal dialysis. Most European countries, Canada, Australia and New Zealand have 20% of their prevalent dialysis patients utilizing peritoneal dialysis for renal replacement therapy.

In 2011, the payment environment established by the “Bundle” changed the financial incentives for dialysis, and in particular, home therapies. The “Bundle” provides the same fixed monthly payment adjusted for case mix for both in-center hemodialysis and home dialysis. In-center hemodialysis with higher fixed costs (overhead costs) such as staff, capital equipment, building infrastructure and medications provides a small profit margin. Thus, the financial incentives have been aligned to encourage home dialysis and, therefore, peritoneal dialysis over in-center hemodialysis.

Given the long time lag of USRDS data publication, is there any current data that suggests that these incentives have had an effect? Nephrology News and Issues publishes renal provider rankings using self-reported patient and modality numbers. Below is a table showing the changes from 1995 to 2011 of the 10 largest renal providers. Peritoneal dialysis growth in the first part of 2011 was 17.7% compared to a growth rate of 1.1% in 2008 to 2009. DaVita had an increase in peritoneal dialysis growth of 18.6%. Based on these preliminary numbers, it appears that the alignment of financial incentives with policy outcomes will drive an increase in the number of patients utilizing peritoneal dialysis. Jerry McGuire appears to be right “Follow the Money” when it comes to changing outcomes in dialysis in the US.

**TABLE I - THE CHANGING FACE OF THE 10 LARGEST RENAL PROVIDERS: 1995-2011**

	1995	2011
Number of patients (total)	75.678	330.441
PD patients	11.954	27.265
HD patients	66.424	303.176
Number of dialysis clinics	1.053	4.394

From NN&I July 2011 with permission.

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US PD over years, international data, choosing PD, bundle effect , recent data form NNI self reporting form LDO's  
Align the incentives  
Need to know patients covered from day one any home therapy  
Education piece reimbursement

## Surveillance Techniques Made Easy: Pressure and Flow

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It should be emphasized that AVG thrombosis is not a homogenous moiety. Its individual incidence varies considerably within a patient population. Most (85 to 90%), but not all, cases are associated with an anatomical lesion; however, thrombosis is almost invariably multifactorial. The basic predisposing cause in most instances is anatomical. The precipitating causes include hypotension, hypovolemia and excessive pressure to obtain hemostasis at the end of dialysis. Surveillance techniques are such that they only detect stenosis and do not directly predict thrombosis. They are effective because by detecting and treating the predisposing cause for most cases, the incidence of the event goes down.

Surveillance refers to the periodic evaluation of the vascular access by means of specialized tests that involve special instrumentation. Of the various techniques that are available for doing surveillance, measuring access blood flow ( $Q_a$ ) and static venous pressure (SVP) are two that are of particular value.

$Q_a$  can be assessed using a variety of indirect techniques. The two most commonly used indirect techniques are ultrasound dilution (UD) and online (real-time) conductivity (OLC) dialysance of sodium which is incorporated into the Fresenius 2008T dialysis machine. Serial measurements with a threshold level that triggers action is perhaps the most commonly applied standard. According to this methodology,  $Q_a$  is measured routinely at some interval and the data is plotted on a scale. If there is a decrease in flow, the patient is referred for diagnostic testing when the declining level drops below the selected threshold. The significant levels that are recommended are 600 ml/min for AVGs and 500 ml/min for AVFs.

Pressure changes detected by the measurement of SVP depend on the location of the lesion relative to the access. As a stenosis develops, the intra-access pressure measured upstream (venous outflow stenosis) increases. Pressure measured downstream from the lesion (arterial inflow narrowing) decreases. By measuring pressures from both the venous and arterial needles, it is possible to distinguish three categories of lesion – venous outflow, intra-graft and arterial inflow.

A relatively new approach to SVP assessment is vascular access pressure ratio test (VAPRT). This utilizes derived static venous access pressures, taken several times during each dialysis treatment. An average for each day is calculated. A positive VAPRT result is defined as three consecutive treatments with a VAPR exceeding 0.55 during a given month. This test has been electronically automated.

It is important to emphasize that a screening surveillance exam to detect stenosis is not intended to be definitive and the sole reason for performing an intervention. Clinical judgement is needed to interpret the data from surveillance tests. Not all stenoses are progressive enough to produce worsening abnormalities in access  $Q_a$  or intra-access pressure over time. Stable lesions should not be treated. Although  $Q_a$  and intra-access pressure studies are sensitive when properly applied, their utility is enhanced when linked together with physical examination.

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## Surveillance Techniques: Why Bother?

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Vascular access related morbidity and mortality remains a significant problem for patients on hemodialysis. In a recent study, which tracked mortality in a large cohort of patients, 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 worst 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 surveillance combined with angioplasty.

The ideal monitoring or surveillance technique should be able to identify an access that has a high probability of thrombosis and the preemptive angioplasty intervention should decrease the possibility of thrombosis resulting in longer access survival. Surveillance of dialysis vascular access using a variety of techniques including access blood flow, static venous pressure, and duplex ultrasound can identify grafts and fistulas with stenosis. However, surveillance fails to predict which grafts will develop a thrombosis and which grafts are not destined to thrombosis. Although observational studies have shown a benefit from surveillance when combined with preemptive angioplasty, randomized controlled trials have failed to show a benefit using surveillance when combined with preemptive angioplasty. Clinical monitoring appears to provide equivalent benefit in terms of graft survival to surveillance programs when coupled with preemptive angioplasty.

Graft patency after preemptive angioplasty in a stenotic graft is significantly longer compared to angioplasty in a graft that has thrombosed. However, the benefit of preemptive angioplasty is poor. The intervention-free patency after preemptive angioplasty is only 50-60% at six months (2). The treatment of a stenotic lesion with preemptive angioplasty may induce aggressive neointimal hyperplasia (3). Taken together, the current use of surveillance coupled with preemptive angioplasty may decrease thrombosis rate but does not improve graft survival and may lead to unnecessary and costly interventions.

Unfortunately, recent health care mandates may preclude clinical research initiatives to develop best practice strategies that could improve outcomes (4). Thus this debate may moot!

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## The Controversies in Surveillance: Can It Prolong AV Access Patency? Yes: If Treatment of Stenosis Worked Better

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The 2006 update of the KDOQI Vascular Access Guidelines states: "Prospective surveillance of fistulae and grafts for hemodynamically significant stenosis, when combined with correction of the anatomic stenosis, may improve patency rates and may decrease the incidence of thrombosis. The Work Group recommends an

organized monitoring/surveillance approach with regular assessment of clinical parameters of the AV access and HD adequacy. Data from the clinical assessment and HD adequacy measurements should be collected and maintained for each patient's access and made available to all staff. The data should be tabulated and tracked within each HD center as part of a Quality Assurance (QA)/CQI program."(1) FistulaFirst also supports this approach in its Change Concept #9, monitoring and maintenance to insure adequate access function: "Facilities adopt standard procedures for monitoring, surveillance, and timely referral for the failing AVF."(2) In a 2007 review of the issue, Besarab et al (3) observed that several clinical trials questioned the value of surveillance in managing vascular accesses, but noted that most of the available evidence suggested that the detection of stenosis and prevention of thrombosis is valuable. However, they emphasized that stenotic lesions should not be repaired just because they are present and, if such procedures are performed, they should be accompanied by intra- or periprocedural measurement of access flow or intra-access pressure should be conducted to demonstrate a functional improvement. It has been argued that the studies which formed the basis for the KDOQI and FistulaFirst recommendation were not randomized prospective trials and were based on historical controls. Several randomized trials have failed to demonstrate an access survival benefit of surveillance-triggered intervention but, nonetheless, a case can be made that even if preemptive percutaneous transluminal angioplasty (PTA) of venous stenosis does not decrease thrombosis rates and prolonged access survival, preemptive PTA makes vascular access procedures elective rather than emergent, preserves future access sites, and may reduce morbidity by decreasing hospitalizations, missed dialysis treatments, catheter use and surgical intervention. It is generally agreed that additional randomized controlled trials will be needed to definitively examine outcome variables including changes in hemodynamic parameters and stenosis, frequency of intervention, thrombosis rates and graft survival. In the meantime, there are data suggesting that improved surveillance technology such as automated intravascular pressure surveillance with vascular access pressure ratio testing may increase the sensitivity and specificity of positive results (4) and that the use of stents (5) and intravascular ultrasound (6) may increase access survival following PTA. The measurement of intra-access blood flow during and 1 week following PTA appears to be valuable in predicting which patients will have favorable outcomes and those who may require additional procedures to prolong access survival (7). For patients with two or more residual stenosis and failure to achieve blood flow of >500 mL/min, prompt surgical revision is favored to maintain long term access patency (8).

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## Controversial Debate Position: No, Surveillance isn't Accurate Enough

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Most arteriovenous grafts (AVG) fail due to irreversible thrombosis, superimposed on an underlying stenosis (1). This observation suggests that early detection of hemodynamically significant (>50%) stenosis, followed by preemptive angioplasty, prevents AVG thrombosis. Several noninvasive methods have been developed to

monitor for AVG stenosis. Clinical monitoring consists of information routinely collected during dialysis. It includes physical examination (absent thrill, discontinuous bruit, or edema distal to AVG); problems noted during HD (difficult cannulation, aspiration of clots, inability to achieve target dialysis blood flow, or prolonged bleeding from needle sites); or an unexplained decrease in dialysis dose (Kt/V). Surveillance methods include access flow monitoring (abnormal value is flow <600 ml/min or decreased >25% from baseline); measurement of static dialysis venous pressure (abnormal value is a ratio of intra-graft to systemic blood pressure >0.6); or duplex ultrasound (abnormal value is a peak systolic velocity ratio >2 across the stenotic lesion). Several observational studies have measured the frequency of AVG thrombosis before and after implementing a program to monitor for graft stenosis. These studies have all shown a 40 to 80% reduction in AVG thrombosis after starting the program. Six randomized clinical trials (RCT) have compared AVG thrombosis and survival in patients undergoing stenosis surveillance, as compared with a control group (2). In each study, the frequency of angioplasty was higher in the surveillance group. However, none of the studies observed a difference in graft thrombosis between the two randomized arms, and only one study found an improvement in graft survival. A meta-analysis of the RCTs found no decrease in the risk of thrombosis (relative risk of 0.94; 95% CI, 0.77 to 1.16; 446 participants) or access loss (RR of 1.08; 95% CI, 0.83 to 1.40) with surveillance compared with controls without the use of such techniques (3). Deployment of stent-grafts may improve the outcomes. However, a recent RCT showed no difference in AVG thrombosis between stent grafts and balloon angioplasty (4).

