Vascular Access Management

Surgical Creation

Survelliance|Cardiac Function

Angioplasty|Surgical Revision

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Acknowledgments

Transonic®, a measurement innovations company, has pioneered three distinct measurement modalities for proactive arteriovenous (AV) vascular access management. These include transit-time ultrasound for volume flow measurements in vessels and tubing, ultrasound dilution technology for surveillance of dialysis adequacy and vascular access flow, and cardiac function assessment during hemodialysis. Third is catheter-based thermal-dilution flowmetry for intragraft measurements during vascular access angioplasty.

The true innovators, though, are our end users: clinicians, such as Dr. Thomas Depner, who are dedicated to the improvement of care for their end-stage renal disease (ESRD) patients through the advancement of new methodologies. We and the larger medical community owe a debt of gratitude to these physicians and researchers without whom the ultimate goal of removing "end-stage" from all end stage renal disease would remain elusive.

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Vascular Access Management:
A "Circle of Care®"

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I. Flow-based Vascular Access Management

Blood Flow: *The quantity of blood that passes a given point in the circulation in a given time (mL/min or L/min). The pumping of blood by the heart through a closed circulatory system was first described in 1628 by English physician William Harvey. His work was influenced by René Descartes and Spanish physician Michael Servetus who were thought to have "re-discovered" and extended the findings of Ibn al-Nafis, a thirteenth century Muslim physician.*

A. Why Flow-based Vascular Access Management?

End-stage renal disease (ESRD) patients whose kidney function is replaced by hemodialysis depend upon a "well-functioning" vascular access. The access must deliver a sufficient blood flow to sustain administration of the dialysis prescription (Kt/V). However, the rate of blood flow through the access can be so high that it causes cardiac or other complications.

Blood flow is, therefore, a fundamental metric of vascular access performance and measurement of vascular access blood flow is the quintessential functionality test for managing vascular access patency - hence Flow-based Vascular Access Management.

B. Transonic Vascular Access "Circle of Care®"

Vascular access blood flow can be measured with Transonic® flow technology at several intersects in its natural history: during access creation, during hemodialysis, and during a corrective intervention and/or surgical revision. Together, these measurements constitute a comprehensive flow-based "Circle of Care" for vascular access management.

1. Flow-based Arteriovenous (AV) Access Creation Surgery

Creation and maturation of a viable AV access is the initial step in enabling successful long-term hemodialysis. During AV access creation, intraoperative blood flow measurements with a Transonic® Perivascular Flowprobe (Fig. 1.1) provide quantitative volume flow values that instantly alert the surgeon to any flow-limiting problems that may jeopardize access maturation.

2. Flow-based Hemodialysis Surveillance and Cardiac Function Assessment

A matured access must deliver sufficient flow for dialysis. Although pressure, bruit and thrill are common surrogates for flow, flow remains the primary functional indicator of vascular access patency.

Monthly vascular access flow surveillance during routine dialysis sessions will detect precipitous drops in access flow. They can trend decreases in flow below safe thresholds which will alert dialysis staff to a failing access in time for minimally invasive corrective action.

Fig. 1.1: Intraoperative Perivascular Flowprobe measures direct volume flow during AV access creation surgery.

Pressure Is Not A Surrogate for Flow

A commonly held assumption is that spot cardiovascular pressure drives cardiovascular flow. However, this notion is contradicted by the Figure from *McDonald's Blood Flow in Arteries*[1] where the flow pulse (Q) clearly precedes the pressure pulse (P). J.B.S. Haldene referred to the observation that pulsatile flow in vessels is driven, not by spot pressure, but by the pressure difference over the vessel segment carrying flow "as a "blinding glimpse of the obvious."[2]

$$\Delta P = Q \bullet Z$$

where: Q = flow
ΔP = pressure differential over a vessel segment carrying flow (Q)
Z = Impedance (=dynamic resistance) to flow of vessel segment

A physiological pressure measurement is a spot measurement compared to ambient atmospheric pressure. It is not a differential pressure measurement across a vessel segment. Therefore, a single pressure measurement can never serve as a surrogate for flow.

[1]Nichols, Wilmer W., and Michael F. O'Rourke. McDonald's Blood Flow in Arteries, Theoretical, Experimental and Clinical Principles, Fifth Edition, London, Hodder Arnold, 2005, p 137.

[2] ibid p.138.
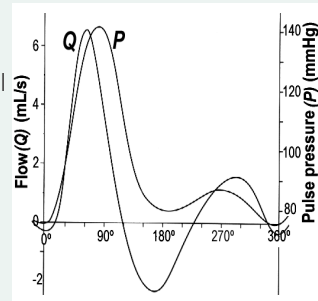
Simultaneously recorded flow velocity pulse (Q) and arterial pressure pulse (P) of a dog femoral artery.[1]

I. Flow-based Vascular Access Management cont.

a. Hemodialysis Surveillance

Transonic® Flow-QC® Hemodialysis Monitors and Flow/dilution Sensors (Fig. 1.2) use Gold Standard Ultrasound Dilution Technology to determine Dialysis Adequacy by measurements of Delivered Blood Flow and Recirculation. The system also measures Vascular Access Flow directly to detect early signs of flow problems wherever they occur in a vascular access.

b. Cardiac Function

Cardiac Function is monitored during hemodialysis by ultrasound dilution measurement of Cardiac Output and simultaneous calculation of Cardiac Index, Central Blood Volume, Central Blood Volume Index and Peripheral Resistance.

Surveillance

Fig. 1.2: Flow/dilution sensors clamp onto blood lines to measure Delivered Blood Flow, Recirculation, Vascular Access Flow and Cardiac Output during hemodialysis.

3. Flow-based AV Access Intervention and/or Surgical Revision

When an AV access either does not mature or exhibits early signs of access failure, the goal of endovascular intervention (angioplasty) and/or surgical revision is to restore adequate flow through the access to sustain continuing hemodialysis.

a. Flow-guided Percutaneous Transluminal Angioplasty (PTA)

PTA is the primary intervention to restore flow within a failing AV access. Elective rather than emergent, less invasive and more cost effective than surgery, it preserves potential future access sites. On-the-spot intragraft flow measurements with the ReoCath® Flow Catheter and HVT100 Endovascular Flowmeter guide interventional radiologists during PTA flow augmentation or in restoration procedures (Fig. 1.3).

b. Flow-based Access Revision Surgery

A variety of surgical techniques are used to restore flows and salvage problematic accesses. AV access flow can be dangerously low or too high. During these procedures, quantitative values of Transonic intraoperative flow measurements assist in surgical management.

Angioplasty

Fig. 1.3: A ReoCath Flow Catheter injects saline into the access to measure intragraft flow during PTA.

I. Flow-based Vascular Access Management cont.

C. "Circle of Care®": Cornerstone of Vascular Access Management

In the current outcomes-driven ESRD climate, quantitative flow data is key to successful vascular access management. Flow measurements inform during vascular access creation, hemodialysis surveillance, cardiac function assessment, angioplasty and/or surgical revision. They are the cornerstone for optimizing vascular access management.

Transonic Flow-QC® measurement capabilities for a "Circle of Care" for vascular access management include overviews of some of the current flow-based vascular access management findings, practices, and protocols. Summarized are the pioneering contributions of clinical researchers.

As innovations in patient care evolve, the challenge for ESRD health care providers is to further define, refine and standardize these flow-based protocols. We welcome your feedback and studies for the next revision of the handbook and hope that you find this handbook informative.

Transonic® Flow-based "Circle of Care" — Measurement Modalities			
Vascular Access Intersect	Measurement		Equipment	Technology
Surgery			Surgical Flowmeter (Optima, 300-Series, AureFlo®) with Flowprobes (vessel-size dependent)	Transit-time Ultrasound
AV Access Creation	Volume Flow	mL/min		
AV Access Revision	Volume Flow			
Hemodialysis Surveillance			HD03 Hemodialysis Flow Monitor; Paired Flow/dilution Sensors: H4FX	Indicator Dilution
Vascular Access Patency	Access Flow	mL/min		
Dialysis Adequacy	Delivered BF	mL/min		
	Recirculation	%		
Cardiac Function	CO, CI, CBV, PR,	various		
Percutaneous Transluminal Angioplasty (PTA)	Intra-access blood flow	mL/min	HVT100 Endovascular Flowmeter; ReoCath® Flow Catheter: antegrade, retrograde	Thermal Dilution
Access Revision				

Table 1.1: Three Transonic Flow-QC® measurement modalities provide quantitative vascular access flow data for comprehensive vascular access management.

II. Flow-based Surgery: AV Access Creation

Intraoperative Blood Flow Measurements
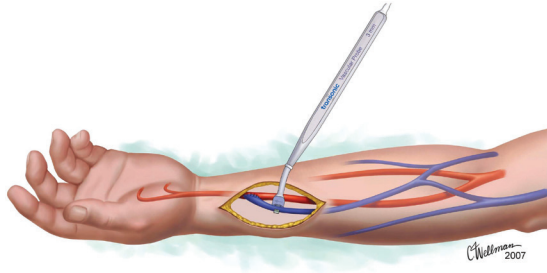
A. Measuring Blood Flow during AV Access Creation

Establishment of a viable AV access is the first step towards effective long-term hemodialysis. During AV access construction surgery, intraoperative blood flow measurements immediately identify flow limiting technical problems, and provide an indication of the future successful maturation of the access.[1-3]

Quantitative blood flow measurements first validate a surgeon's clinical assessment and assure that the surgery is technically sound. Secondly, good intraoperative flow measurements provide the surgeon with an early, on-the-spot indication of the probability that the access will mature successfully. This information is critical in this Fistula First era where it has been reported that twenty-eight to fifty-three percent of fistulas do not mature.[4] Flows below certain thresholds foreshadow poor maturation potential. Moreover, intraoperative blood flows correlate with access outcomes including patency, number of interventions, and mean time to intervention.[1]

This chapter presents the technology and protocols for intraoperative blood flow measurements during surgical creation of autologous AV fistulas and prosthetic AV grafts including synopsis of studies.[1-8]

II. Flow-based Surgery: AV Access Creation cont.

B. Transit-Time Ultrasound Flow Measurements

Transit-time ultrasound technology provides quick, quantitative, intraoperative volume flow measurements without constricting an artery or vein. Vascular Flowprobes feature a convenient handle and an application-specific Probe head sized for vessels from 1.3 to 16 millimeters in diameter (Fig. 2.1). The new OptiMax® Flowprobe (pictures on page 88), with specially-designed tape-on supports on a flexible neck, stabilize the Probe on the vessel during a procedure and enable extended flow measurements to guide intraoperative procedures.

The J-bracket reflector on the Probe's head defines the flowsensing window, holds ultrasound couplant gel in place, and maintains the vessel in alignment with the Probe. The flexible Probe neck allows positioning of the Probe head to conform to vessel orientation. The Probe can be easily slipped around a vessel and then quickly released.

Volume flow in milliliters per minute is displayed on the flowmetering system. FlowSound® allows the surgeon to listen to volume flow without looking away from the surgical field. Flow waveforms are recorded and can be printed for the patient's record.

Fig. 2.1: Transonic® Vascular Flowprobes feature a convenient handle, a flexible neck and customized Probe head.

Transit-Time Ultrasound[9]
Ultrasound That Measures Volume Flow, Not Velocity

Using wide-beam illumination, transducers inside a non-constrictive Perivascular Flowprobe send ultrasonic signals back and forth, alternately intersecting flowing blood in upstream and downstream directions. The transit time of the ultrasonic beam is decreased when traveling downstream with the blood flow and increased when traveling upstream against the flow. The difference between the integrated transit times is a measure of volume flow.[9]
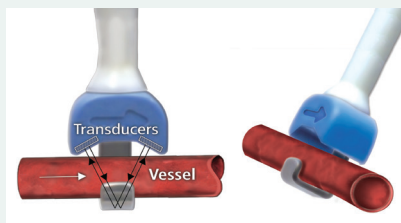
Loose-fitting Perivascular Flowprobe is applied around a vessel exposed during surgery. Ultrasound couplant provides full ultrasound passage within the flowsensing window.

II. Flow-based Surgery: AV Access Creation cont.

C. Flow-based AV Fistula Construction

Autogenous arteriovenous fistulas (AVFs) are the vascular access of choice because they remain patent longer and exhibit fewer complications than AV grafts or catheters. No matter where the fistula is constructed, measuring flow intraoperatively at the time of its construction assures the surgeon of early post-op patency and absence of hidden flow obstructions. Secondly, good initial fistula flows bode successful fistula maturation.