Only one RCT has evaluated surveillance and preemptive PTA in AVF's. It showed better AVF survival in patients undergoing flow monitoring (5). However, there is uncertainty about whether surgical revision is superior to angioplasty.

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## Surgical Revision of AV Graft Stenosis is the Best Approach

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As percutaneous approaches have become popular, surgical intervention of the failing/failed AV shunt is less common today. Comparisons of outcomes of the two approaches are few in number, with conflicting outcomes (1-3). The interventional suite scheduling may be easier, and repeated procedures better tolerated, but significant resources are consumed. The surgical revision may be more durable. Certainly, most programs consider a combined approach utilizing local strengths of the interventional radiologist, nephrologist and surgeon.

One must consider all three anatomic and physiologic abnormalities when considering a failing or failed access, including the inflow, conduit and outflow. Outflow lesions are the most common cause of graft failure (4), and are therefore what are addressed most commonly. One must always conserve as much venous outflow as possible for the future, making patch angioplasty or short jump grafts desirable (5). However, there are concurrent lesions that can be addressed at the same time. As grafts survive longer, physical failure of the conduit can occur. Luminal abnormalities or pseudo aneurysm formation can be addressed by local graft replacement. Arterial inflow lesions have been considered to be unusual in the past, however newer observations have documented these as an important contribution to dysfunction or failure (6).

Surgical intervention to the failing graft at multiple levels can provide a functional and durable result. The planned intervention should always consider future options to maintain optimal choices for venous outflow and ongoing graft patency.

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## **Creation Of AVGs That Are Stent-Supported At The Venous End**

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A primary cause of arteriovenous graft (AVG) failure is the development of intimal hyperplasia at the venous anastomosis leading to recurrent thrombosis and the need for multiple interventions to maintain graft patency. In addition, creation of a long-term hemodialysis access remains a significant challenge especially in patients with multiple previously failed arteriovenous accesses, morbidly obese patients, and elderly patients with small veins. The new GORE® Hybrid Vascular Graft is an ePTFE graft that has a section reinforced with nitinol which can be deployed in the vein to create a sutureless end-to-end anastomosis, shielding the vessel lumen area most susceptible to failure. The nitinol reinforced section on the venous end makes it possible to access challenging site locations and, in many cases, allows the patient to continue hemodialysis through the same limb. Additionally, the sutureless end-to-end anastomosis improves the hemodynamics at the venous anastomosis with laminar flow directed in line with the vessel. The reduction in vessel manipulation and dissection may also decrease the incidence of intimal hyperplasia and subsequent AVG failure.

Since September 2010, the GORE® Hybrid Device has been implanted in challenging dialysis access patients (n=70) in which, for the majority of patients, the only outflow vein available was centrally located. All implants were performed over-the-wire with fluoroscopy to visualize the central venous system and the outflow landing zone. In many cases, the venous outflow portion of the device was implanted percutaneously. Balloon angioplasty was performed post-deployment to ensure apposition of the nitinol reinforced section against the vein wall.

Six month follow-up suggests that the GORE® Hybrid Vascular Graft improves outcomes by delaying the onset of intimal hyperplasia and the time to intervention in the most challenging patient population. The near percutaneous implantation technique with the GORE® Hybrid Vascular Graft simplifies difficult procedures, and without the use of the device, many of these cases would have been time intensive and invasive surgical procedures, previously resulting in abandonment of the access site. The GORE® Hybrid Vascular Graft is safe and effective in multiple types of AV access procedures including revisions, de novo access placements when an arteriovenous fistula is not an option, and in challenging site locations (i.e. deep axillary vein). In addition, revisions of the device are effective and extremely simple to perform. Further investigation is needed to assess the long-term effectiveness of the device.

## **Improved Patency With Heparin Bonded e-PTFE Grafts**

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The search for the ultimate prosthetic vascular conduit for hemodialysis continues. One of the newer approaches to improve the functionality of these grafts is the application of a heparin bonding technique to the luminal surface

of a prosthetic graft (PTFE). In addition to the anti-thrombotic properties of heparin, it has an anti-proliferative effect on vascular smooth muscle cells. In a large, randomized prospective trial, the use of this technology reduced the overall risk of primary graft failure in lower extremity arterial grafting by 37%, and the risk reduction was 50% in femoro-popliteal bypass and in those with critical ischemia (1). There are limited reports of the use of this heparin-bonded graft in vascular access creation. The largest series has been reported by Davidson et al (2) in a non-randomized study with a control group of e-PTFE grafts. They report a clot-free survival for the heparin bonded graft of 76% at one year, compared to 58% for the standard PTFE. They concluded that with a 20% improvement in primary patency at one year, the heparin bonded graft provides, in their setting, superior outcomes. Gallkowski (3) has presented 10 consecutive upper extremity accesses created with the heparin bonded graft to have a six month primary patency of 100%. In a retrospective study with 50 patients, Anaya-Ayala (4) demonstrated a 64% one-year primary patency using the heparin bonded graft for hemodialysis access, which they felt was superior to current literature results for standard PTFE. While there are limited reports of utilization of this heparin bonded graft for hemodialysis access, there are suggestions that this graft may provide improved patency for those patients requiring prosthetic grafts. Clearly, the vascular access community will require larger trials and more experience with this graft before definitive statements can be made as to its routine application.

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## **Impact Of Modified Flow Dynamics On AVG Outcomes**

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Graft dysfunction and failure is often the result of the development of intimal hyperplasia at the distal anastomosis resulting in graft thrombosis. Hemodynamic forces or flow dynamics have been demonstrated to play a key role in the development of endothelial damage. Low shear stress appears to be a key component of inciting flow vessel wall abnormalities. The concept of turbulent blood flow creating cell injury in both the arterial and venous limbs has been well documented. Endothelial cells at the distal outflow region are sensitive to changes in the flow environment. It is thought that the intimal hyperplastic response seen at the venous limbs of AVG's is often noted to be in response to abnormal flow dynamics.

There have been 3 models designed for application in altering the flow dynamics in AVG's in hopes to improve outcomes in patency rates. These models include: Hooded graft concept seen in the Venoflo graft by CR Bard, The Swirl Graft developed by Veryan and the Tayside Flow Spiral flow developed by Tayside.

Each of these models has extremely exciting in vitro and mechanical concepts that allows for altered blood flow to reach the venous anastomosis. The Hooded concept developed by Dr. Schmidt of Berlin creates reduced turbulent flow at the venous limb with development of increased shear stress at the endothelial sites.

The Swirl Graft seen in the pig model allowed for the creation of laminar flow at the venous anastomosis through a series of spirals within the ePTFE graft. These spirals reduced the turbulence of the flow and created a laminar flow at the venous limb. In animal models, there was a significant reduction in the development of intimal hyperplasia at the venous limb.

The Tayside flow model creates a spiral flow at the venous anastomosis through an alteration only near the venous or distal anastomosis. The concept developed by this model mimics normal spiral blood flow seen in the aorta and distal arterial circulation. These flow alterations have been corroborated with Doppler ultrasound as well as MRI dynamic flow studies.

Although the in vitro and bench studies appear to be very exciting and the science implied by these studies appears on target, we have not been able to see significant improvement in patency rates within grafts that have flow dynamic changes.

Several studies with the Venoflo graft in its use in AVG have not determined that this graft has improved outcomes in regards to patency rates. Only one study out of the Mayo Clinic, a comparison study comparing patency rates in upper arm AVG between standard ePTfe and the Venoflo graft demonstrated improved patency rates with the Venoflo graft. Although significance was obtained, this was a small study. Other randomized studies however, have not shown any significance in outcomes using the Venoflo graft in hemoaccess.

The Swirl Graft underwent a multicenter, prospective randomized study comparing this graft to standard ePTFE grafts; 188 patients were randomized to this study. Patency, both primary and secondary patency rates were evaluated after 12 months. No significant difference was seen in both the primary and secondary patency rates between the two groups.

Lastly, the Tayside graft has elegant in vitro studies and very exciting Doppler evaluations. However, to date there has not been any prospective studies comparing the outcomes of this graft to standard ePTFE grafts.

In conclusion, bench testing and mechanical studies have conjured much excitement in the field. However, we have not been able to establish improved outcomes with modified flow changes in our AVG's.

## Arteriovenous Anastomosis Creation using the Optiflow™ Anastomotic Connector

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**Background:** Arteriovenous fistula (AVF) maturation failure and poor long term patency are major clinical problems. Recent data suggests that 20% of newly created AVF's thrombose within six weeks and 62% fail to attain suitability for dialysis (1). In another study, 1.75 procedures per access year were required to maintain access patency (2). The geometry of the preformed Optiflow implant (Figs. 1, 2) yields a reproducible laminar flow path which is designed to optimize hemodynamics. Further, the Optiflow provides a mechanical scaffold which shields the perianastomotic (PA) region from aggressive stenosis. Thus, the Optiflow™ implant is designed to improve AVF long term function by providing a highly controlled flow path.

Clinical data for patients treated with the Optiflow™ was collected and analyzed in order to evaluate safety and clinical performance.

**Methods:** End to side AV fistulae were created with a novel anastomotic device (Optiflow™). The study population included fifty three patients treated in Paraguay, Hungary, Greece, and the United Kingdom. Forty seven patients were evaluable for patency (5 were not assessed for patency due to acute technical failures and 1 patient due to a perioperative cardiac event). Unassisted primary patency was evaluated in two different study groups with follow-up time points of 14 (n=47), 42 (n=46) and 90 days (n=39) respectively. The safety endpoint was freedom from serious adverse events (SAE's) and unanticipated adverse device events (UADE's) during the follow-up period.

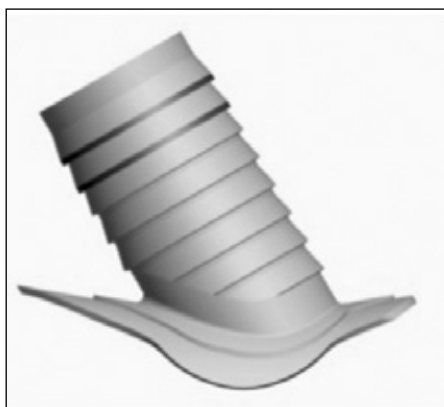


Fig. 1 - Optiflow Implant

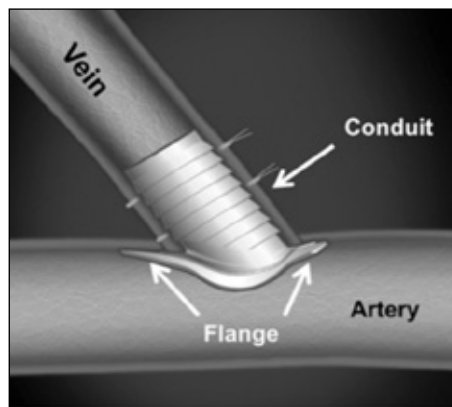


Fig 2 - Optiflow AVF

**Results:** Of the 47 patients, 47% were male and 39% were diabetic. Table I describes the study results at different time points. Aside from the technical failures, there were no device related SAE's or UADE's.

**TABLE I - STUDY RESULTS**

14d Primary Patency	42d Primary Patency	90d Primary Patency	42d ultrasound Vein Size (mm)
100%	91%	82%	6.6 +/- 2.2

**Conclusions:** The results support the safety and effectiveness of the Optiflow. The 82% unassisted primary patency rate at 90 days for Optiflow™ is favorable when compared to published unassisted primary patency rates of 70% (2) (Falk, 2006) for sutured AVF. Additionally, 42 day ultrasound follow-up performed on 31 patients demonstrated an average vein diameter of 6.6 mm. These initial results suggest that the Optiflow™ could potentially play an important role in enhancing AVF maturation.

The Optiflow™ received the CE mark in August 2010.

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## AVF Access Needle Guide

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**Background:** Failure to access an arterio-venous fistula (AVF) due to excessive depth is common for both new and existing AVFs. Superficialization or transposition is typically required to create a cannulatable access. Buttonhole cannulation technique is the least AVF damaging access technique. A deep AVF makes use of buttonhole cannulation very difficult.

We report the results of the First In Human clinical trial of the Venous Window Needle Guide (VWNG), an aide to cannulation of deep AVF. The VWNG is a single component, surgically implanted device made from titanium, having palpation ridge, needle guide funnel, aperture, suture holes for attachment to AVF and ingrowth surface for long term attachment.

**Methods:** A First In Human clinical trial of the Needle Guide is continuing in New Zealand. The trial objective was to determine feasibility of VWNGs to facilitate access of a difficult to access AVF using buttonhole cannulation technique. AVF access through VWNG using a blunt needle was evaluated at 3 months. Other safety and functional characteristics were evaluated for 6 months. In each patient the AVF cannulation through the VWNG was compared to cannulation through standard superficial site.

**Results:** Sixteen VWNG devices have been successfully implanted in 8 patients. Three patients were withdrawn from the study for non-device related reasons. Cannulation of the deep AVF segment was successful in 5 of 5 subjects

	VWNG Site (Distal Device)	Non-Implant Site
Total Access Procedures	258	253
Successful Site Use	97%	88%
Successful Cannulation	97%	99%
Single Stick Success	90%	95%
Ease of Insertion	1.55 (0.99)	1.70 (1.50)
Insertion Pain	0.74 (1.35)	0.41 (0.81)
Time to Hemostasis (min.)	7.80 (2.71)	7.05 (2.57)
Back wall Puncture	1.2%	0.9%
Bleeding Around Needle	1.5%	4.7%
Infiltration	1.5%	0%
Overall Complications	4.4%	4.7%
Cannulation related infection	0%	0%

through the VWNG using a standard blunt dialysis needle. This included one patient who achieved self-cannulation of a deep cannulation site. There have been 261 successful cannulations in 270 attempts (97% success rate). There have been no device related AVF stenosis, thrombosis or infection. There has been no AVF loss or intervention due to the device. Palpability, insertion attempts, ease of insertion, insertion pain and time to hemostasis are clinically comparable to non-VWNG cannulation site.

**Discussion:** First In Human clinical experience demonstrates good functionality and safety of VWNG as an implanted needle guide to provide buttonhole access to a previously difficult to cannulate, deep AVF. Access to AVF through the VWNG is comparable to an accessible AVF site. There have been no serious complications resulting from use of the device including stenosis, thrombosis or infection.

## Randomized Trial Utilizing Elastase for AVF Surgery

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**Background:** AVF utilization has improved dramatically in response to the Fistula First Initiative. AVF maturation however has continued to be quite variable and generally falls below hoped for levels. Elastase utilization at the time of AVF creation has been proposed to potentially improve AVF outcomes with increased vein diameters and improved fistula maturation.

**Methods:** A trial sponsored by Proteon Therapeutics randomized patients to placebo vs. escalating doses of PRT201, a recombinant human elastase, as a Phase 1/2 study in patients undergoing creation of a radiocephalic or brachiocephalic fistula. Investigational drug was dripped onto the anastomotic area for 10 minutes after fistula creation and then irrigated with saline for 1 minute. Patients were followed for up to 12 months with duplex evaluations at 6 weeks, 3 months, and 6 months. Outcomes measured included immediate vasodilation, changes in blood flow, patency, maturation, and adverse events. The treatment groups were lumped into placebo, low, medium, and high doses for analysis purposes.

**Results:** Analysis of results continues at the time of writing this abstract. No safety concerns were identified. No significant immediate change in vessel diameter occurred. Vessel diameter and blood flow increased in all patient groups with no significant difference in maturation at 6 weeks or primary patency at 6 months. There were 3 early failures in the low dose group (within 14 days) that were not thought to be due to the study drug. If these 3 failures are excluded from analysis, primary patency, maturation, and reduction in hemodynamically significant stenoses are all improved in the low dose group compared to the placebo group.

**Conclusion:** Elastase treatment of the anastomotic area of AVF's appears to be safe and maybe efficacious in improving AVF outcomes. Further data collection and analysis of the current trial is required to better evaluate these results. Another study is currently underway with more adequately powered subject numbers to further explore the outcomes of PRT201.

## Tissue Engineered Blood Vessels for A-V Access: Transitioning toward Widespread Clinical Use

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End Stage Renal Disease (ESRD) is one of the most costly and debilitating chronic diseases in the industrialized world, with nearly 400,000 patients on hemodialysis in the U.S. alone (1). Creation and maintenance of access shunts continues to be a principal challenge associated with dialysis, and accounts for nearly 20% of all ESRD-related expenses (2,3). While recent initiatives to decrease graft usage have been successful in shifting clinical

practice toward increased fistula placement, overall access related costs continue to rise (2,4). Increasing 'failure to mature' rates and increased catheter dependence may partially explain this trend (5). A more efficacious and cost-effective solution to hemodialysis access is therefore a critical priority. Biological grafts built from chemically modified xenogenic or allogeneic tissues have been used for many years. While these biological grafts tend to have very low incidence of infection, they are susceptible to aneurysm and distal stenosis, demonstrating overall intervention rates similar to ePTFE. Hypothesizing that chronic inflammatory responses to these fixed or modified tissues was linked to the key failure mechanisms, we set out to build a tissue engineered blood vessel that was completely biological, lacked branches or lesions, and needed no chemical fixation. Using a process termed Tissue Engineering by Self-assembly (TESA), we are able to grow sheets and threads comprised exclusively of cells, and extracellular matrix proteins produced by the cells. These completely biological materials can be used as basic building blocks to assemble more complex tissues and organs such as blood vessels. Tissue engineered blood vessels (TEBVs) built using the TESA approach demonstrate burst pressures in excess of 6000 mmHg, and like arteries, can be punctured without maturation. In the first clinical study using a TEBV in the high pressure arterial circulation, we reported excellent initial results using an autologous graft called Lifeline™ (6). With time points out to 3 years, we report a 4.2-fold reduction in overall event rate relative to the 6 months immediately prior to implantation (7). Recently, we transitioned to a second generation device, built using an allogeneic master cell line. With time points out to 3 months, the allogeneic grafts demonstrate similarly low event rates, and no evidence of immune rejection. Doppler exams demonstrate excellent hemodynamics, unaltered diameter, and appropriate pulse waveform (Fig. 1). A third generation device, built using woven, cell-synthesized threads, demonstrates promising results in preclinical studies. These second and third generation devices decrease total production time and cost, and show great potential for dramatically reducing the overall cost and complexity of hemodialysis access. Thus the goal of an off the shelf, tissue engineered vascular access suitable for widespread clinical use may finally be within reach.