1. Flow Studies during AV Fistula Construction

Clinical researchers at the University of Wisconsin and the Southern Arizona Vascular Institute have measured flows at the time of AV fistula construction to identify fistulas that are unlikely to mature and require immediate revision.[1-2]

Johnson et al measured venous outflows of 227 autologous AV fistulas intraoperatively 5-10 minutes after their completion over a four year period.[1] Berman measured 72 autologous AV fistulas over a 12 month period.[2]

The Johnson study concluded that flow rate was the single most important determinant of primary and secondary patency. They found that AVFs with flow rates of ≤ 280 ml/min had significantly worse patency rates compared to higher flow counterparts.

Other findings from the Johnson study include:
1) Intraoperative measurements of access blood flows are predictive of both short and long-term patency.
2) Patency rates in AV fistulas are higher than in PTFE grafts.
3) Higher flow AV fistulas and grafts had higher patency rates than lower flow AV fistulas and grafts.
4) Blood flow levels in newly created fistulas and grafts correlate with the average number of future interventions and the time to the first intervention.
5) Higher flow AV accesses required fewer interventions per patient and a longer time to the first intervention than do low flow accesses.

Tables 2.1 and 2.2 on page 8 summarize the results of the Johnson study.

II. Flow-based Surgery: AV Access Creation cont.

AV-Fistulas	Flow (ml/min)	Failure within 90 days (Requiring Intervention)	p value
Radiocephalic	< 170; >170	56 %; 15% respectively	.001
Brachiocephalic	< 280; > 280	64 %; 18% respectively	.01

Table 2.1: In radiocephalic fistulas, initial flows of less than 170 ml/min correlated with failure within 90 days. In brachiocephalic fistulas, that threshold was 280 ml/min.[1]

Johnson et al recommended that an access site be abandoned if flow is ≤ 100 mL/min. For access flow rates between 100 and 300 mL/min, they recognized that the access was at risk for early failure and recommended close observation of the fistula for at least four to six weeks before being used for hemodialysis. If the initial blood flow rate was > 300 mL/min, they recommended allowing four to six weeks for the fistula to mature before cannulation (Table 2.2).

Fistula Construction Guidelines (Johnson)[1]	
Flow Rate (mL/min)	Recommendation
≤ 100	Abandon site
100 - 300	At risk for early failure; observe closely; allow to mature > 4-6 weeks before using
> 300	Allow to mature > 4-6 weeks before using

Table 2.2: AV Fistula guidelines as identified by Johnson study.[1]

Berman reported significant differences in blood flow rates between functional and non-functional radiocephalic and brachiocephalic AV fistulas. His data suggest a threshold value of 140 mL/min for radiocephalic AV fistulas and 308 mL/min for brachiocephalic fistulas to predict maturation to a functional access.[2] Two Asian studies by Won[3] and Lin[5] report thresholds to predict radiocephalic fistula maturation of > 160 mL/min and > 200 mL/min, respectively. A 2010 Swiss study by Saucy[12] of 58 radiocephalic fistulas concluded that 120 mL/min would be a predictive threshold for maturation. Results of studies are summarized in Table 2.3.

Thresholds (ml/min) to predict Fistula Maturation: Comparison of Studies					
AV Fistulas	Berman 2008[2]	Johnson 1998[1]	Won 2000[3]	Lin 2008[5]	Saucy 2010[10]
Radiocephalic	> 140 (n = 21)	> 170 (n = 94)	> 160 (n = 50)	> 200 (n = 109)	> 120 (n = 58)
Brachiocephalic	> 308 (n = 49)	> 280 (n= 128)			

Table 2.3: Comparison of thresholds of five studies to predict maturation of AV Fistulas.

II. Flow-based Surgery: AV Access Creation cont.

2. AV Fistula Measurement Steps

Intraoperative flow measurements with transit time-ultrasound Flowprobes during creation of an AV access are quick and easy when following the measurement steps outlined below.

a. Identify Vessel to Be Measured

Expose and identify AV fistula venous outflow.

b. Select Flowprobe Sizes

Measure the diameter of the vein with a gauge. Select a Probe size so that the vein diameter is between 60% - 100% of the size of the flowsensing window (Fig. 2.2). Probe size recommendations for autogenous AV fistulas are shown in Table 2.4.
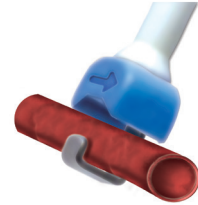
Fig. 2.2: Vessel filling 60% - 100% of the flowsensing window.

Site	Probe Size	Non-restrictive vessel diameter
Radial artery	2 mm	1.5 - 2.7 mm
	3 mm	2.4 - 3.7 mm
Brachial artery	3 mm	2.4 - 3.7 mm
	4 mm	3.2 - 5.3 mm

Table 2.4: Recommended Flowprobe sizes for intraoperative measurements during creation of an AV Fistula or prosthetic graft.

c. Apply Flowprobe to Measure Venous Outflow

Select a site on the vein wide enough to accommodate the Probe's acoustic reflector. Apply sterile Aquasonic Gel 100 to the Flowprobe lumen to provide ultrasound coupling between the Probe body and Probe reflector. Apply the Flowprobe to the vein, bending the Probe's flexible neck segment as necessary, so that the entire vein lies within the lumen of the Probe and aligns with the Probe body (Fig. 2.2). Listen to FlowSound® as the Flowprobe is applied to the vessel. The higher the pitch, the greater the flow.

Re-apply sterile gel into the Probe lumen as needed and check the Signal Quality Indicator on the flowmeteing system for good ultrasound transmission. An acoustic error message will be displayed if ultrasound contact falls below an acceptable minimum.

II. Flow-based Surgery: AV Access Creation cont.

END-TO-SIDE ANASTOMOSIS

When the AVF is constructed with end-to-side anastomosis, simply measure venous outflow distal to the venous anastomosis (Fig. 2.3).
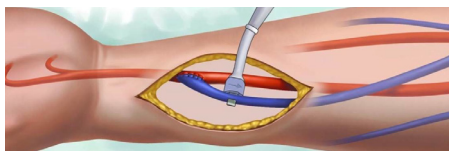
Fig. 2.3: Measuring venous outflow flow in a fistula anastomosed end to side.

SIDE-TO-SIDE ANASTOMOSIS

If the anastomosis is constructed with a venous-side-to-arterial-side anastomosis, occlude the vein (Fig. 2.4) proximal to the venous anastomosis while measuring flow distal to the anastomosis.

If spasm occurs, papaverine can be locally infused along the artery and vein while flow is measured.
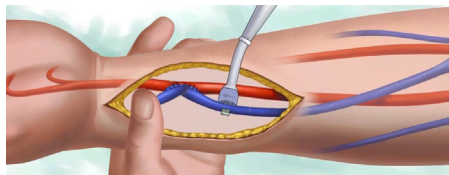
Fig. 2.4: Measuring venous outflow flow in a fistula anastomosed side to side.

d. Document Flows

After applying a Flowprobe to a vein, wait 10-15 seconds for mean readings to stabilize before documenting the measurement via the [PRINT] button on an HT300-Series Flowmeter or capturing a snapshot of the display on the AureFlo® System. If flow is negative on the flowmeter display, press the [INVERT] button to change the polarity before printing the waveform.

II. Flow-based Surgery: AV Access Creation cont.

Protocol: Intraoperative Blood Flow Measurement during AV Fistula Creation Surgery

1. Create AVF

2. Measure Vein Diameter; Select Flowprobe size.

3. Measure BP

Systolic BP < 100 mmHg →

3b. Wait until systolic BP > 100 mmHg

Systolic BP > 100 mmHg

4a. Apply Flowprobe

End-to-end or venous end-to-arterial side anastomosis.

Side-to-side or arterial end-to-venous side anastomosis.

5a. Measure venous outflow distal to anastomosis

5b. Measure outflow distal to anastomosis while occluding vein proximal to anastomosis

6. Evaluate Flow
per pre-established thresholds
Radiocephalic: >250-300 mL/min
Brachiocephalic: > 400 mL/min
Basilic vein transposition: > 500 mL/min

Flow does not meet pre-established threshold

7b. Examine anastomosis and site. Revise, if necessary

Apply papaverine & wait several minutes

Flow meets threshold.

7a. Fistula likely to mature

Flow meets threshold.

8. Remeasure and Evaluate Flow

Flow does not meet threshold.

9. Fistula maturity tenuous
Revise or alert dialysis staff to suspect fistula (Monitor fistulas with flows between 100-300 mL/min weekly) or seek another fistula site.

II. Flow-based Surgery: AV Access Creation cont.

D. Flow-based AV Prosthetic Graft Construction

1. Non-Autogenous Prosthetic Grafts

When native veins are unsuitable or fistula sites exhausted, a prosthetic bridge graft, usually from expanded polytetrafluoroethylene (ePTFE) is used.

Forearm PTFE Graft

Grafts can be looped or straight (Figs. 2.6-2.8) and are most commonly constructed with inflow from the radial or brachial artery to either the superficial or deep veins (Fig. 2.5). Although grafts have lower patency rates than fistulas and are more prone to infection and thrombosis. They can be used for hemodialysis within a couple of weeks of implant. This reduces the acute use of a catheter at the onset of hemodialysis.

Fig. 2.5: Loop ePTFE graft from brachial artery to cephalic vein.

2. Intraoperative Prosthetic Grafts Flow Study[2]

In their study, Dr. Christopher Johnson and colleagues measured 162 prosthetic PTFE graft venous outflows five to ten minutes after completion of the anastomoses.[1] Grafts with flow rates of ≤ 400 ml/min had significantly worse patency rates than their higher flow counterparts (Table 2.5).

Graft Type	Flow(ml/min)	Failure within 90 Days (Requiring Intervention)	p value
PTFE Grafts	< 400	65 %	.01
	> 400	40 %	

Table 2.5: In prosthetic grafts, initial flows of less than 400 ml/min foreshadowed failure within 90 days.

This and other studies attest to the value of routine intraoperative measurement of access blood flow.[1-3,5-8] It is suggested that, if the flow through a prosthetic graft is equal or less than 250 ml/min, the site should be reassessed. If graft flow is 250 to 400 ml/min, consider prophylactic anticoagulation. The recommendations are summarized in Table 2.6 on the next page.

II. Flow-based Surgery: AV Access Creation cont.

ePTFE-Grafts	
Flow Rate	Recommendation
≤ 250 ml/min	Abandon site immediately
250 - 400 ml/min	Consider prophylactic anti-coagulation

Table. 2.6: In prosthetic grafts, initial flows of less than 400 ml/min foreshadowed graft failure within 90 days.

3. Intraoperative Graft Flow Measurements

Flow cannot be measured directly on newly inserted prosthetic ePTFE grafts because the presence of air within the synthetic graft walls blocks ultrasound transmission. Graft outflow is therefore measured on the outflow vein following completion of both the arterial and venous anastomoses (Figs. 2.6, 2.7). If the distal vein has not been ligated, flow is still measured proximal to the anastomosis, while the distal unligated section of the vein is temporarily occluded (Fig. 2.8).
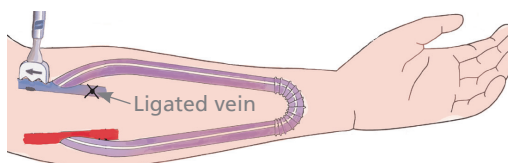
Fig. 2.6: Loop ePTFE Graft anastomosed to the side of an artery and end of ligated vein.
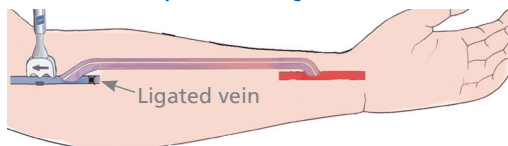
Fig. 2.7: Fig. 2.8: Straight ePTFE Graft anastomosed to the side of an artery and end of a vein.
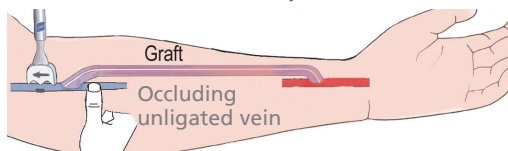
Fig. 2.8: In a graft anastomosed to an unligated vein, flow is measured while the distal portion of the vein is temporarily occluded.

4. AV Prosthetic Graft Measurement Steps

To measure flow intraoperatively during creation of a prosthetic graft access, the following protocol is suggested:

a. Identify & Prepare Vein to Be Measured

Identify exposed segments of the venous outflow conduit for the graft. Determine the optimum site (wide enough to accommodate the Probe's acoustic reflector) for applying the Probe, and remove fat and excess tissue from the site.

b. Select Flowprobe Sizes

Estimate the vein diameter. Select a Probe size so that the vein will fill 60%-100% of the Flowprobe's sensing window (Fig. 2.2).