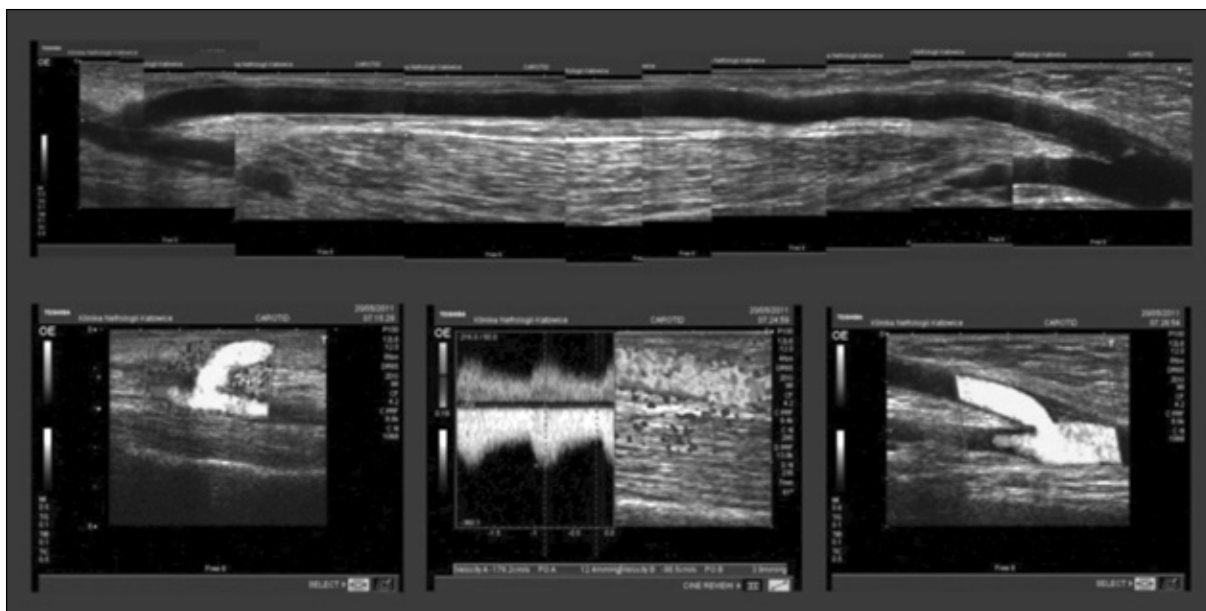


Fig. 1

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## An AV Graft With An On/Off Switch

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Arteriovenous (AV) grafts are associated with complications which result in considerable patient morbidity and cost to society. Although the medical device industry has vigorously explored numerous technological solutions to decrease these complications, these efforts largely have been futile. Consequently, since its introduction nearly 40 years ago, the complications and cost of AV graft placement and maintenance have not appreciably changed. Six of the seven major complications associated with AV grafts (thrombosis, access-related limb ischemia, pseudoaneurysm, cannulation site bleeding, venous hypertension, congestive heart failure) result from the adverse hemodynamic effects of continuous blood flow through the graft. However, the AV graft is only used for dialysis 9 to 12 hours per week. CreatiVasc Medical LLC has developed a device, the Hemoaccess Valve System (HVS), that "turns on" blood flow in an AV graft only when it is being used for dialysis. By closing the valve between dialysis sessions when the graft is not being used, these hemodynamic complications may be significantly reduced or eliminated.

The HVS is activated by injecting 3 cc of saline into a subcutaneously implanted port. This closes hydraulic valves that are located near the arterial and venous anastomoses. Once the valves are closed, the dialysis lines are used to flush blood out of the graft with heparinized saline. The valves are opened by aspirating saline from the port. The reliability and feasibility of the concept underlying the HVS has been established in both animal and human studies.



Fig. 1 - CreatiVasc Hemoaccess Valve System.

## Beyond the Fistulogram: When is the Intervention Done?

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*Rules of the Game:* The National Kidney Foundation Disease Outcomes Quality Initiative (NKF KDOQI) has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease and related complications since 1997. The current definitions guiding the treatment of hemodialysis access related stenoses have not changed much since that time. The NKF KDOQI GUIDELINES: Clinical Practice Guidelines and Clinical

Practice Recommendations 2006 Updates Vascular Access states that stenoses associated with arteriovenous grafts (AVG) greater than 50% and associated with clinical/physiological abnormalities of an abnormal physical finding, decreasing intragraft blood flow (<600 mL/min) or elevated static pressures within the graft should be treated with angioplasty. The outcome of angioplasty should be less than 30% residual stenosis and the clinical/physiologic parameters used to detect the stenosis should return to acceptable limits after the intervention. A primary patency rate of 50% at 6 months is expected (1). These premises have been maintained by our professional societies and dictate the way we practice (2). Of note, the assignment of 30% and 50% stenosis as angiographic measurements were values chosen arbitrarily in 1997 and have not changed to this day.

*The Reality:* Many non-randomized, retrospective and observational studies have maintained the myths described above. Beathard et al states a 98% success rate of angioplasty to treat AVG stenoses in 3,560 cases, success rate based on angiographic results. (3) These cases were performed in outpatient centers with portable C-arms, thus the quality of imaging may have been variable.

Two prospective, randomized trials bring into question that which we have come to accept as dogma. In The Use of the Peripheral Cutting Balloon to Treat Hemodialysis Related Stenoses, 167 patients were randomized to angioplasty alone. The procedural success (anatomic and clinical success) was only 75% with a target lesion primary patency of 41% at 6 months and an access circuit primary patency of 36% at 6 months (4). In Stent Graft versus Balloon Angioplasty for Failing Dialysis Access Grafts, 93 patients treated with angioplasty alone demonstrated a 6 month target lesion primary patency of 23% and a 6 month access circuit primary patency of 20%. (5) The K/DOQI expectation of a 6 month primary patency rate following angioplasty of 50% proved to be unattainable.

*If the Angiogram is Worthless What Can We Use?* Because a significant stenosis is associated with an abnormal physical finding/examination, decreasing intragraft blood flow and/or elevated static pressure within the graft, these measurements also provide a method to assess the results of our interventions and therefore may be used to define vascular access treatment success (1, 6, 7).

*Summary:* The entire vascular access circuit is defined from the cardiac pump, through the inflow arteries, through the access and returning to the heart through the outflow veins. Many variables, such as cardiac output, blood pressure and fluid status, influence the function of the access circuit. Treat the patient, not the picture and remember that clinical, hemodynamic and anatomic endpoints all contribute to the definition of success.

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## Use of the VIABAHN® Stent-Graft for the Primary Treatment of Cephalic Arch Stenosis in Brachio-Cephalic Autogenous Hemodialysis Accesses: A Retrospective Study

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**Objective:** To determine 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

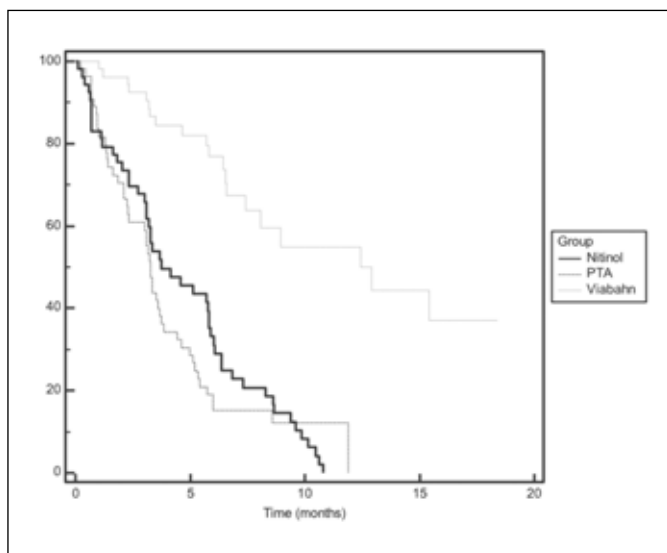


architecture and propensity to intravascular scar formation leading to early access failure. While the technical success of endovascular balloon angioplasty treatments are generally satisfying, the outcome is wholly inadequate as the six month primary patency for angioplasty alone ranges from 8-43% (1,2). 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 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% 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.



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

**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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## Incisional Thrombectomy: Salvage of Occluded Aneurysmal Arteriovenous Fistula by Direct Thrombus Extraction

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Percutaneous thrombectomy has gained wide acceptance as the preferred initial therapy for treatment of thrombosed native arteriovenous fistulae. Several studies using a variety of pharmacological & mechanical techniques have demonstrated high procedural success rates: Turmel-Rodriguez reported 93% success with forearm and 76% with upper arm fistulae using combinations of aspiration and urokinase infusion. Shatsky reported 87% technical success using the Arrow-Trerotola Percutaneous Thrombectomy Device™. Schon reported 92% success using tissue plasminogen activator and thrombus maceration. Post-thrombectomy one-year primary patency was reported in these series from 9% to 49% and one-year secondary patency rates 50% to 81%. Each of these studies acknowledged that fistulae with large aneurysms or organized thrombus presented particular technical problems and may have contributed to procedure failure, although this factor is not specifically analyzed. None of these studies described treatment of especially large aneurysmal fistulae with massive thrombus burden, often referred to as "mega-fistula."

We recognized that thrombosed fistulae with large aneurysms were particularly challenging to treat using conventional percutaneous methods due to the large thrombus burden and organized thrombus which often appears to have formed in the aneurysmal areas well before the patient presented with frank thrombosis. When combinations of aspiration, maceration, and pharmacologic thrombolysis prove ineffective in removing thrombus, the fistula may be lost and there may be increased risk for clinically significant thrombo-embolism. For such cases, we postulated that direct thrombus extraction via a small incision utilizing balloon occlusion of the fistula inflow & outflow would provide an effective minimally invasive treatment alternative and potentially avoid the morbidity of venous catheter access and new access surgery.

A general description of this procedure follows: Two 7 French sheaths are inserted into the fistula, separated as far apart as possible in opposite crossed orientations. A guide wire is placed across the arterial anastomosis into the brachial artery and a second guide wire placed centrally through the venous outflow. A suitably sized angioplasty or balloon is advanced across the venous outflow stenosis and a second angioplasty balloon or embolectomy catheter is advanced into the arterial inflow segment of the fistula; both are inflated to achieve complete proximal and distal fistula occlusion. A site is selected for incision where there is relatively thick healthy skin and vessel, typically along the medial or lateral aspect of the largest aneurysm, avoiding any recent needle puncture areas. A #11 scalpel is used to make a 1.0 to 1.5 cm incision through the skin and vein; there is typically no discernable plane of separation due to scarring from previous needle punctures. Thrombus is then expressed by manually by firmly "milking" from both ends toward the incision. Thrombus can also be directly extracted by grasping with a curved hemostat taking care not to interfere with the wires or catheters traversing the fistula. Serial imaging is performed by direct contrast injection into the incision or via the sheaths until no significant residual thrombus can be seen. Ultrasound may be used to confirm the presence and location of residual thrombus and guide further extraction maneuvers. After thrombus is fully cleared the incision is closed securely with a layered interrupted subcutaneous 3-0 Vicryl and a running superficial 3-0 or 2-0 Nylon suture. Separate closure of the vessel wall and overlying skin is not usually possible due to matting of these tissue layers. All identified outflow stenoses are then angioplastied using appropriately sized balloons; the arterial occlusion balloon is then deflated and inflow restored. Final imaging is performed and any remaining thrombus or stenosis addressed as warranted. All patients are brought back seven to ten days post thrombectomy for examination and suture removal.

We retrospectively reviewed 13 cases of thrombosed aneurysmal fistula treated from 2008 to 2010 using the incisional thrombectomy procedure as described. All procedures were technically successful. One patient developed

acute ipsilateral subclavian vein thrombosis with symptomatic venous hypertension one day post thrombectomy, attributed to delayed thrombo-embolism from the fistula. There were no cases of clinically evident pulmonary embolism. No patient developed rupture or infection of the sutured incision. One patient developed sepsis and bleeding from an infected ulceration site remote from the thrombectomy incision 12 days post procedure leading to fistula ligation. At six months primary patency was 15% and secondary patency 54%. Six fistulae were abandoned within one year due to re-thrombosis or unsuitability for continued needle access. It should be emphasized that none of the fistulae treated in this series was considered to be a "mega-fistula" with diffuse vein dilation and massive thrombus volume. Such cases may be amenable to incisional thrombectomy, but there may be increased risk for significant pulmonary embolism.

Thrombosed fistulae with large needle-site aneurysms are challenging to treat using conventional percutaneous methods due to the large volume of organized thrombus. When aspiration, maceration, and pharmacologic thrombolysis are ineffective, the fistula may be lost and there may be increased risk for clinically significant thrombo-embolism. Direct thrombus extraction via a small incision utilizing balloon occlusion of the fistula inflow & outflow provides an effective alternative for such cases and may avoid the morbidity of venous catheter access and new access construction. Procedure technical success rate is high, with few procedure-related complications. However, infection related to fistula ulcerations or thrombus is a concern; prophylactic antibiotics should be utilized and all patients monitored closely for infectious complications. Primary patency rates are poor, partly reflecting a very low threshold applied to follow-up study of these high-risk fistulae. Secondary patency rates are also relatively low compared to those reported for other percutaneous fistula thrombectomy series; this may be due to the generally poor condition of some aneurysmal fistulae and our choice to abandon those that continue to function poorly or re-thrombose. Nevertheless, this technique may be useful for selected cases when conventional percutaneous thrombectomy methods prove ineffective.

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## Ultrasound Guided Arterio-Venous Access Interventions

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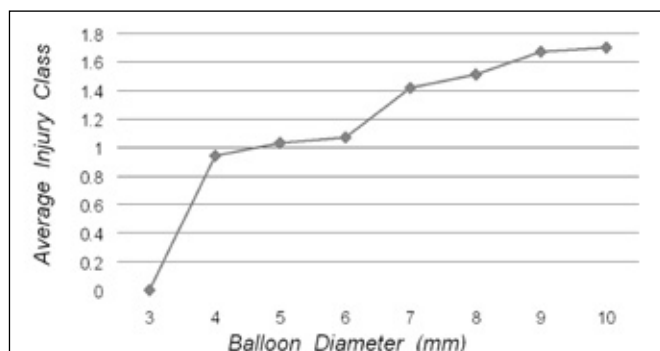
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**Introduction:** It has been suggested that up to 30% to 50% of arterial-venous fistulas created are not matured by 3 months after placement. The technique of balloon-assisted maturation (BAM) has recently been introduced as another approach to improve the rates of vein maturation and utilization. Herein we analyze the results obtained with the largest series so far described of office-based duplex-guided BAM cases.

**Methods:** Over the last 4 years 120 patients with chronic renal insufficiency and non-maturing or failing autogenous AVFs underwent 340 office-based duplex-guided balloon angioplasty procedures. These were 83 cases in 50 patients with failing AVFs and 257 BAM cases (range 1-8 procedures, mean 4.1±2) in 70 patients with newly created AVFs.

**BAM technique.** Access site puncture and cannulation with short sheath, wire and balloon advancement and inflation were guided by duplex only. Venous injuries were classified based on meticulous duplex assessment. Class O-no injury (130 cases, 50.8%); class I-intimal flaps (12 cases, 4.7%); class II-wall hematoma of measurable thickness (86 cases, 33.5%); class III-vein rupture with minor bleed (25 cases, 9.8%), class IV – pseudoaneurysm (2 cases, 0.8%), class V – vein rupture with major bleed (1 case, 0.4%). All patients had follow-up duplex scans within a week after BAM.

**Results:** All procedures but one (99.6%) BAM cases were completed successfully. Smaller balloons (3-6mm, 113 cases) caused fewer class II-V injuries (42 cases, 37%) as compared to the larger balloons (7-10mm, 143 cases) similar injuries (74 cases, 52%) with a P<0.03. (Correlation of highest class of venous injuries and balloon diameter demonstrated in Chart 1.



In the BAM group 57 fistulas (81%) were matured and ready for dialysis.

**Conclusion:** This experience suggests that office-based BAM of AV access under duplex-guidance is feasible, safe and accelerates maturation without the use of nephrotoxic agents or radiation exposure. High-resolution duplex images identify various types of venous injuries and their healing process. Severity of venous injury increases with balloon diameter.

## Covered Stents in AV Fistulae

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The Kidney Disease Outcomes Quality Initiative (KDOQI) indicates that a 50% primary patency at 6 months is expected based on retrospective data (1). Two randomized prospective studies indicate that primary patency of angioplasty (PTA), at least within prosthetic grafts at the venous anastomosis are actually much poorer and ranges from 23-40% (2, 3). Given relatively poor patency of PTA and the associated attendant costs, a better solution is desirable and stent grafts have become recognized as a potentially effective alternative.

The mechanism of action may simply be exclusion of areas of pathology i.e. intimal hyperplasia non-traumatically compared to surgical intervention and PTA/uncovered stents. Off-label, stent grafts have been used for recurrent venous stenosis, failure of angioplasty, venous rupture, exclusion of venous aneurysms within fistulas and pseudoaneurysms within grafts, to exclude clot within accesses, and in-stent stenosis. In the largest randomized study performed, the FLAIR device (CR Bard, Tempe, AZ), used for primary treatment of stenosis at the venous anastomosis of prosthetic hemodialysis grafts, was associated with a significantly higher primary patency than angioplasty at 6 months (50% versus 23%) (2). This study differs from many studies with an objective measure of mandatory two and six month angiographic follow-up. In another small randomized prospective single center study with no justification of sample size, stent-grafts were found to have significantly better six month primary patency than stenting for cephalic arch stenosis (82% versus 39%) (4).

A few retrospective studies using the Fluency stent graft (CR Bard, Tempe, AZ) have examined outcomes for other indications. One study looked at salvaging fistulas that were unsalvageable with traditional endovascular techniques. The study population included clotted fistulas and aneurysms but did not contain any central venous stenoses/occlusions. Primary patency was 88% at 6 months (5). Another study examined use of Viabahn stent grafts (WL Gore, Flagstaff, AZ) for central venous occlusions and stenoses in 30 patients with autogenous fistulas. Primary patency was found to be 67% at 12 months (6). In another retrospective study examining angioplasty induced rupture salvaged with stent-grafts, 21 patients were salvaged with a primary access circuit patency of 20% at six months (7).

Stent-grafts are still prone to failure. The most common pattern of failure is edge stenosis that occurs within 5mm of each end of the stent graft. Also, questions remain including the need for prophylactic antibiotics, use of antiplatelet agents prior to and following placement of these devices and safety/outcomes from puncturing across stent-grafts within AV accesses. There are concerns for infection of these devices and actual risk has yet to be determined (8, 9). Long term durability and fatigability of these devices in certain locations has not been assessed. Also, the financial costs/benefits have yet to be ascertained or properly quantified.

In conclusion, stent grafts have shown superior patency to PTA and uncovered stents for multiple specific lesions

within autogenous fistulas and prosthetic grafts. However, these outcomes to date do not translate into universal use and outstanding concerns require addressing.