Site	Flowprobe size	Non-restrictive vessel size
Venous Outflow of Graft	4 mm	3.2 - 5.3 mm
	6 mm	4.5 - 7.5 mm

Table 2.7: Probe size recommendations for venous outflows of prosthetic grafts.

c. Apply Flowprobe to Measure Venous Outflow

Apply sterile gel to the Flowprobe and apply the Flowprobe to the vein, proximal to the anastomosis, bending the Probe's flexible neck segment as necessary, so that the entire vessel lies within the Flowprobe sensing window and aligns with the Probe body (Fig. 2.2). Listen to FlowSound® as the Probe is applied. The higher the pitch, the greater the flow.

Check the Signal Quality Indicator on the flowmetering system to ensure good ultrasonic transmission.

d. Measure and Evaluate Venous Outflow

With the Flowprobe positioned as described in Step 3, measure average venous flow. As the surgical site recovers, graft flow will increase to hemodialysis flow levels (> 600 mL/min).

e. Document Flows

After applying a Flowprobe to a vessel, wait 10-15 seconds for mean readings to stabilize before documenting the measurement via the [PRINT] button on an HT300-Series Flowmeter or capturing a snapshot of the display on the AureFlo® System.

II. Flow-based Surgery: AV Access Creation cont.

Protocol: Intraoperative Blood Flow Measurement during AV Prosthetic Graft Construction

1. Create AV Graft

↓

2. Measure Vein Diameter; Select Flowprobe size.

↓

3. Measure BP — Systolic BP < 100 mmHg → **3b. Wait until systolic BP > 100 mmHg**

Systolic BP > 100 mmHg

↓

4a. Apply Flowprobe

End-to-end or venous end-to-arterial side anastomosis.

Side-to-side or arterial end-to-venous side anastomosis.

↓

5a. Measure venous outflow distal to anastomosis

5b. Measure outflow distal to anastomosis while occluding vein proximal to anastomosis

↓

6. Evaluate Flow per pre-established thresholds

Flow does not meet pre-established threshold

7b. Examine anastomosis and site. Revise, if necessary

Venous Outflow > 400 mL/min

Apply papaverine & wait several minutes

Flow meets threshold.

7a. AV Graft likely to be able to be used.

8. Remeasure and Evaluate Flow

Flow does not meet threshold.

9. AV Prosthetic Graft use tenuous Abandon, construct another graft

E. AV Access Creation References

1   Johnson CP *et al*, "Prognostic Value of Intraoperative Blood Flow Measurements in Vascular Access Surgery," Surgery 1998; 124: 729-38. (Transonic Reference # 1504AH)

2   Berman SS *et al*, "Predicting Arteriovenous Fistula Maturation with Intraoperative Blood Flow Measurements," J Vasc Access. 2008 Oct-Dec;9(4):241-7. (Transonic Reference # 7710AH)

3   Won T *et al*, "Effects of Intraoperative Blood Flow on the Early Patency of Radiocephalic Fistulas," Ann Vasc Surg 2000; 14(5): 468-72. (Transonic Reference # 2411AH)

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IIIa. Flow-based Vascular Access Surveillance

A. Hemodialysis Vascular Access Surveillance

A hemodialysis patient's vascular access is his or her lifeline. If it fails, underdialysis can occur that can lead to costly hospitalizations[1]. Therefore, the National Kidney Foundation's Kidney Disease Outcome Quality Initiative (KDOQI) Guidelines, the European Renal Association-European Dialysis and Transplant Association's (ERA-EDTA) European Best Practice Guidelines on Haemodialysis, the Australian CARI and Canadian Guidelines all advise proactive vascular access management.[1-4] KDOQI Guidelines recommend surveillance at intervals of at least once a month to diagnose asymptomatic, but hemodynamically significant stenosis to prevent progression to a functionally significant stenosis, the substrate for thrombosis. According to KDOQI Guidelines, these monthly measurements should be, "…tabulated and tracked within each dialysis center as part of a Quality Assurance/ Continuous Quality Improvement program" and evaluated to look for trends toward decreases in flow in order to proactively identify access stenoses for expeditious referral for corrective procedures.[1]

Monthly Transonic® Hemodialysis Surveillance tracks a patient's vascular access flow over time (Fig. 3a.1, page 19). If access flow decreases below a critical threshold, fistulograms or interventions can be scheduled proactively to delay access failure. Such early intervention with minimally invasive restorative flow procedures reduces morbidity and costs.[6] The clinic can continue to administer dialysis, collect and analyze data, and reduce its dependence on outside services for costly studies and lab tests.

Transonic Flow-QC® Hemodialysis Surveillance is the cornerstone of a comprehensive Vascular Access Management program.[29] Flow-QC measurements tell clinicians the following:

1. Hemodialysis Adequacy

- Tests calibration of the blood pump;
- Verifies true delivered blood flow; compares delivered blood flow to pump setting to identify flow disparity and avoid underdialysis. If disparity is significant, Flow-QC® assists in determining cause (blood pump calibration versus inflow restriction/excessive pre-pump negative arterial pressure);
- Detects and quantifies access recirculation in AV access, catheters;
- Identifies inadvertent reversal of dialysis lines to prevent recirculation and/or underdialysis;
- Determines proper needle placement;
- Identifies sources of large negative arterial blood line pressure (and its resulting underdialysis);
- Determines the most appropriate blood pump setting for a low flow access when it is not feasible to increase access flow;
- Provides delivered flow and recirculation measurements to maximize catheter function.

Venous Pressure Does Not Correlate with Flow Measurements[7-8]

The top vessel graphic below shows that increased resistance caused by a stenosis located past the site of a venous pressure measurement produces an increase in venous pressure. When the stenosis occurs at inflow, before the point where pressure is measured (middle graphic), venous pressure actually decreases. If multiple stenoses occur (bottom graphic), one before the point of pressure measurement, and another one after, the increased and decreased pressure components could cancel one another out, ultimately resulting in no change in venous pressure. However, hemodynamically significant stenoses can result in all sites and produce a decrease in actual access flow.

Stenosis Development at Different Sites in An Access — Venous Pressure — Blood Flow
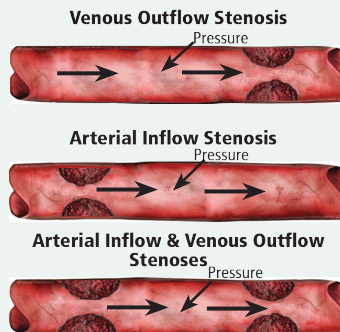
Venous Outflow Stenosis
Pressure

Arterial Inflow Stenosis
Pressure

Arterial Inflow & Venous Outflow Stenoses
Pressure
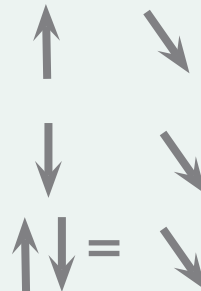
IIIa. Flow-based Vascular Access Surveillance cont.

2. Vascular Access Measurements

- Measures actual function in AV grafts and fistulas in order to identify failing accesses and avert underdialysis and/or thrombosis;
- Indicates effectiveness of interventions (post-intervention surveillance) or limb ischemia;
- Excludes access dysfunction quickly as cause of underdialysis;
- Identifies a mid-access obstruction;
- Identifies high-flow versus low flow accesses to select ideal treatment plan for correction (flow-restricting versus re-vascularization procedure);
- Permits access surveillance to be performed by the clinic's staff who then can alert nephrologist to possible onset of access dysfunction;
- Implements KDOQI Guidelines;
- Implements Best Practices for patient care with Gold Standard reference method.

"A hemodynamically significant stenosis is the substrate for thrombosis by reducing flow, increasing turbulence, and increasing platelet activation and residence time against the vessel wall." KDOQI Guidelines 2006[1]
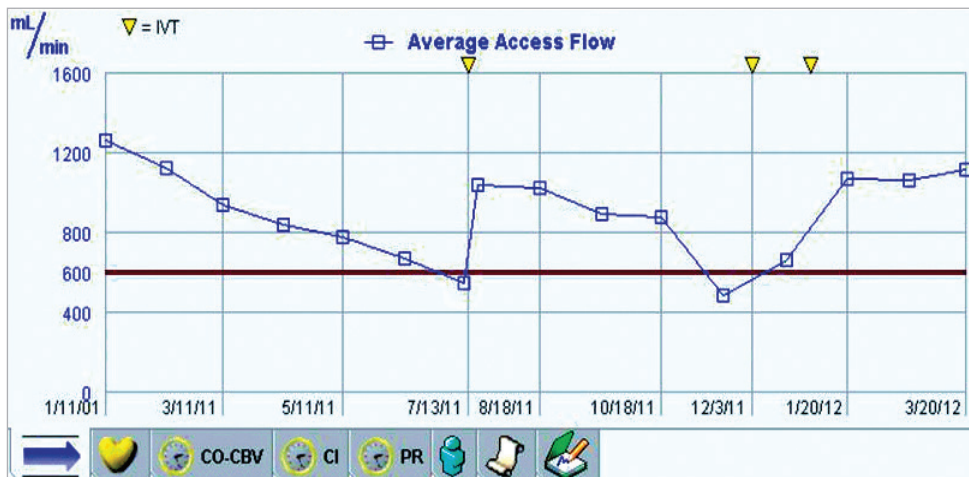
Fig. 3a.1: Access Flow Trend: This flow history of a patient's AV access shows that the onset of stenoses were identified by decreases in flow below 600 ml/min. Interventions, indicated by the inverted arrows, resulted in immediate increases in access flow.

IIIa. Flow-based Vascular Access Surveillance cont.

B. Ultrasound Dilution Technology — The Gold Standard

The Transonic Flow-QC® Hemodialysis Monitor marries two gold standard technologies: ultrasonic transit time and indicator dilution[7,8]. Transonic® transit- time ultrasound flow measurements through sterile tubing is the gold standard for blood flow verification. Transonic ultrasound dilution access flow surveillance, the Krivitski Method, is the recognized gold standard technology for dialysis patient access flow measurement. The Krivitski Method calls for the temporary reversal of arterial and venous blood lines at their respective needle connections to create mixing conditions conducive for an indicator dilution flow measurement when a bolus of isotonic saline is injected into the blood circuit (Fig. 3a.2). Classical dilution equations are used to calculate vascular access flow.[5]
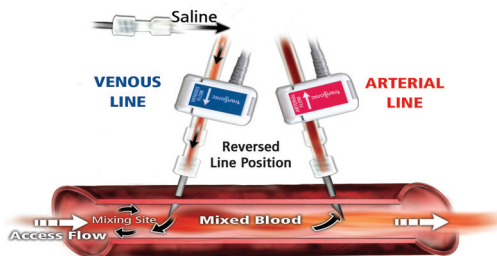
Fig. 3a.2: "Krivitski Method" is the temporary reversal of blood lines at needle connections to create proper mixing conditions. When dialysis lines are thus reversed to induce recirculation, vascular access flow (Q_a) can be calculated.[10]

1. Hemodialysis Adequacy

a. True Delivered Blood Flow Verified by Transit-Time Ultrasound[8]

Effective dialysis depends on delivery of the dialysis prescription through functional blood lines into a patent vascular access. Underdialysis is often caused by poor delivered blood flow. By comparing the flow reading of Transonic actual delivered blood flow through the dialysis lines, connected to either a graft, fistula or catheter, with the dialysis pump setting, dialysis delivery problems can be quickly identified and resolved.

Fig. 3a.3: Blood line inserted into the groove of the flow/dilution sensor body.

To measure true delivered blood flow, matched Flow/dilution Sensors clip onto the arterial and venous dialysis lines during hemodialysis (Fig. 3a.3) See correct technique in sidebar on page 22). Each sensor emits an ultrasound beam that transects the tubing and blood in upstream and downstream directions. When the ultrasound beam travels in the direction of flow, the transit

time it takes to traverse the distance through the tubing and blood is decreased by a flow-dependent amount. When the beam travels in the opposite direction, against the flow in the tubing, the beam's transit time is increased by a flow-dependent amount. By subtracting the integrated upstream and downstream transit times, volume flow is calculated.[8] The Hemodialysis Monitor continuously displays this delivered blood flow.

b. Access Recirculation by Ultrasound Dilution Technology

The Flow-QC® Hemodialysis Monitor can also measure access recirculation, a late indicator of vascular access dysfunction, in fistulas, grafts and catheters.