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## **Drug Coated Balloons (or Stents) for AV Access: Will They Work?**

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Venous stenosis is the hallmark of vascular access graft and fistula failure resulting in thrombosis and the loss of access patency. The underlying biology which engenders venous stenosis is still an area of intense research but is best characterized by hemodynamic and inflammatory stress on the outflow vein leading to both intimal and medial thickening of the vascular segment exposed to the stress (1). In recent years a number of local and systemic therapies have been evaluated to potentially reduce the inflammatory and proliferative phenotype of the target outflow vein of arteriovenous access. These therapies have included systemic antiplatelet or anticoagulant medications and the local delivery of gene, cell, and antiproliferative drugs. Antiproliferative drugs have been applied to venous targets in the form of wraps or gels (extravascular) and stents/balloons (intravascular). Due to the widespread use of drug eluting stents in the coronary circulation, some have suggested that the anti-proliferative effect of these devices might also reduce the proliferative venous pathology observed in dialysis access dysfunction and failure. Two major platforms of antiproliferative drugs have been applied to stent and balloon devices, Sirolimus and Paclitaxel, which share a similar anti-proliferative function, but vary, by different mechanisms of action. In recent years, drug-eluting stent platforms have been tested in a swine model of arteriovenous graft intimal hyperplasia (IH) and demonstrated a reduction in IH at 28 days when compared to control implants (2). Further, recent testing in humans in a small randomized clinical study comparing the use of drug-eluting stents to angioplasty in access graft failure suggested a small but not statistically significant improvement in patency at 6 months (3). While intriguing, these early results appear far too preliminary to establish this emerging technology as new standard of treatment for access care. However, the concept of local drug delivery in the form of anti-proliferative therapy to reduce venous intimal hyperplasia for vascular access is a progressive idea that warrants further investigation. Also the aforementioned drugs may not ultimately prevail as the most efficacious therapy for vascular access proliferative failure, but may play an important role in the investigation of using local therapies to alter the process of arteriovenous access dysfunction. In the future, the ideal local treatment to reduce the proliferative phenotype of arteriovenous access dysfunction may consist of variety of cell, gene, radiation, or drug therapy based on a patients specific genotype and underlying vascular biology.

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## The Conundrum of delivering high quality care in today's health care financing

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In general, expenditure per capita for health care is nearly twice that of developed countries throughout the world. At the same time, the quality of care and variations of care are lacking. In renal care, we spend 10% of health care dollars on less than 1% of patients whether within Medicare or the private sector. Despite this disproportionate spending, quality outcomes are lacking. Indeed, in the arena of vascular access management, quality outcomes are less than optimum. 85% of patients start dialysis with a catheter and most alarming is that 75% of patients start dialysis with catheter despite being followed by a nephrologist for more than six months. Mortality rates in the US are twice that of most European countries. There are clearly wide variations in care with parts of the country having low mortality, low hospitalizations rates and high AVF rates. The ability to get the timely placement of an access has multiple barriers.

Renal Health care expenditures are driven by the unacceptably high central venous catheter rates. The high renal care expenditures are directly related to the higher CVC rates-hospitalizations, mortality and use of erythropoietin stimulating agents.

As of January, 2011, ESRD reimbursement has entered a new prospective payment system which is a bundled payment for services provided to patients on dialysis. Physician services included vascular access works are not bundled. Additionally, the current theme of health care reimbursement includes bundled payments and discussion of accountable care organizations (ACO).

This lecture will discuss how changing reimbursement models will impact on the ability to deliver high quality of care for patients with chronic kidney disease.

## What We Know and What We Don't Know About Occluded Central Veins

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Central venous stenosis and occlusions in the hemodialysis patient are unique clinical problems that are associated with previous central venous catheter insertions, particularly from the subclavian vein approach and left sided approaches (1, 2). Insertion of pacemaker wires, central venous ports and peripherally inserted central catheters (PICC) are also contribute to an increased incidence of central venous lesions. This is perhaps one of the most significant problems to be addressed in the near future for dialysis patients as they live longer from advances in medical therapy and interventions.

Overall primary patency for endovascular interventions including angioplasty and/or stenting range from 14-67% at 12 months (1, 3, 4). Stent grafts, primarily with the Fluency and Viabahn devices are another unexplored option and patency has not yet been properly studied although one retrospective study suggests patency that exceed POBA and bare metal stenting (67% at 12 months) (5). For interventions across pacemaker leads, limited anecdotal reports and two retrospective studies suggest that it is safe to do so with limited primary patency of <20% (PTA)-45% (stenting) at 6 months (6, 7).

Surgical options are available and should not be discounted. Primary and secondary patency rates of axillary to axillary PTFE bypasses are quite good (72% and 89% at one year, respectively) (8). Alternatively, arterio-arterial bypasses, for example axillo-axillary or fem-femoral bypasses, have also been used in patients with central vein stenosis (9) with good patency rates (73% primary and 96% secondary at one year).

Despite these outcomes, many questions persist. What is the optimal technique to cross areas of occlusion safely? One particularly vexing question is if endovascular interventions result in improved cumulative patency of the access and when it should be performed. One study found that central vein PTA resulted in acceleration of symptomatology (10). Another question is if currently designed stents and stent grafts are structurally optimal for central veins. The actual cause of central venous stenosis/occlusion (CVS/CVO) has not been determined, only associations and rate of progression has not been ascertained. Beyond devices, another clinical question is the need to intervene when well formed venous collaterals are present.

In summary, the exact etiology and progression of CVS/CVO has not been ascertained. Although percutaneous and surgical options exist, when to treat remains a question, optimal treatment has not yet been determined and current options have relatively limited patency.

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## **Surgical Management of Central Venous Occlusion: When is it the Right Choice?**

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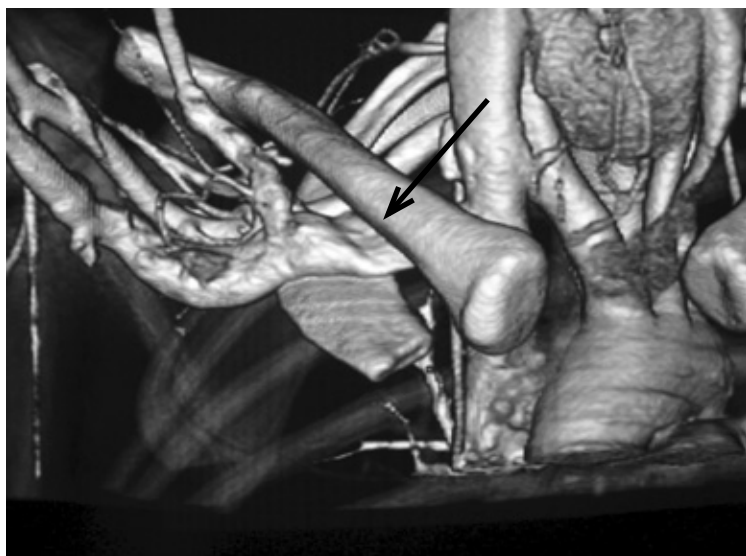
The most common cause of AV access failure is "outflow" obstruction, meaning abnormally high venous resistance, usually due to a stenosis or occlusion. The prevalence of central vein stenosis is between 15 - 20% in all patients undergoing dialysis, 30% in those with a history of prior catheter placement, and as high as 50% in those considered "symptomatic" (1,2). It is overly simplistic to lump all vascular access-associated venous stenoses or occlusions together and to treat them with a single interventional technique. Problems can occur in one (or more) of three general areas, defined by anatomically driven therapeutic approaches: The arm, the costoclavicular junction, and within the chest. Veins in the first and last situations are bounded only by soft tissue, and endovascular intervention is the preferred and usually successful option. The subclavian vein at the costoclavicular junction, however, is firmly bounded by bone, and represents an entirely different situation (Fig. 1). Little attention has been paid to this area by the AV access community. This situation, however, has been very

well analyzed in patients with venous thoracic outlet syndrome (VTOS). Several points are well established in patients with this problem (3):

- The first rib and clavicle, anchored anteriorly, produce a “nutcracker” effect (the subclavian vein being the “nut”),
- As a result, this is an area of unusual hemodynamic stress and is prone to injury,
- In situ venoplasty yields poor results, and stents have a high rate of fracture (both factors due to persistence of the extrinsic bony compression),
- Removal of one of the bones making up this junction (usually the first rib) is required for long-term success,
- Endovenous intervention following decompression is safe and effective, and
- Using this algorithm (after removing acute clot, not usually an issue in patients with AV access-associated stenosis) permanent “cure” can be expected in 95 to 100% of patients.

Because the relevant anatomy is identical and hemodynamic and structural stresses similar, we believe that stenoses in this area act in an identical fashion to those in patients with VTOS and should be treated identically – i.e., that mandatory surgical decompression (with concomitant endovascular intervention, if needed) provides the best hope for long-term success (4).

The literature reporting the outcome for balloon angioplasty of access-related “central vein obstruction” is highly variable, with six month patency rates ranging from 30% to 60%. Unfortunately, the use of stents has not dramatically altered these marginal results (5). A potential reason for this variability is the fact that most reports combine outcome for stenoses and occlusions and do not define the anatomic location of the lesion, and the inclusion of patients with venous stenosis at the costo-clavicular junction in these reports may account for many of these treatment failures. It has been suggested that subclavian vein stenoses at the costo-clavicular junction in patients with threatened AV access respond poorly to endovenous intervention (6), but little attention has been paid to this issue otherwise. Since November 2008, we have treated 12 patients at the University of Rochester with access-related central venous stenoses or occlusions with open surgical intervention (7). The procedures were performed to salvage an access in patients with severe venous hypertension and access dysfunction. All patients had multiple previous endovascular interventions (mean 2.3 interventions) at the costo-clavicular vein segment. Eight patients underwent transaxillary first rib resection with venolysis and subsequent balloon angioplasty and/or stenting of the residual stenosis while four patients underwent claviclectomy with direct venous repair or bypass. The overall mean follow-up in our series was eight months. Salvage of the access occurred in 8 cases and relief of the upper extremity swelling occurred in 9 cases. In summary, stenosis at the costo-clavicular junction should be considered “AV access related thoracic outlet syndrome,” respond extremely poorly to endovenous intervention, and based on extensive data from the VTOS literature, require thoracic outlet decompression (followed by intervention as appropriate) for long-term cure.



**Fig. 1** - CT reconstruction of the costo-clavicular junction in a patient with venous thoracic outlet syndrome showing the subclavian vein (arrow) being compressed by the clavicle (and radiolucent subclavian muscle) and first rib (courtesy Wallace Foster, MD).

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## Central Venous Stenosis: Best Avoided; if Found, Best Ignored; if Treated, Best Ballooned; if Stented, Best Covered?

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It has been over two decades since it became clear that subclavian catheterization for hemodialysis access produced unacceptable morbidity and that morbidity could be dramatically reduced by using the internal jugular vein instead. In practices where there are rigorous venous preservation policies in place, and subclavian catheterization is judiciously avoided, symptomatic central venous stenosis (CVS) is something seen on a monthly, rather than weekly or even daily basis as it once was. It has been repeatedly stated that the most effective way of managing CVS is prevention; this statement reflects not only the value of avoiding CVS but also the limited armamentarium interventionalists have to treat it. Indeed, there is little evidence, and certainly no proof, that our treatments for CVS today are any better than they were 20 years ago. Thus, it is of critical importance to ensure that venous preservation policies are in place and enforced if one expects to effectively "manage" CVS. Yet, as well established as this concept is, there continues to be a huge disconnect between the practice of central venous catheterization for hemodialysis and that for cardiac rhythm device (CRD) placement (1). In that forum, subclavian catheterization remains the rule with an expected (from prior HD catheter work) and observed 50% incidence of central venous stenosis and occlusion. How can such a disconnect exist in the information era? The answer, according to electrophysiology specialists, lies in labeling of CRD leads for subclavian use only, non-evidence based concerns regarding possible fracture due to tighter curves needed for IJ catheterization, and most importantly in simple resistance to change. Change can, however, come in different forms. If even when faced with evidence that IJ CRD lead placement can be performed safely, as is done in pockets of Europe for example, EP specialists are unwilling to change their habits, nephrologists and interventionalists should then pursue alternate routes, to wit, epicardial lead placement. This approach has been adopted in some centers with a high degree of success (1), and is in fact superior to an IJ only approach as the latter will still result in some CVS. It is precisely this approach that is being promulgated at the Fistula First level, and if widespread adoption occurs, perhaps coupled with an overall decrease in CRD use (eg, prophylactic CRD) in the ESRD population, CVS will most definitely decrease significantly.

Even if epicardial leads eliminate CRD related CVS at some point in the future, and subclavian catheterization for HD is eliminated, some catheter-related CVS from IJ catheterization, as well as uncommon lesions due to extrinsic compression (2), will nonetheless remain. How best to manage these? Most importantly, it must be understood that CVS is often asymptomatic and that asymptomatic CVS should almost never be treated (3). The venous system has tremendous capacity for collateral formation, and even in the setting of complete occlusion ipsilateral to a functioning access, it is not at all uncommon to see no arm, face or breast swelling at all. It has been shown by Levit et al that treating asymptomatic CVS only serves to make the situation worse (3); further data in support of this important concept are forthcoming (Turmel-Rodrigues, L, personal communication, 2011). It appears that CVS is less likely to be symptomatic and respond better to treatment with fistulae than with grafts (4); this may relate to venous capacitance and/or disruption of collateral networks with graft (particularly upper arm) placement compared to fistula creation. Thus, in general, prophylactic treatment of stenosis prior to access placement is unwarranted (it can be done transfemorally in the event the patient does develop symptoms before access maturation). Further, the oculotherapeutic reflex is to be avoided. Indeed, the only setting in which an argument can be made to treat an asymptomatic CVS is in the setting of a very tight CVS in a patient with clotted access; in this setting undersized PTA to prevent "logjamming" of any centrally embolized clot may be warranted; though this concept has not been rigorously studied. It has been theorized, without proof, that CVS can compromise access patency (5). Excluding central grafts such as chest wall "necklace" and "chandelier" grafts with subclavian

venous anastomoses for which a CVS is simply a venous outflow stenosis, it is exceedingly rare for a central (ie subclavian, brachiocephalic or SVC) stenosis to be the cause of access dysfunction. Because of the rarity of this event, the burden of proof that such a lesion is the cause of access dysfunction is on the operator; using such tools as pullback pressures to look for a waveform change from venous to arterial upstream of the stenosis (absent other culpable lesions) would constitute one form of such proof. With careful attention to these tenets, treatment of central lesions absent arm, face or breast swelling will be a rare event indeed. In our practice, CVS remains untouched in the vast majority of patients in whom it is seen, with no adverse consequences whatsoever. As alluded to already, if the above tenets are heeded, treatment of CVS will be uncommon. Nonetheless, for the foreseeable future, interventionalists will be called upon to treat symptomatic CVS on a regular basis. As also noted above, the present evidentiary status is that PTA remains the best treatment for CVS. Carefully performed and with adequately sized balloons (generally 14 mm for subclavian, 16-18 mm for brachiocephalic), and with generous use of prolonged PTA, this tried and true technique will yield favorable and durable results. The major exceptions to this are chronic occlusions for which PTA is often (but not always) ineffective and certain lesions beneath the clavicle (see below). Because of our venous preservation policies, the majority of lesions seen in our practice are brachiocephalic unless CRD lead related, and thus PTA is an effective mainstay. When PTA fails, at present our options remain limited by available devices and a striking lack of evidence basis. While it is tempting to extrapolate the results of randomized trials showing favorable results for stent grafts (6, 7) to the central veins, it is not appropriate to do so especially in light of the inadequate device sizes available for stent grafts in the US. With the exception of some subclavian lesions, the maximum available device size of 13 mm is simply not large enough for most patients with subclavian lesions and nearly all patients with brachiocephalic lesions. Fortunately there is interest in the medical device manufacturing community in bringing large stent grafts for CVS to the market, and this will foster the much needed prospective randomized trials. There is no question that some very favorable results have been reported in a non-randomized fashion for stent-grafts (8); and it can reasonably be argued that if the vein is on the smaller side and 13 mm would be adequate, AND PTA fails, then instead of placing a bare metal stent (BMS), a stent graft may be worth the added expense. However, for larger veins, including essentially all brachiocephalic veins in adults, BMS remain the mainstay. We prefer large balloon expandable stents in the brachiocephalic veins, especially on the right, because these devices are ideally suited to these very short, large diameter veins. For more tortuous veins, especially left brachiocephalic, the Wallstent still has a limited role due to the larger devices available. One major problem with stent placement, covered or otherwise in the central veins is compression between the clavicle and first rib. This has become an area of great interest with some calling for more surgical decompression of this area, such as is done for primary axillosubclavian thrombosis (eg, transaxillary first rib resection) (9). We have seen a few patients over the years in whom we have been convinced, based on venography with maneuvers, of this pathophysiologic situation (without thrombosis) in patients with access-related arm swelling and have recommended surgery; to date we have yet to convince any of our surgical colleagues to perform this surgery. Yet, if a stent or stent-graft is placed in this area it inevitably becomes damaged and/or has such vigorous restenosis over time, and thus viable alternatives absolutely must be sought. To the extent it can be ethically carried out, a prospective randomized controlled trial of surgery versus PTA and/or stent devices in central subclavian stenosis is clearly warranted. One cannot help remembering, however, if making a case for an overlapping relationship between access related subclavian stenosis and PAST, that many patients undergoing surgery for PAST nonetheless go on to rethrombose their subclavian veins asymptotically...which brings the thoughtful interventionalist back to key concept of leaving asymptomatic and even mildly symptomatic lesions alone, as the natural history may be for symptom resolution as collaterals form, a natural and effective passive treatment.

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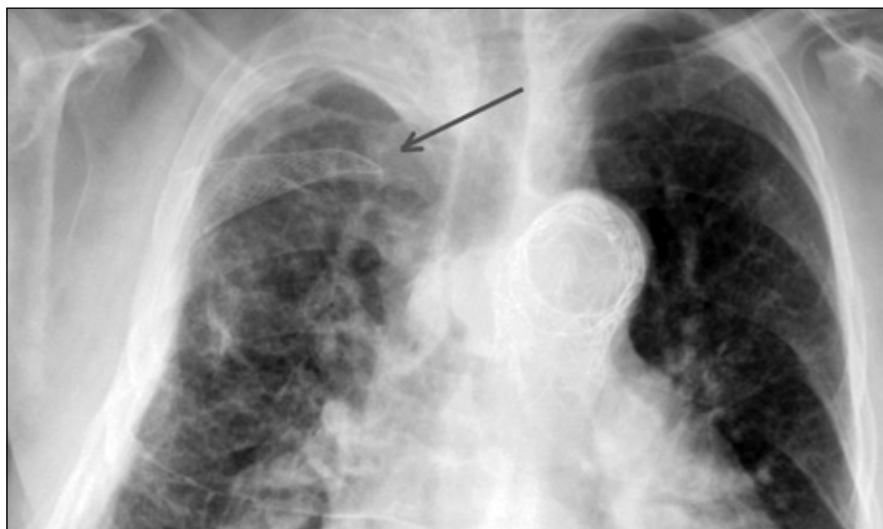
## Symptomatic Subclavian Vein Stenosis in the Dialysis Patient: Surgical Decompression Should be Tried First!