To measure vascular access recirculation, Flow/dilution Sensors monitor the blood's ultrasound velocity (1560 - 1590 m/sec). The greater the protein concentration in the blood, the faster ultrasound will travel. When a bolus of isotonic saline (velocity in blood is 1533 m/sec) is injected into the blood, the blood protein concentration is diluted. Flow/dilution Sensors detect the reduced ultrasound velocity.[10]

When recirculation occurs, the saline indicator returns immediately to the arterial line (Fig. 3a.4) where the diluted blood is detected by the arterial sensor. Flow-QC software converts the data into conventional dilution curves (Fig. 3a.5). The first blue curve indicates the saline dilution as blood flows through the venous sensor. The second red curve represents saline dilution as flow passes through the arterial sensor. Recirculation is calculated as a ratio of the area under the arterial curve to the area under the venous curve.
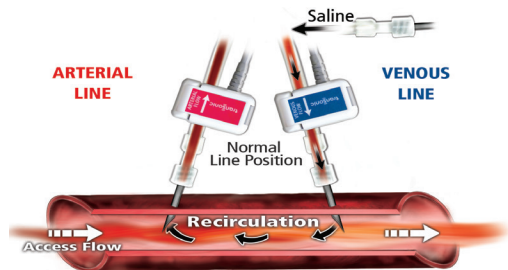
Fig. 3a.4: Recirculation Measurement. Saline is introduced into the venous sensor with the dialysis lines in normal position. Access recirculation (backflow) through the vascular access into the arterial needle is measured.
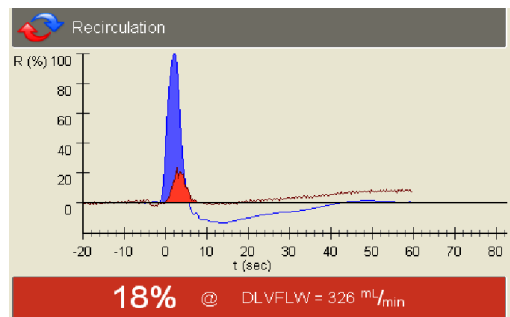
Fig. 3a.5: A blue venous (upper) dilution curve followed by a red (lower)arterial curve. The ratio of the areas under the curves indicates 18% recirculation.

IIIa. Flow-based Vascular Access Surveillance cont.

Flow/Dilution Sensor Set-up

1. Open the door of the first paired Flow/dilution Sensor.

2. Place the tubing segment to be inserted next to the Flow/dilution Sensor. The arrow on the Sensor must point in the direction of flow.

3. Open a 70% isopropyl alcohol wipe (prep pad).

4. Wipe the entire circumference of the tubing segment which will be inserted into the Flow/dilution Sensor.

5. Immediately insert this tubing segment into the Flow/dilution Sensor

6. Close the Tubing Sensor door.

7. Repeat the same [Wipe, Insert, Close Door] sequence for the second paired Flow/dilution Sensor and tubing segment.

Open and closed arterial Flow/dilution Sensor on tubing.

8. Verify Signal Strength indicator on the upper left of the Hemodialysis Monitor screen is green when the Monitor has been turned on. This means that the paired Flow/dilution Sensors have adequate contact with the tubing. If the Signal Strength indicator is not green, repeat the [Wipe-Insert-Close door] sequence to achieve proper contact.

Note: If you are using Flow-QC® tubing, place the arterial sensor in the center of the arterial Flow-QC segment and the venous sensor in the center of the venous Flow-QC segment.

Zero Percent Recirculation (0% Access Recirculation (AR))

As a late indicator of a failing access, recirculation generally occurs when access flow (AF) is less than dialysis pump flow (Qb). Because Transonic® ultrasound dilution technology is able to separate actual peripheral vascular access recirculation from cardiopulmonary recirculation, measurement of zero percent access recirculation has become the new recirculation standard.[11-13] Modalities which cannot separate cardio-pulmonary recirculation from access recirculation will indicate false positive recirculation.

Venous Stenosis

When a venous stenosis occurs, and access flow does not meet pump demands, some newly dialyzed blood from the venous line recirculates immediately back into the arterial line to compensate for a flow deficit at the arterial needle (Fig. 3a.6).
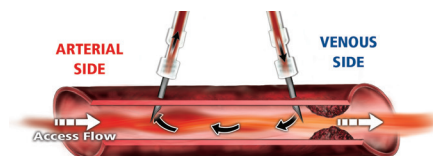
Fig. 3a.6: Access recirculation caused by venous stenosis. Some dialyzed blood recirculates back from the venous needle to the arterial needle.

Stenosis Between Needles

Although access recirculation generally occurs when access flow is less than dialysis pump flow, an important exception exists when a stenosis occurs between the dialysis needles (Fig. 3a.7). Because the stenosis limits flow through the access, the pump simply bypasses the stenosis (the area of greatest hemodynamic resistance) altogether and zero recirculation is reported.
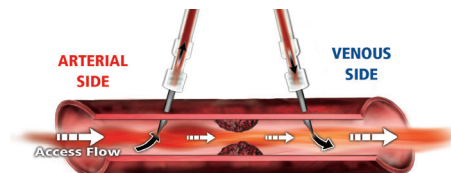
Fig. 3a.7: When 0% recirculation occurs although access flow is less than delivered blood flow, a mid-graft stenosis limits access flow. Pump flow (Qb) bypasses the stenosis.

Inadvertent Reversal of Blood Lines

If Flow-QC® surveillance detects vascular access recirculation but the recirculation disappears after the blood lines are reversed, the hemodialysis lines have been inadvertently reversed.

Identifying a New Reality: Zero Vascular Access Recirculation Using Ultrasound Dilution
MacDonald JT *et al*, ANNA J 1996; 23(6): 603-8. (Transonic Reference # HD4T)

Background
Access recirculation occurs when a portion of the blood returning from the dialyzer recirculates though the arterial line rather than passing through the venous circuit. Underdialysis occurs when recirculation is present. Recirculation is now considered a late indicator of access dysfunction. Because traditional methods such as blood urea nitrogen (BUN) sampling can not separate recirculation of dialyzed blood through the access from recirculation through the cardiopulmonary system (cardiopulmonary recirculation or CPR), recirculation is often overestimated.

When recirculation is present, the saline indicator passes through the arterial sensor and produces dilution curves.

Objective
Access recirculation was studied to better understand the rate of true access recirculation caused by close needle position *(in vitro)* or by low vascular access flow *(in vivo)*.
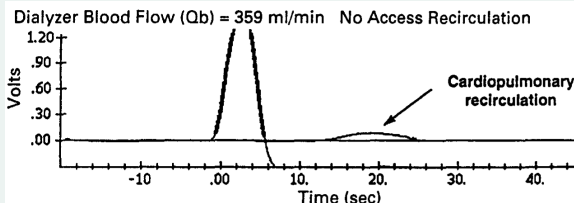
A flattened arterial dilution curve in the first ten seconds following saline injection confirms the zero percent recirculation.

Study
- Testing of needle position *in vitro*: The distance between insertion of the arterial and venous needles was varied from 1.5 cm to 12 cm in a laminar access flow model. Dialyzer blood flow and recirculation were measured.
- 74 patients were tested for access recirculation with the Hemodialysis Monitor.

Results
- Recirculation only occurred when access flow was smaller than or close to pump flow regardless of needle position.
- Two of 74 patients had recirculation with access flows less than pump flows; a second group had no recirculation with high access flows; a third group (7) had no access recirculation, but low access flows which required further investigation (two had stenoses between the needles).

Conclusions
- Ultrasound dilution monitor provides a rapid, simple and noninvasive method of measuring access flow and recirculation during hemodialysis which eliminates the false positives of BUN measurements.
- Data reveal that the prevalence of recirculation measured by ultrasound dilution is significantly less than that found by other methodologies.
- Zero recirculation is a reality, due to ultrasound dilution's ability to separate CPR from access recirculation.

IIIa. Flow-based Vascular Access Surveillance cont.

2. Vascular Access Flow

Flow-QC® access flow measurements are performed in prosthetic grafts and fistulas created with an end-to-side anastomosis by reversing the blood lines at their needle connections (Krivitski Method) (Fig. 3a.2).[11-13] The dialyzer removes blood from the venous side of the access and returns it to the arterial side to create the mixing conditions needed for an indicator dilution measurement of access flow (Fig. 3a.8).

When saline is introduced into the venous line, it dilutes the blood's protein concentration and reduces ultrasound velocity This blood protein concentration change is detected first by the sensor clipped onto the venous blood line. Flow-QC software then generates a venous dilution curve. The diluted blood from the venous line then enters the access and mixes with the incoming access flow. Upon reaching the arterial needle, a portion of mixed blood is removed from the access by the dialyzer. The diluted blood is then detected by the arterial sensor. Flow-QC software generates an arterial dilution curve. Access flow is calculated from the ratio of the area under the venous curve to the area under the arterial curve (Fig. 3a.9). The use of two sensors, (arterial and venous) effectively eliminates the multiple factors such as viscosity that influences ultrasound velocity.

Fig. 3a.8: Hemodynamics of access flow measurement with lines reversed by Krivitski Method. Line reversal creates an artificial recirculation loop with a mixing site at the arterial side of the access.
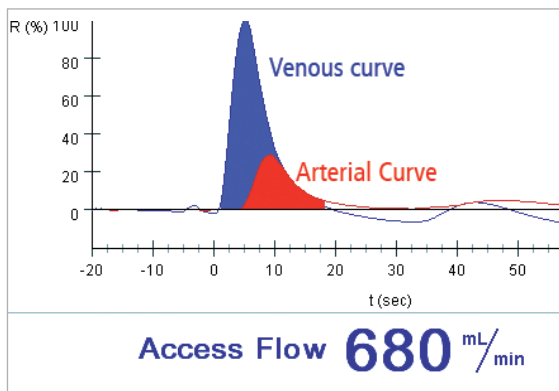
Fig. 3a.9: Result showing flow/dilution curves and access flow measurement of 680 ml/min flow.

IIIa. Flow-based Vascular Access Surveillance cont.

Access Flow Measurement in Fistulas with Side-to-Side Anastomosis "Proximal Branch Flow" as Access Flow Surrogate[12]

End-to-Side Anastomosis

When a AV fistula is constructed with an end-to-side anastomosis, access flow is measured with the blood lines reversed as described on page 25.

Fistula created with end-to-side anastomosis connecting the arterial inflow and venous outflow conduits.
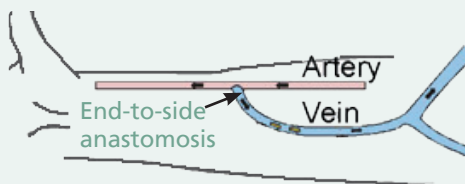
Side-to-Side Anastomosis

However, when a fistula is created with a side-to-side anastomosis, the flow pattern becomes more complex.[12] The venous limb of the fistula now has two branches: a "proximal" branch oriented towards the shoulder and a "distal" branch oriented towards the hand. Blood flow is usually greater in the proximal branch.
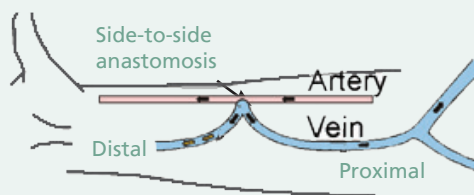
Fistula created with side-to-side anastomosis showing proximal and distal branches of venous outflow limb of the fistula.

Access Flow Measurement

AV fistulas created with a side-to-side anastomosis may have the hemodialysis needles placed so that blood is withdrawn from the distal branch of the venous limb by the arterial needle and is returned to the proximal branch of the venous limb through the venous needle.
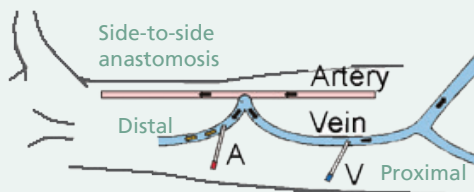
Fistula created with side-to-side anastomosis with the needles placed in the proximal and distal limbs of the fistula's venous outflow for normal dialysis. Unsuitable for access flow measurement.

This configuration positions the dialysis needles on opposing venous limbs of the arterial-venous anastomosis and is therefore unsuitable for Krivitski Method access flow measurements.

TRANSONIC FLOW-QC®

Access Flow Measurement in Fistulas with Side-to-Side Anastomosis "Proximal Branch Flow" as Access Flow Surrogate cont.

Repositioning the Needles

Therefore, to measure access flow in fistulas with a side-to-side anastomoses with the Krivistki Method, the arterial needle must be repositioned into the proximal branch. The arterial needle should face the flow if the distance between needle tips is less then 2-3 cm, or if there is a large aneurysm at the needle. With both needles now in the proximal branch of the venous limb, the blood lines can be reversed as usual and access flow measured. Access flow should be recorded as "Proximal Branch Flow." Proximal branch flow serves, in essence, as a surrogate for total access flow.
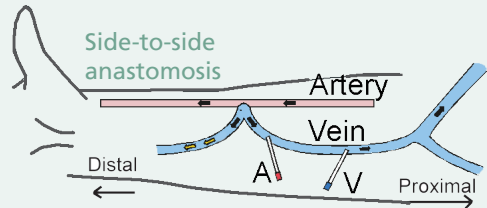
Needle reposition into the proximal branch to measure "proximal" branch flow.

This protocol, with both needles in the proximal branch, raises a red flag when:

- Proximal branch flow drops by 25% over a four-month period indicating changes in the vascular resistance at the fistula anastomosis or the proximal branch.

- Access Flow falls below 500 ml/min. Since proximal branch flow is less than or equal to access flow, access flow may still be above 500 ml/min when proximal branch flow registers 500 ml/min. For example, if proximal branch flow is 80% of access flow, access flow would actually be 625 ml/min. This means that proximal branch flow surveillance may signal a premature need for a fistulogram.

Summary

The assumption "access flow is equal to proximal branch flow" is a safe assumption. Proximal branch underestimation of flow will not cause a misdiagnosis of a failing access. It may, however, prompt premature fistulography for a deteriorating access.

Reference: Transonic Technical Note DL-4-tn "Measuring Flow in AV Fistulae," Krivitski, NM, 2005.[14]

C. Flow-QC® Hemodialysis Surveillance Protocols

Transonic® Flow-QC Hemodialysis Surveillance, combined with a patient's medical history, type of vascular access, and Kt/V prescription creates an opportunity to customize a patient's treatment in order to:
- Optimize dialysis delivery
- Prolong the life of the vascular access
- Maintain cardiovascular health

A Flow-QC Surveillance Protocol (Flow Chart, page 30) consists of an initial Dialysis Adequacy Flow Study followed by periodic Access Patency Surveillance. The flow chart outlines a general protocol in which the nephrologist sets a critical access flow threshold. As soon as access flow drops below this critical threshold, falls below 1000 mL/min and drops more than 25% during a four-month period, per KDOQI Guidelines, additional diagnostic studies are recommended. Thereafter, monthly access flow surveillance is performed.

1. Hemodialysis Dialysis Adequacy Flow Protocol

When a patient begins hemodialysis, a baseline Dialysis Adequacy Flow Study confirms dialysis delivery and can be used to set vascular access parameters. During an initial dialysis adequacy analysis, delivered blood flow, recirculation and vascular access flow are evaluated in relation to their "normal" dialysis conditions. Delivered blood flow is expected to be within 10% of the dialysis pump setting. In a healthy access, zero percent recirculation is the norm. A sufficient access flow rate is necessary to maintain access patency. Its mechanical shear force delays stenosis and subsequent thrombosis by working against the body's clotting mechanisms.

a. **Delivered Blood Flow**
   Prescribed delivered blood flow can be verified by comparing the reading of delivered blood flow on the Flow-QC Hemodialysis Monitor to the setting on the dialysis machine. At high blood pump settings, it is not uncommon to see a difference between the two due to the size of the access needles (Fig. 3a.10, page 29). Larger diameter needles (15G) deliver flow more efficiently than smaller diameter needles (16G). Underdelivery of prescribed blood flow may also be caused by the site of needle placement in the access. The tip of the arterial needle may be too close to the vessel wall.

If the arterial needle does not face the incoming access flow (needle is down rather than up), it may also be difficult to achieve high delivered blood flow. Other access factors may also limit delivery of prescribed delivered blood flow.

Discrepancy between Delivered Blood Flow and Pump Setting[16-20]

To diagnose large delivered blood flow differences between the pump and the monitor, turn the pump speed to 200 mL/min. At this speed, pump errors due to high negative pressures are negligible and the monitor's delivered blood flow reading should correspond to the dialysis pump setting. If the readings agree at this setting, the deviations at the high pump settings were due to one of the factors described above.

Fig. 3a.10: Discrepancy between delivered blood flow and the pump setting can be caused by: negative pressure effects of the roller pump; access condition; needle size and placement; kinked or occluded tubing; calibration of dialysis machine or sensors.

Delivered Blood Flow Disparity at Pump Speed 200 mL/min

If the monitor and pump delivered blood flow readings do not agree at the 200 mL/min pump setting, check the tubing selection on the monitor to make sure it matches the dialysis tubing being used. Ultrasound dilution sensors are sensitive to differences in tubing brands and accuracy decreases if the sensor is not calibrated for the specific tubing being used. In general, the accuracy of the Transonic® Delivered Blood Flow reading is ± 6%. Other possible causes for pump and hemodialysis monitor blood flow discrepancies could be:
* the dialysis machine is not in calibration
* the arterial needle tip is too close to the vessel wall.

Flow-QC® Protocol for AV Grafts & Fistulas

Start
New patient or revised vascular accesss

↓

Initial Dialysis Adequacy & Vascular Access Patency
Measure initial AR, AF, Qb

↓

Nephrologist Analysis
- Establish Critical Access Flow level
- Establish frequency of testing (typically monthly per KDOQI)

↓

Vascular Access Patency Study
(at monthly or other periodic interval)

↓

Yes — Is AF above the critical threshold?

NO

↓

Nephrologist Analysis
Schedule appropriate flow restoration procedure or refer patient for duplex scan and/or fistulogram.

↓

After flow restoration procedure ....

The Flow-QC® Protocol includes an initial Dialysis Adequacy study followed by periodic Access Patency surveillance to track the progression of stenoses in AV grafts and fistulas.

IIIa. Flow-based Vascular Access Surveillance cont.

b. Access Recirculation

Measurement of Access Recirculation (Flow Chart, page 33) is the next step in the Flow-QC® Hemodialysis Adequacy Flow Study. Most patients have zero percent access recirculation.[11] If recirculation is reported, confirm the measurement by a second recircualtion measurement. If the second measurement reports zero percent recirculation, a third measurement is advised as the deciding "vote." In some cases where there is borderline recirculation (< 5%), it is recommended that pump flow be increased to confirm recirculation.

A theoretical model (Fig. 3a.11) demonstrates that at a blood flow of 400 mL/min, access recirculation is likely to begin appearing. When access flow is 300 mL/min and blood flow is 400 ml/min, 100 mL/min must be drawn from the venous return to make up the deficit at the arterial needle. Recirculation then equals 100/400 ml/min or 25%. If repeat measurements confirm the presence of recirculation, two possibilities exist:

Fig. 3a.11: Recirculation (theoretical): When delivered blood flow (Qb) is 400 mL/min, access recirculation theoretically appears at an access flow of 399 mL/min or anything below the delivered blood flow. If measured access flow is 300 mL/min, there is theoretically 25% recirculation; at 200 mL/min measured access flow, 50% recirculation; at 100 mL/min measured access flow, 75% recirculation.

Inadvertent Line Reversal

At times blood lines are inadvertently reversed with respect to conventional dialysis line orientation. To determine if this is the case, examine whether the venous needle is placed upstream from the arterial needle with respect to the direction of the access flow. Then repeat the recirculation measurement after intentionally cross-connecting the arterial line to the venous needle and vice-versa.

If the result is zero percent recirculation, or if the recirculation measurement is less than the first for the same delivered blood flow, the lines have been inadvertently reversed and the second blood line orientation is correct. Document this correct orientation on the patient's record to prevent recurrence of inadvertent blood line reversal.

True Recirculation — Access at Risk
When recirculation is not accounted for by blood line reversal, the patient's access may be at risk for thrombosis because recirculation is a late predictor of access dysfunction.

c. Access Flow Measurement
The final step in the initial Dialysis Adequacy Flow Study (Flow Chart, page 30) is a baseline access flow measurement. Once completed, the nephrologist can integrate its results with other patient factors to tailor a customized vascular access management program for the patient that will ensure optimum delivery of the dialysis prescription, identify access concerns that require further investigation, and establish an early stenosis onset detection program.

Tips for Adequate Saline Mixing in Fistulas

1. If delivered blood flow is 200-300 ml/min, any needle orientation (toward or away from incoming access flow) produces adequate mixing for up to 2 liters of flow.

2. In fistulas with a large aneurysm, or in upper arm fistulas with >2 L/min of flow, the arterial needle should be positioned so that it faces incoming access flow.

3. When measuring access flow with a needle in a collateral or branch of the vein, you may see the message "Check Line Reversal and Needle Placement." Confirm the message by repeating the measurement. If the message reappears, occlude the collateral fistula branch downstream from the needle for 2-3 minutes and remeasure access flow.

Flow-QC® Recirculation Protocol

```
┌─────────────────┐   0% Recirculation    ┌─────────────────┐
│ Perform Initial │ ────────────────────► │ Proceed to      │
│ Recirculation   │                       │ Access Flow     │
│ Measurement     │                       │ Measurement     │
└─────────────────┘                       └─────────────────┘
         │                                         ▲
         ▼                                    0% Recirculation
┌─────────────────┐   0% Recirculation    ┌─────────────────┐
│ Perform Second  │ ────────────────────► │ Confirm Zero %  │
│ Recirculation   │                       │ Recirculation   │
│ Measurement     │                       │ with a third    │
└─────────────────┘                       │ Measurement     │
         │                                └─────────────────┘
         ▼                                   > 0% Recirculation
┌─────────────────────────┐ ◄──────────────────────┘
│ Reverse blood lines at  │
│ needle tubing           │
│ connection.             │
└─────────────────────────┘
         │
         ▼
┌─────────────────┐   0% Recirculation    ┌───────────────────────────┐
│ Perform a       │ ────────────────────► │ Lines are now in          │
│ Reversed Line   │                       │ conventional position for │
│ Recirculation   │                       │ dialysis, but were        │
│ Measurement     │                       │ reversed for initial      │
└─────────────────┘                       │ measurement               │
         │                                └───────────────────────────┘
    0% Recirculation
         ▼
┌─────────────────┐   greater     ┌───────────────────────────┐
│ Is reversed     │ ────────────► │ Lines are now reversed,   │
│ line recirc >   │               │ initial measurements were │
│ or < than       │               │ made with lines in        │
│ initial Recirc?.│               │ conventional position.    │
└─────────────────┘               └───────────────────────────┘
         │
       less
         ▼
┌───────────────────────────────────┐
│ Lines are now in conventional     │
│ position for dialysis, but were   │
│ reversed for initial measurement  │
└───────────────────────────────────┘
         │
         ▼
┌───────────────────────────────────────────────────────┐
│ Document Correct Line Placement & Direction of Access  │
│ Flow                                                   │
└───────────────────────────────────────────────────────┘
```

When 0% recirculation is confirmed, proceed directly to an access flow measurement. When recirculation is present, a series of steps is presented to identify the cause.

Hemodialysis Adequacy in Central Venous Catheters

Even though central venous catheters are prone to thrombosis and infection, 75% of hemodialysis patients receive catheters either to initiate hemodialysis or for permanent hemodialysis delivery. KDOQI Guidelines define central venous catheter dysfunction as failure to attain and maintain blood flow sufficient to perform hemodialysis without significantly lengthening hemodialysis treatment. The Guidelines recommend catheter blood flow be maintained at more than 300 mL/min to ensure adequate hemodialysis.

Transonic Flow-QC® and Catheter Hemodialysis Dose Delivery

Delivery of the prescribed dose of dialysis closely correlates to the amount of blood cycled through the dialyzer and therefore, to the rate of delivered blood flow. The use of catheters for dialysis delivery has two potential pitfalls that can be avoided through Flow-QC Monitoring:

1. A tissue flap and/or fibrin sheath blocking the lumen of the catheter's arterial entry port, impeding flow and causing a severe drop in dialysis dose delivery. This can be identified and often corrected via the Flow-QC Delivered Blood Flow Test.
2. The close proximity of the catheter's arterial entry and venous return ports make recirculation likely. If there is, for instance, 10% recirculation, the amount of blood cycled through the dialyzer is effectively 10% less and underdialysis can occur. This is monitored and can be corrected via the Flow-QC Recirculation Test.

Flow-QC® Delivered Blood Flow Test

During hemodialysis, the nurse compares the Transonic Delivered Flow reading with the dialysis pump setting. The test takes less than a minute and can be performed in normal or reversed line configuration. If the disparity is more than 10%, kinked tubing, a tissue flap and/or fibrin sheath may be causing possible inflow obstruction and reduced dose delivery. Check the tubing for kinks and/or reverse the dialysis lines. Again compare Transonic Delivered Flow with the machine pump setting. If the two are now within 10%, dialysis may be continued with the lines in this configuration. If a large discrepancy between the two readings persists, central venous catheter failure may be indicated and the nephrologist should be alerted.

Hemodialysis Adequacy in Central Venous Catheters cont.

Flow-QC® Recirculation Test

A Transonic recirculation measurement can be performed with lines in either normal or reversed configuration. By knowing the percent of recirculation:

- The nurse can adjust dialysis delivery parameters (time, pump setting etc.) to compensate for recirculation and deliver the prescribed dose of dialysis to the patient.
- Dialysis lines may be reversed. Correction might also correct high recirculation.

The nurse should report unusual delivered blood flow and recirculation readings to the Patient Care Team or nephrologist to ensure optimum short- and long-term management of the patient's hemodialysis treatment.

Case Example:

Flow-QC Hemodialysis Adequacy Test Detects Hemolysis Risk

ESRD Patient

75-year-old woman with Central Venous Catheter: Blood Lines: normal line position; Pump Setting: 300 mL/min; Delivered Blood Flow: 190 mL/min; Recirculation: 0%.