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It is difficult to debate such a master of the field, someone who is so eloquent, intelligent, and even good looking. I'm sure Dr. Trerotola will be able to overcome these difficulties, however, and get his message across! If a vein draining (or part of) an AV access is stenotic in the arm or even within the chest, endovascular intervention is clearly the first and usually best step. This intervention works, however, because veins in this area are surrounded by soft tissue only. A very common site for venous stenosis in patients with threatened AV access, as we have just discussed, is in the subclavian vein as it passes by the costoclavicular junction (the venous thoracic outlet). This has been attributed to subclavian catheter use, but many patients with jugular catheters still develop these lesions (1) and we have certainly not seen a decline in these cases in the era of "jugular-only" access. As discussed a few minutes ago, we strongly believe that this situation is exactly analogous to that of patients with venous thoracic outlet syndrome. The subclavian vein is tethered to the junction of the clavicle and underlying subclavius muscle, first rib, and costoclavicular ligament joining the two bones anteriorly. While the bones don't move very much they do so with massive force, producing external compression that no stent or balloon can overcome. This issue has not been well explored in the AV access community. However, there is extensive data and many decades' worth of experience in exactly this situation in patients without AV access – patients with venous thoracic outlet syndrome (VTOS) (all arguments below referenced in 2):

- The subclavian vein is easily compressed in normal subjects at the costoclavicular space.
- The vein in this location at exploration is tethered by dense fibrotic scar tissue.
- Patients treated conservatively have residual symptoms and obstruction in up to 90% of cases.
- Stenting has been shown to be associated with a very high failure rate (Fig. 1) due to fracture.
- Bony decompression is associated with a long-term success rate of 95 to 100%, even in patients who have suffered acute thrombotic occlusion and were thrombolysed.



**Fig. 1** - Plain chest radiograph of a patient with a subclavian vein stent crushed by the costoclavicular junction (arrow).

My worthy opponent is tasked with making the argument that stenoses in this area respond well to angioplasty alone (I hope he won't try to convince us to stent these lesions as there is extensive literature condemning this practice). I will concede that they do in the short term, which I define as a few weeks. If that is defined as meaning "perform angioplasty first," so be it, but I argue that any intervention that lasts only a few weeks and does not cure the problem is not worth performing at all. In our series (discussed in the preceding lecture) all patients had undergone numerous attempts at endovascular intervention, without success – while the mean number of interventions was 2.3, it was not unusual for these patients to have had four or five attempts at angioplasty, all without success for any meaningful period of time (3). Angioplasty just doesn't work – and this is not criticizing the technique, but is due to the fact that the bones, tendons, and scar tissue in this area are not willing to compromise. Angioplasty can make you feel better about things, but as long as the bones remain the problem will very quickly recur. Anyone who feels that angioplasty is solving the problem is not following these patients long enough!

In the end, though, I have to convince you that surgery is the best option. I make this argument not only because angioplasty is very temporary, but also because surgery really works well. In the TOS literature lifetime "cure" rates are achieved in almost every patient; the numbers cited in the largest couple of series, in fact, being 95% and 100% (4,5). To our knowledge ours is the only series thus far to explore the option of "preferential" (admittedly after failed angioplasty) first rib resection for this problem. We cannot present numbers close to this, but did achieve 8 month fistula salvage in 66% of patients so treated, all of whom would have otherwise required ligation for control of symptoms.

In summary, if you accept the fact that anatomy and hemodynamic and bony forces at the costoclavicular junction are the same in patients with our without an AV access, you'll need to accept the extensive literature showing what has and has not worked in patients with venous TOS, and this literature clearly demonstrates that bony decompression is required for cure of this problem. Sure, go ahead and perform angioplasty (but not stenting!), but recognize that success will literally be measured in weeks. For this reason we reiterate that the bones will need to come out sooner or later – so go ahead and cure rather than palliate.

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## **Is It Ever Too Early To Attempt AVF Dec clotting? Graft Dec clotting?**

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(AVF portion modified from CIDA 2009)

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

If there is not a visible or palpable vein, the next step is to determine whether there is a collapsed vein with high grade stenosis or short segment occlusion in the inflow, a readily treatable lesion, versus complete occlusion of the inflow with either a very short or very small segment of vein and no vein beyond this. In my opinion, as well as that of Turmel-Rodrigues et al, these fistulae are not salvageable and even if patency can be restored, the long term results are poor (1-3). Conversely, the results associated with short segment occlusions, as reported by Liang et al (4) and Wu et al (5), are excellent. Incidentally, we prefer not to refer to these as "declots" because of the tiny clot burden associated with them (6). However, in order to make this distinction, one may need either an ultrasound exam or fistulogram (performed with 3F arterial puncture, as for an immature fistula study), as the physical examination may be inadequate to detect a collapsed but still viable vein beyond the occlusion.

Whether to attempt salvage of an early failing graft is at once more complex and more simple. Unlike AVF, where there is little evidence and mostly opinion, early-failing grafts have recently received some attention in the literature, with apparently conflicting results. However, when one delves deeply into the small literature on the subject, there is actually far more agreement than disagreement. It has been stated for decades, without evidence basis, that early failing grafts, nominally those failing within 30 days of creation, should not be declotted percutaneously. Reasons provided have included incomplete incorporation of the graft within the tunnel and ensuing perigraft collections as well as a supposed preponderance of technical problems uncorrectable or poorly correctable with percutaneous techniques. Shemesh et al reported a series of 20 early failing grafts, managed percutaneously, and reported only one technical problem encountered (7). Indeed, in the remaining 19 grafts, they postulated that previously unsuspected central venous disease, found in roughly half, was the cause of early failure; in the others, no lesion was found and a variety of hypotensive and coagulopathic possible explanations were discussed. Their paper did not report primary patency (according to a subsequent communication from the authors, it was 40% at 3 months and 35% at 6 months, ie meeting K/DOQI expectations, JVIR 2011, in press), however access circuit patency was well within an acceptable range. They concluded that early-failing accesses warranted declotting. Yurkovic et al reported dramatically different results (8). Not only did they find 0% 90 day primary patency in 23 grafts clotting within 30 days of creation, in 16 grafts clotting between 30 and 60 days of creation the patency was only 17% at 90 days, still well short of K/DOQI recommendations. Also unlike Shemesh et al, they found technical problems (including tiny outflow veins) in 62% of the under 30 day group and 33% of the 30-60 day group. They concluded that for most patients, unless they had severely limited venous reserve, the "declot" procedure should stop at a pullback venogram coupled with mapping the rest of the veins for access revision. Thus it would appear there is a stark difference in the patient populations studied, one might reasonably conclude that if a pullback study shows no technical problem, perhaps declotting should proceed at least once, whereas if a technical problem is encountered the declot should be aborted. In any event, given the markedly disparate results, there is room for further study of early failing graft declotting. In summary, every early fistula failure should be considered for possible declotting with a careful physical examination. However, the majority of such failures will prove not amenable to percutaneous management. Whether the early failing access is a graft or fistula, the focus is generally on mapping for subsequent access creation rather than trying to resurrect the failed access.

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## Bioactive Catheter Coatings: Does the Data Support Their Use?

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Catheter based dialysis remains an important means of dialysis access while patients await the creation and maturation of a surgical access. Unfortunately tunneled dialysis catheters are prone to a relatively high rate of infectious and thrombotic complications relative to AVFs and grafts. In addition patients receiving dialysis via

catheter have a higher morbidity and mortality over AVFs and grafts. Over the years optimization of catheter materials and design has led to improvements in the ability of catheters to allow effective dialysis however infectious and thrombotic complications still remain a problem. Catheter coatings with various antiseptic and antithrombotic properties have been shown to result in improved outcomes relative to infection and thrombosis in specific non-tunneled acute applications. To date there has been no controlled prospective data that evaluates the outcomes of coated vs. uncoated tunneled dialysis catheters with regards to infection or thrombosis over the timeframe in which these catheters are typically used. There have been some smaller retrospective studies that have shown some promising results of heparin catheter coatings, but much still needs to be worked out. In a world of shrinking healthcare funds it will be increasingly difficult to justify increased cost of catheter coatings without rigorous studies to document benefit in terms of outcome or cost.

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## Eradication of Central Venous Catheters - A Physician Responsibility

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Unfortunately, 80% of prevalent hemodialysis patients start dialysis with a central venous catheter. Alarming, 75% of patients followed by a nephrologist for more than six months initiate dialysis with a CVC, negating the argument that it is the late referral of patients that is the dominant reason for the use of CVC. 25% of prevalent dialysis patients have a CVC. Numerous studies have demonstrated the pernicious effect of CVC including higher erythropoietin stimulating agent use and their incumbent costs (some 40% of overall healthcare expenditures in the ESRD program), higher hospitalization rates and higher mortality rates. Indeed, studies confirm that the leading etiology for the high mortality rates (24%) can be accounted for by the high use of CVC. There is no one singular reason that accounts for the noted use of CVC. Late referral to the nephrologist, poor communication between referring primary care physicians and nephrologists, a lack of co-management between physicians, lack of communication between nephrologists and surgeon, inadequate financial reimbursement for surgeons and barriers to getting the patient into the surgeon and timely access placement are all candidates, all are culprits that need to be addressed. The noted disparity of delivering optimum quality of care in ESRD flies in the face that there are three well established clinical practice guidelines (CPG) dealing with vascular access placement. In addition, numerous efforts (Fistula First, ESRD Networks and providers of dialysis) are underway, yet we continue to have the unacceptable rates of CVC contributing to the noted higher morbidity, mortality and costs. A major problem in eradicating CVC is that having a CPG is not sufficient, it is the implementation of the CPG that is critical. Implementation requires process changes and the use of specifically designed tools to implement the CPG. The Renal Physicians Association along with numerous others in the renal community have developed a collaborative approach to provide physician and providers the implementation tools needed to ensure implementation of CPG. Finally, the key factor is that nephrologists, interventionalists, providers and hospitals must assume responsibility and be accountable to implement the CPG to virtually eliminate CVC as an access for patients with ESRD.