A 35% disparity between pump setting (300 mL/min) and delivered blood flow (190 mL/min) indicated a significant risk of hemolysis.

Response

Lines were checked to see that they were not kinked. Blood lines were then reversed and the pump was reset to 300 mL/min. Delivered blood flow and recirculation were again measured.

- Delivered Flow: 290 mL/min
- Flow-QC Recirculation: 2-3%

Results

The patient received better treatment with the lines in a reversed position and the pump delivering 290 mL/min.

Take Home

Catheter patient treatment can be optimized with Flow-QC Delivered Flow and Recirculation measurements.

2. Vascular Access Surveillance Program

KDOQI, European, Australian and Canadian Guidelines advise that periodic access flow surveillance is an effective tool for predicting hemodynamically significant stenoses and declining access health.[1-4] To establish a surveillance program, the nephrologist sets:

- **Access Flow Trending Threshold:**
  Flow at which the access is at higher risk for failure.

- **Critical Access Flow Threshold:**
  Flows at or below which indicate a significant stenosis and require immediate verification and follow up.

KDOQI Guidelines recommend monthly surveillance to diagnose the onset of stenosis.[1] For native fistulas, the threshold for the critical flow threshold is >500 mL/min (Fig. 3a.12). European Guidelines set the flow threshold of >300 mL/min in forearm fistulas as an indication for preemptive intervention.[2] For vascular access prosthetic grafts, both KDOQI and European Guidelines set the Critical Flow Threshold at >600 mL/min (Fig. 3a.13) or access flow of less than 1000 mL/min if flow drops 25% (European Guidelines: 20%) or more over four months.

Nephrologists should also consider a patient's history when setting flow thresholds to ensure that the level is set high enough to permit proactive action before access failure.

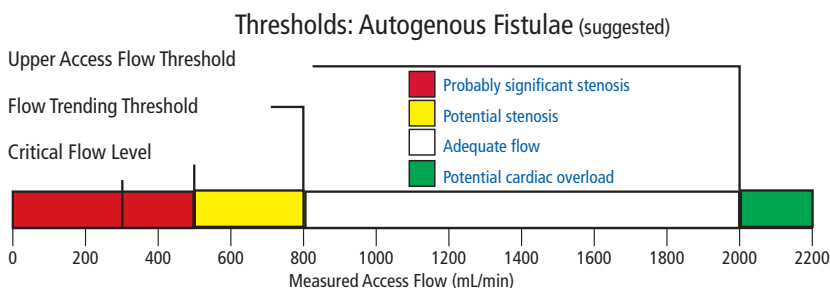### Thresholds: Autogenous Fistulae (suggested)

Fig. 3a.12: Access Flow Level Guidelines for Fistulas, Adult Patients: KDOQI sets a Critical Level at 500 mL/min. European Guidelines recommend >300 mL/min. The Flow Trending Threshold is 800 mL/min, and the potential for cardiac overload exists at flows of over 2000 mL/min. Actual flow levels should be customized for each patient by the nephrologist.

A third threshold to be observed is the Upper Access Flow Threshold. It is generally accepted that in both fistulas (Fig. 3a.12) and grafts (Fig. 3a.13), 2000 mL/min is a good upper access flow threshold. Above 2000 mL/min, the patient may be at risk for cardiomegaly or other conditions resulting from cardiac overload. Cardiac output measurements are recommended when, in the absence of recirculation, access flow levels are above this upper threshold.

a. Chronological Trending of Measurements

Once an access flow surveillance schedule has been established, each patient's data should be examined within the context of the patient's chronological history (Fig. 3a.1, page 19). When a patient's access flow is below the Critical Flow Threshold, Flow-QC® software automatically alerts the clinician. Patients who fall into the high risk or critical categories defined by the threshold of critical access flow should be brought to the attention of a nephrologist.

b. Minimizing Access Flow Surveillance Errors

KDOQI Guidelines address multiple issues that should be considered as an access surveillance program is implemented. In addition, published data[18-21] suggest the application of some simple rules during access flow data analysis. The following recommendations are advised to improve outcome quality:

Thresholds: Prosthetic PTFE Grafts (suggested)

Upper Access Flow Threshold
Flow Trending Threshold
Critical Flow Level

- Probably significant stenosis
- Potential stenosis
- Adequate flow
- Potential cardiac overload

0   200   400   600   800   1000   1200   1400   1600   1800   2000   2200
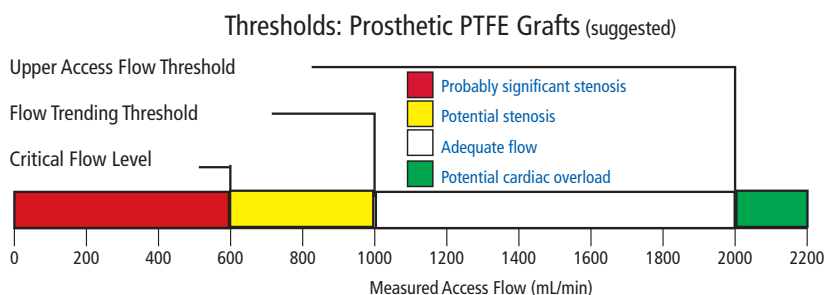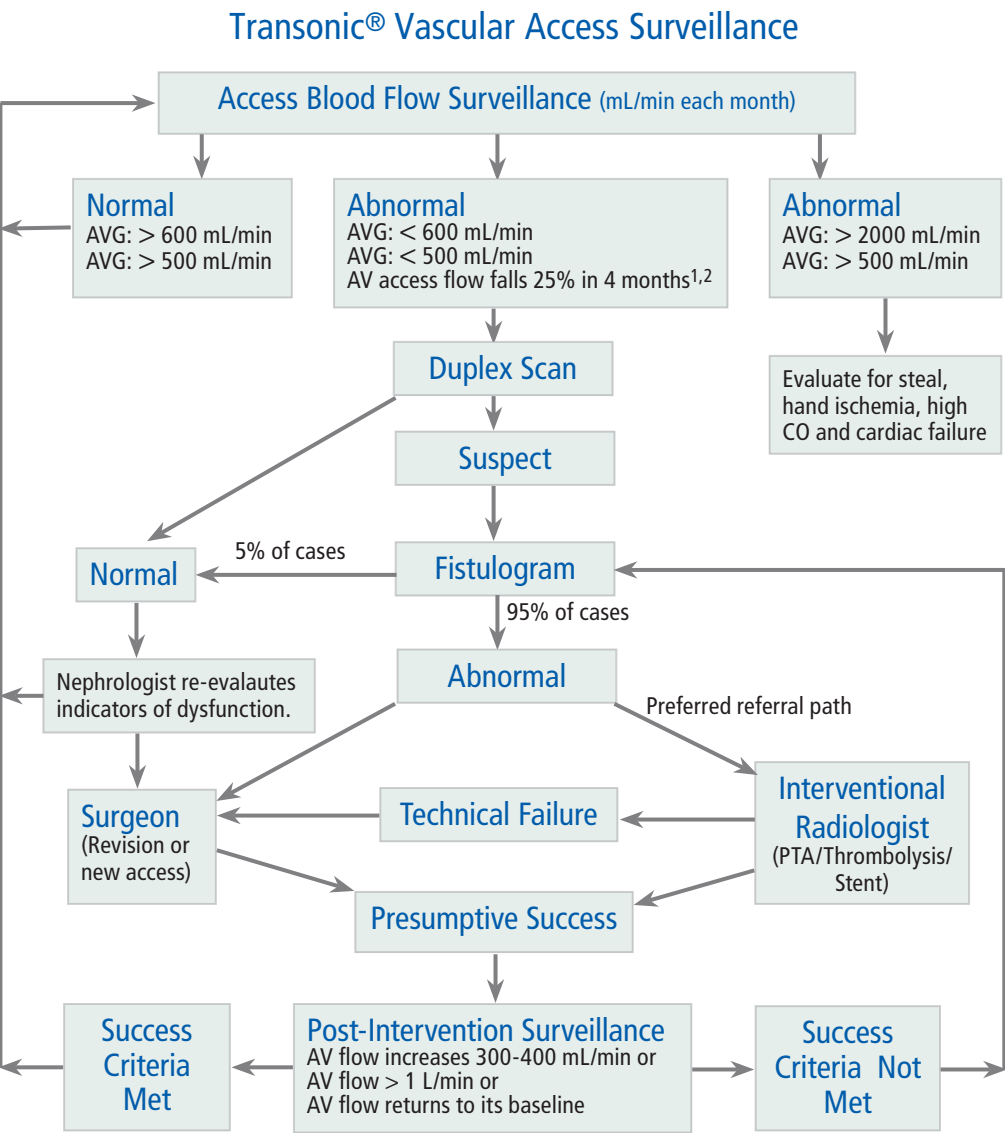
Measured Access Flow (mL/min)

Fig. 3a.13: PTFE Grafts Access Flow Level Guidelines, Adult Patients: KDOQI and European guidelines set the Critical Level at > 600 mL/min for prosthetic grafts. The Flow Trending Threshold is 1000 mL/min, and the potential for cardiac overload exists at flows of over 2000 mL/min. Actual flow levels should be tailored for each patient by the nephrologist.

IIIa. Flow-based Vascular Access Surveillance cont.

- For AV grafts, use both KDOQI recommended thresholds: absolute threshold of 600 mL/min; dynamic threshold of a 25% decrease within 4 months. Using both these thresholds should decrease false-positive rates. The dynamic threshold may be more predictive of stenosis. Using only one threshold may not be as effective and may lead to a misleading message about the effectiveness of flow surveillance.[23]

- It is generally recommended that access flow measurements be performed during the first hour and one-half to two hours of a dialysis session. However, this approach may not always avoid hypotensive episodes or other abnormal situations. If a 20-30% decrease in flow is observed, it may be the result of significant stenosis, or a decrease in systemic pressure. If a significant decrease in mean arterial pressure (MAP) is observed, the patient's previous access flows and MAPs should be reviewed.[21-22] Before the patient is referred for angiography, the access flow measurement should be repeated at the patient's next session to confirm that the decrease also exists when the patient's MAP is in its normal range.

- Flow measurements should be performed at least once a month in AV grafts to avoid thrombosis events.[23]

- For native fistulas, outcomes could possibly improve by decreasing the absolute threshold to 500 ml/min[23-26] or as low as 300 ml/min in forearm fistulas as recommended by 2007 ERA-EDTA guidelines.[2] This threshold takes into account that fistulas generally have longer life spans with lower flows, and that the initial access flows at distal locations (anatomical snuffbox) are generally lower.

IIIa. Flow-based Vascular Access Surveillance cont.

Transonic® Vascular Access Surveillance

Access Blood Flow Surveillance (mL/min each month)

Normal
AVG: > 600 mL/min
AVG: > 500 mL/min

Abnormal
AVG: < 600 mL/min
AVG: < 500 mL/min
AV access flow falls 25% in 4 months[1,2]

Abnormal
AVG: > 2000 mL/min
AVG: > 500 mL/min

Duplex Scan

Evaluate for steal, hand ischemia, high CO and cardiac failure

Suspect

Normal ← 5% of cases — **Fistulogram**

95% of cases

Nephrologist re-evalautes indicators of dysfunction.

Abnormal

Preferred referral path

Surgeon
(Revision or new access)

Technical Failure

Interventional Radiologist
(PTA/Thrombolysis/Stent)

Presumptive Success

Success Criteria Met

Post-Intervention Surveillance
AV flow increases 300-400 mL/min or
AV flow > 1 L/min or
AV flow returns to its baseline

Success Criteria Not Met

1 If AVG flow falls by 25% in four months, and flow i< 1000mL/min, refer for fistulogram per KDOQI Guidelines.
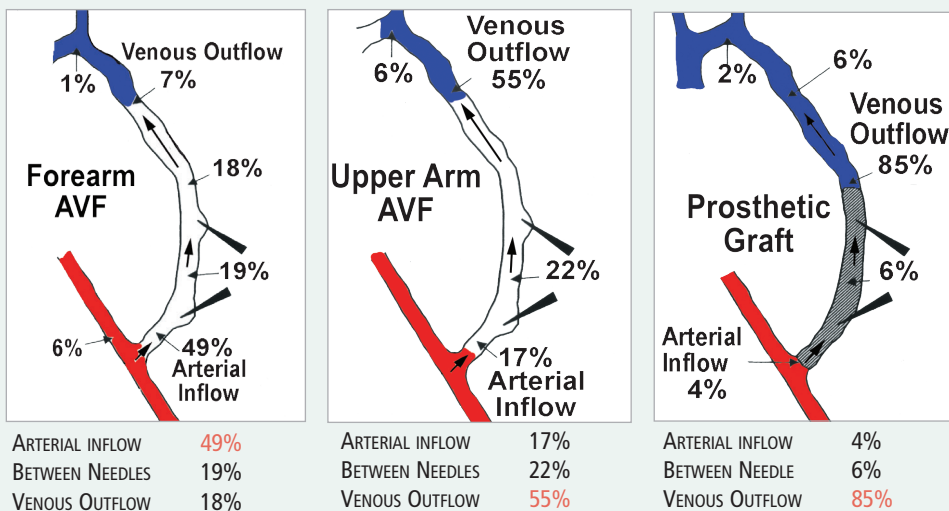2 Lower access flow may result if a patient's BP is significantly lower than his or her BP history. Therefore, compare current BP with BP history and/or confirm measurement results by repeating measurement before referring for fistulogram.

Transonic Flow-QC® Surveillance

Transonic Flow-QC® surveillance detects hemodynamically significant stenoses at all sites (arterial inflow, between the dialysis needles, venous outflow) in the vascular circuit in both AV fistulas and prosthetic grafts. While other technologies are used to detect venous outflow stenoses, the site where a majority of stenoses form in prosthetic grafts, they do not detect stenoses at all sites within the circuit.

The Fistula First initiative advocates increasing the number of autogenous fistulas for hemodialysis delivery. Whereas in prosthetic grafts, most stenosis do occur at the venous outlet, a significant number of stenoses may also occur at the arterial inlet and/or between the needles in fistulas. This makes Flow-QC's capability to measure flow to detect stenoses anywhere in the circuit (including inflow sites) unique. KDOQI Guidelines now acknowledge that inflow stenoses are more common than previously believed and occur in up to one-third of patients with clinical symptoms of venous stenosis or thrombosis.[1,26-27]

Forearm AVF	
ARTERIAL INFLOW	49%
BETWEEN NEEDLES	19%
VENOUS OUTFLOW	18%

Upper Arm AVF	
ARTERIAL INFLOW	17%
BETWEEN NEEDLES	22%
VENOUS OUTFLOW	55%

Prosthetic Graft	
ARTERIAL INFLOW	4%
BETWEEN NEEDLE	6%
VENOUS OUTFLOW	85%

Stenosis Sites in AV Fistulas and Grafts: The figures above show the sites of most frequent stenoses for AV fistulas and prosthetic grafts. Note that in forearm fistulas, 49% of stenoses are inflow stenosis. Adapted from Turmel-Rodrigues et al, Nephrol Dial Transplant 2000; 15: 2029-2036.[28]

c. Multidisciplinary Vascular Access Care program (pages 42-43)[29]

Hemodialysis providers are now implementing multidisciplinary vascular access care programs to proactively address access-related morbidity among hemodialysis patients. These programs are designed to improve all vascular access-related outcomes, prolong vascular access life, and reduce hospitalization costs associated with vascular access.[30] The benefits of a vascular access care program include improved quality care and satisfaction outcomes, cost-effectiveness, optimizing seamless care delivery, and empowering the nephrologist in the delivery of vascular access care.

Duda et al's Process Implementation Model published in Nephrology News and Issues (April, 2000) and printed on the following pages presents the process and timetable for implementation and core competencies. An Assessment Phase evaluates the current access care and baseline data. This is accompanied by a thorough and ongoing Educational Phase to develop vascular access core competency among all team members. The heart of a vascular access care program is a fully integrated and proven Access Surveillance Program and referral process. The objectives of these protocols are to:

*   detect and intervene when significant access stenosis is suspected to prevent access thrombosis;
*   prolong access life;
*   prevent inadequate dialysis;
*   reduce access-related morbidity and hospitalizations;
*   decrease the number of missed dialysis treatments.

Other components of the program include the Diagnosis Phase to identify patients at risk for vascular access stenosis or other causes of access dysfunction to determine whether an intervention should be radiologic or surgical. During the Intervention Phase the patient actually undergoes a procedure to correct the diagnosed complication. Finally, Documentation of vascular access care program indicators is essential for the success of the continuing quality improvement (CQI) process. CQI recommends monthly analysis of data and benchmarking of vascular access performance criteria.

This and other multidisciplinary access management programs implement KDOQI guidelines, prolong access life, prevent inadequate dialysis and reduce access-related morbidity and hospitalizations.[28-30]

Vascular Access Care Program (VACP)		
PHASE	PROGRAM	DEFINITION
ASSESSMENT PHASE	Assessment	Evaluation of the current access care delivered by a multidisciplinary team in a Dialysis Facility and the collection of vascular access baseline data for subsequent comparison.
EDUCATION PHASE	Education	Thorough and ongoing process to develop VA care core competency of all team members.
SURVEILLANCE PHASE	Surveillance	Prospective VA surveillance techniques performed on each patient monthly and following any access intervention.
DIAGNOSIS PHASE	Diagnosis	Identify patients at risk for vascular access by completing a fistulogram or other diagnostic test to identify stenosis or other cause of access dysfunction. Provides information necessary to determine whether an intervention should be radiologic or surgical.
RADIOLOGIC OR SURGICAL INTERVENTION	Intervention	The phase when the patient actually undergoes a procedure to correct the diagnosed access complication.
DOCUMENTATION OF VACP INDICATORS		The VACP documentation requirements and process.
CQI TO ACHIEVE OUTCOMES AND BEST DEMONSTRATED PRACTICES	CQI	The GAMBRO Continuous Improvement Process (CIP) which enables monthly analysis of data and benchmarking of VA performance criteria.

Process Implementation Model[27]

PURPOSE	CORE COMPONENTS	TIME LINE
Standardizes assessment criteria and provides VA benchmarks for the continuous improvement process (CIP).	1. Assess clinic staff and patient for vascular access care behavior and knowledge 2. Assess each patient's access each treatment	1st Month and Ongoing
Assure that all members of the VA Care team are knowledge-able and capable of providing VA care.	1. Access Care Basics and Techniques 2. How to apply VACP in my Center 3. Access evaluation techniques to assess potential stenosis 4. When to refer for diagnosis	1st Month and Ongoing
Detects access dysfunction early and to permit sufficient lead time for a planned access intervention as well as assess the "success" of any completed access intervention (radiological or surgical).	1. Identifies patients at risk with access problems 2. Defines access intervention required	1st Month and Ongoing
Provides a clear "road map" for any subsequent access intervention.	1. Identifies patients at risk with access problems 2. Defines access intervention required	1st Month and Ongoing
Intervention is planned and delivered specifically to correct a diagnosed access problem.	1. per Radiology 2. per Surgery	Ongoing per diagnosis
Facilitates the tracking of each patient's VA history and ensures center-specific and national data are collected, monitored and trended.	1. Access status for each patient each treatment 2. Access Clinical Indicators for each patient each treatment	Ongoing per intervention and flow
Evaluates each Centers own standards of care against the national goals and benchmarks to promote each Center's CIP to achieve best-demonstrated practices in VA care.	1. Trend and analyze VACP Clinical Indicators each month 2. Maintain and monitor center-specific VA care improvement.	Ongoing per monthly CQI meeting process

d. **Pediatric Access Flow Surveillance**

In 2003, 4,500 U.S. children and adolescents underwent treatment for ESRD, many of whom would receive kidney transplants within two years. Approximately 60% of this population was less than 12 years old. The remaining 40% were adolescents.

Since patients range from neonatal to teenagers, the blood tubing used to dialyze these patients comes in many sizes and configurations. To overcome the challenge of small tubing sizes for young children, Transonic® recommends the use of standard sensors on Transonic Flow-QC® tubing sets inserted between the smaller blood lines and needle lines. Transonic Flow-QC software normalizes access flow in children by correcting the raw access flow data for body surface area and reporting ml/min/1.73m^2.

Texas Children's Hospital Studies

Goldstein and colleagues from Texas Children's Hospital report that ultrasound dilution (UD) is a valid indicator of access flow in children.[29-31] "When the uncorrected flow value reported by UD is corrected for patient body surface area, UD is predictive for the presence or absence of severe AV graft stenosis, regardless of patient size. In 2001, Texas Children's Hospital instituted a rapid referral policy (within 48 hours) for arteriovenous fistula or graft angioplasty using monthly Flow-QC surveillance to access vascular access flow. Children with a corrected vascular access flow of less than 650 ml/min per 1.73m^2 were referred for balloon angioplasty. The practice led to a 90% reduction on vascular access thrombosis rates and a 40% reduction in vascular access management costs, compared with the institution's previous venography surveillance protocol. Moreover, it also led to fewer missed school days, less separation from family and peers, and fewer invasive procedures.[29]

Optimizing Catheter Measurements

Many pediatric ESRD patients are dialyzed via a catheter. In these patients, the Transonic Flow-QC Monitor can measure Dialysis Adequacy by measurements of Delivered Blood Flow and Recirculation. Optimum blood pump speed to customize dialysis prescription can be determined by Delivered Blood Flow. Catheter dysfunction is identified by the presence of high Recirculation (see pages 34-35).

D. Vascular Access Surveillance References

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IIIb. Cardiac Function Assessment during Hemodialysis

A. Cardiovascuar Disease — An ESRD Epidemic

"ESRD patients are prone to sudden death, stroke and myocardial infarction between dialysis sessions."[1]

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality in patients with End-Stage Renal Disease (ESRD).[2-3] It accounts for half of the deaths and one-third of hospitalizations of dialysis patients.[4]

"In addition, cardiovascular collapse is a major cause of complications during hemodialysis treatments."[5] Congestive heart failure (CHF) in these ESRD patients results from cardiac overload, anemia, severe hypertension and cardiac dysfunction. With CVD mortality rates approximately 30 times that of the general population[4], nephrologists are now called upon to assume a greater role in the cardiovascular management of their dialysis patients.

Patients who do not feel well at the end of a dialysis session are subject to an unidentified decrease in Cardiac Index (CI) to critical ICU levels of <2 L/min/m^2.

As an AV fistula steals flow from an already limited systemic circulation, low CI can become a major contributor to decreased myocardial perfusion leading to sudden death.

Probability of Sudden Death
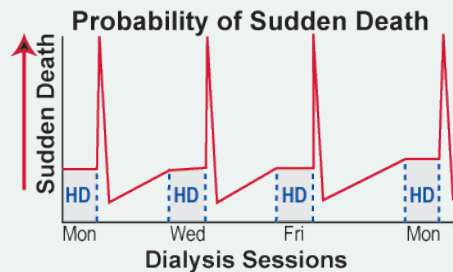
"35% of deaths occurred in the first 12-hour interval ... 27% of these deaths occurred during dialysis and 33% occurred in the first hour after the dialysis treatment."[6]

IIIb. Cardiac Function Assessment cont.

1. Hemodialysis — A Stress Test for Cardiac Function

> "*Hemodynamic stability is threatened and often severely compromised by hemodialysis largely because of the obligate fluid removal during a short time span.*"[7]

Dr. Thomas Depner from the University of California at Davis underscores the importance of testing cardiac function during hemodialysis.[4,8] He explains that the rapid removal of large volumes of fluid during hemodialysis severely tests the limits of a patient's cardiac function. Just as a stress test on a treadmill indicates a heart's response to exercise, cardiac output measurements during hemodialysis monitor a heart's response to fluid removal during the treatment. Because cardiovascular parameters can change dramatically during dialysis, multiple cardiac measurements are advised during a dialysis session in order to assess a patient's clinical condition.[8]

2. Cardiac Output and Access Flow

The AV access is also often overlooked as a source of cardiac dysfunction. By bypassing the customary arteriole/capillary beds and establishing a direct high flow connection between the arterial and venous systems, an AV access causes a precipitous drop in peripheral arterial resistance which significantly affects blood flow. In order to maintain blood pressure and improve cardiac output, the body compensates for this immediate drop in resistance by increasing heart rate and stroke volume.[3,9,10] First observed in World War II in soldiers with trauma-induced arteriovenous fistulas.[3]. Iwashima et al reported an 15% increase in cardiac output by the seventh day after arteriovenous fistula creation[10]. This increased cardiac workload can lead to an increase in size of the left ventricle (left ventricular hypertrophy)[9,10]. Especially in patients with histories of coronary artery bypass surgery, coronary ischemia may result from the increased cardiac workload from an AV access.

MacRae *et al* have also reported the high output cardiac failure associated with high flow AVFs (> 1.5.L/min), particularly in men with upper arm fistulas and previous access surgeries.[3,9,10] The ratio between access flow and cardiac output is an important clinical indicator. When access flow exceeds 25% of cardiac output, a potential cardiac problem can exist. MacRae suggests that hemodialysis patients be screened for potential high-output cardiac failure using a Qa/CO ratio and patients with a Qa/CO ratio ≥ 30% undergo further testing.[10]

IIIb. Cardiac Function Assessment cont.

The nephrologist can order these tests, request periodic monitoring, and/or reduce access flow by banding the access. While access flow remains fairly constant during hemodialysis, cardiac output decreases an average of 20% during the hemodialysis treatment causing less and less blood flow to be available to sustain the body's vital functions. A healthy body will respond to this by increasing peripheral resistance to sustain the blood supply to the heart and brain. Other considerations include:

- The site of a vascular access affects average flow values. Upper arm sites typically have higher flows than lower arm sites.

- Patients with initial high flow fistulas are at greater risk for cardiovascular problems. A fistula may "over-mature" and present a flow over 2 L/min.

- Autologous fistulas tend to remain sufficiently patent to sustain dialysis at lower flows than do prosthetic grafts.

- A straight upper arm prosthetic graft may initially exhibit an overly high flow. Graft flow tends to decrease over time, so banding a prosthetic graft is not advised. Access flow and cardiac function of these patients should be monitored monthly to ensure that access flow drops before cardiac complications arise.

As the correlation between an AV access and the cardiac workload becomes more recognized, it is increasingly important to consider routine cardiac function assessment in ESRD patients undergoing hemodialysis several times a week.

"The ability to monitor cardiac output is one of the important cornerstones of hemodynamic assessment ...in particular in patients with pre-existing cardiovascular comorbidities."[11]

B. Cardiac Function Assessment

1. Methodology

Cardiac output is the volume of blood being pumped by the heart in one minute. An average resting cardiac output is 5.6 L/min for a human male and 4.9 L/min for a female.[1]

"It is astonishing that no one has arrived at the following obvious method by which the amount of blood ejected by the ventricle of the heart with each systole may be determined directly..." Adolf Fick, 1870.

Adolf Fick thus introduced a method to measure an animal's cardiac output (CO) from arterial and venous blood oxygen measurements. His principle later formed the foundation of Stewart's indicator-dilution technology. In 1928, Stewart's equation was modified by Hamilton who described the bell-shape of a classic dilution curve (Fig. 3b.1).

A variety of indicators has been used with this time-tested technology. With all there are three criteria that must be met. They are:

1) Injection Phase: a known indicator is introduced into the circulatory system.
2) Mixing/dilution Phase: the indicator mixes with the blood.
3) Detection Phase: The indicator concentration is measured downstream from its introduction.

$$CO = K \frac{V_{co}}{S_{co}}$$

$V_{co} = 30$ ml of 0.9% saline
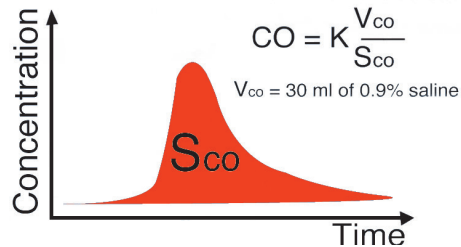
Fig. 3b.1: Time concentration curve showing saline indicator dilution curve. CO is inversely related to the average dilution indicator concentration and the total time of indicator passage or CO is the amount of indicator injected/area of the dilution curve.
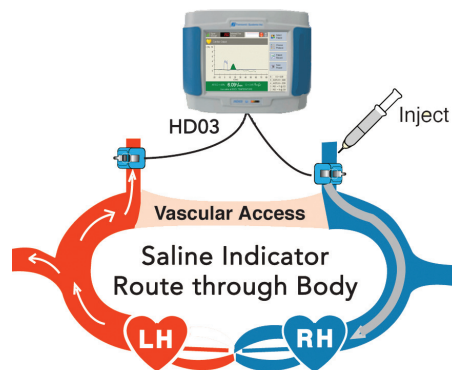
Fig. 3b.2: Saline Indicator Route: Body temperature saline is injected into the venous line, travels through the heart and lungs and returns via the arterial system where a flow/dilution sensor records the diluted concentration.

IIIb. Cardiac Function Assessment cont.

Ultrasound dilution methodology, pioneered by Nikolai Krivistki PhD, DSc, uses body temperature saline, an innocuous indicator, injected into a patient's peripheral vascular access during the dialysis treatment. The indicator is injected into the venous line, travels through the heart and lungs and returns via the arterial system where a Flow/dilution Sensor records the diluted blood concentration (Fig. 3b.2). Classic Stewart-Hamilton equations are then used to calculate cardiac function and central hemodynamic parameters including Cardiac Output (CO), Cardiac Index (CI), Peripheral Resistance (PR) and Central Blood Volume (CBV).

2. Flow-QC® Cardiac Function Assessment

Transonic Flow-QC® Cardiac Function Monitoring with ultrasound indicator dilution technology provides a way to integrate cardiac function studies into a hemodialysis clinic's treatment protocol in order to forestall the devastating consequences of CVD.

Transonic® Flow-QC cardiac function measurements help diagnose cardiac overload in ESRD patients.[1,11] When access flows measured during the dialysis session are unusually high (>2 L/min), cardiac overload can be suspected. A follow-up Flow-QC cardiac output measurement will verify whether the heart is stressed.

Flow-QC cardiac output measurements combined with access flow identifies:
a) Prolonged high access flow to cardiac output ratio that stresses the heart and can result in cardiomegaly and heart failure.

b) Dangerously low cardiac index that places patients at high risk for cardiovascular complications and failure.

c) Dramatic decreases of cardiac index during hemodialysis due to inaccurate dry weight estimation and/or inadequate medication.

d) Dangerous decrease in central blood volume during hemodialysis that may portend hypotensive episodes.

3. Flow-QC® Cardiac Function Parameters

Cardiac Output and calculated parameters are related to age and gender, and depend on a patient's clinical status such as the presence of diabetes or cardiac diseases and may change dramatically during a hemodialysis session.

Cardiac Output (CO)
Normal Range[1]: 5 - 8 L/min;
The volume of blood in liters ejected from the heart within one minute, is a fundamental measure of human hemodynamic performance. Typical values for hemodialysis patients range from 4 to 8 L/min with the determination of "normal CO" depending on a patient's body size."

Cardiac Index (CI)
Normal Range[1]: 2.2 - 4.5 L/min/m^2
Cardiac output divided by estimated Body Surface Area (BSA). A primary criterion of cardiac adequacy, CI is useful in comparing different sized patients. Cardiac Indexes from 6 - 8 L/min/m^2 may indicate high access flow. A low CI (< 2 L/min/m^2) at the beginning of a hemodialysis session indicates significant deterioration of cardiac function. A decrease in CI during the hemodialysis session indicates potential cardiac problems, inadequate dry weight estimation, and/or inadequate medication prescription.

Peripheral Resistance (PR)
Normal Range[1]: 9.6 - 18.8 mmHg x min/L (770 - 1500 dyne x sec/cm^5)
The average resistance to systemic blood flow is approximated as Mean Arterial Pressure divided by Cardiac Output. Patients diagnosed with diabetes may have substantially higher PR. Because CO

generally decreases during hemodialysis and pressure is maintained, PR will increase during hemodialysis for most patients. Dr. Depner suggests that patients whose PR does not increase during treatment may have fluid overload. The Depner study correlated an increased 1-year mortality risk with a failure of PR to increase in response to the stress of hemodialysis, combined with higher initial PR and lower initial CO.[8]

Central Blood Volume (CBV)
Normal values range from 0.8 - 1.6 L
Central Blood Volume Index (CBVI)
The volume of blood in the heart, lungs, and great vessels. CBVI is CBV divided by the patient's weight (typical range, 11 - 17 ml/kg). CBV maintenance may be a factor in blood pressure regulation. CBV decreases during hemodialysis are similar to CO, and probably precede CO. When CBV is depleted, hypotensive episodes may occur. Therefore, monitoring CBV repeatedly during ultrafiltration may indicate how fast a patient can be dialyzed without hypovolemic collapse.

$$CBV = CO \times MTT$$
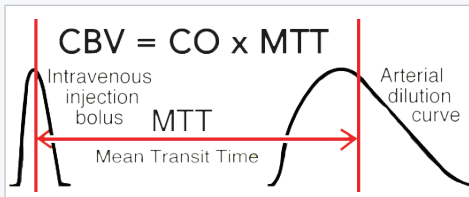
Central Blood Volume is calculated by multiplying cardiac output (CO) by the mean transit time (MTT) from the indicator injection to the arterial dilution curve.

IIIb. Cardiac Function Assessment cont.

Flow-QC® Cardiac Function Parameters				
PARAMETER	**TYPICAL RANGE**	**ABNORMAL RANGE**	**CLINICAL RELEVANCE**	**INTERPRETATION & RECOMMEDNAIONS**
Access Flow (AF)	500 - 1600 ml/min	< 500 ml/min > 1600 ml/min for naive fistula	Heart compensates AF > 30% of CO CI < 2.2	Consider reducing AF by banding or other surgical procedure to avoid prolonged heart overload Body tissues are not adequately perfused due to A-V fistulae stealing. Repair or consider closure of fistula.
Cardiac Index (CI) (AF)	2.5 - 4.2 L/min/m^2	CI > 5 L/min/m^2	Usually indicates heart overload due to high access flow (see above).eqv Significant volume of accumulated liquid between dialysis sessions. May indicate low hematocrit	The reason for the increased CI should be identified and proper treatment implemented including: • A-V access intervention; • Change in dialysis prescription; • Change of erythropoietin prescription.
		CI < 2.0 L/min/m^2	Observed at the beginning of the HD session: indicates significant deterioration of CO function.	Refer to cardiologist for full study.
			Observed as a drop in CI during HD session: indicates potential cardiac conditions, inadequate dry weight estimation and/or medication prescription.	The dry weight and medications should be examined and/or changed and central hemodynamic profiling (CHP) measurements repeated.
Central Blood Volume Index (CBVI)	11 - 17 ml/kg	< 10 ml/kg	Usually observed in obese patients where heart-lung system is relatively small compared to body weight.	Observation of CBVI decrease during or at the end of CHP may indicate patient is at risk for hypovolemic collapse. Dialysis prescription may be reconsidered
		> 20 ml/kg	High CBVI usually (especially if maintained during CHP) indicates extra fluid in lung circulation or left ventricular dilation	Perform follow-up studies.

* Parameters are given for research purposes. Some do not have well-established normal values.
[1]Darovic G.O.: Hemodynamic Monitoring *Invasive and Noninvasive Clinical Application*. WB Saunders Company, 1987.

IIIb. Cardiac Function Assessment cont.

4. Measuring Cardiac Function

Cardiac function measurements with a Transonic® HD03 Flow-QC®
Hemodialysis Monitor require:
- Cardiac Output DTM inserted into the top rear of the HD03 Hemodialysis
  Monitor
- Flow-QC Clear Advantage® Tubing Set with a dedicated injection port for
  saline indicator injections into the venous blood line
- 30-ml syringes filled with saline warmed to body temperature.

Disposable Flow-QC Clear Advantage Tubing Set
A Flow-QC Clear Advantage Tubing Set provides a safe injection port for a
rapid 4 -7 second injection of a Cardiac Output saline bolus. The Flow-QC
Clear Advantage Tubing Set provides a consistent measurement environment.
The ultrasonic and mechanical properties of these tubing sets are controlled
to guarantee measurement accuracy, eliminate measurement variability from
blood line brands, and reduce the need for periodic sensor calibration.

The Flow-QC Clear Advantage Tubing Set is placed in the hemodialysis circuit
between the bloodline tubing and the venous and arterial needle tubing
with the Flow/dilution Sensors positioned on the Flow-QC Clear Advantage
Tubing. A bolus injection at another site, such as the bubble trap, would
become too long and the software program may not be able to separate the
timing of the first pass of the saline bolus from subsequent passes.

NORMAL CARDIAC FUNCTION VALUES (Hemodialysis Population)

Cardiac function depends on age, gender, and medical history (diabetes or
cardiac disease). Cardiac parameters may fluctuate dramatically during a
hemodialysis treatment. Flow-QC Surveillance measures:

CO	Cardiac Output	5 to 8 L/min (wgt & hgt dependent)
CI	Cardiac Index	2.2 to 4.5 L/min/m^2
CBV	Central Blood Volume	0.8 to 1.6 L (weight dependent)
CBVI	Central Blood Volume Index	11 - 17 ml/kg
PR	Peripheral Resistance	9.6 - 18.8 mmHg/L/min

IIIb. Cardiac Function Assessment cont.

To measure cardiac output and related parameters with the HD02 Monitor, fill a 30 ml syringe with 30 ml of saline warmed to body temperature. Insert Flow-QC® Clear Advantage® tubing segment into the hemodialysis circuit as shown (Fig. 3b.3) and then prime tubing.

Attach the arterial & venous Flow-QC Clear Advantage tubing to the needle tubing (c) in normal line position with the flow/dilution sensors positioned in the middle of the Flow-QC Clear Advantage tubing lines and the arrows on the sensors each pointed in the direction of flow.

Fig. 3b.3: The red-banded end of the arterial segment is connected to the male end of the arterial bloodline and the blue-banded branch of the Y end is connected to the male luer-lock connector on the venous bloodline.

With a Cardiac Output Data Transfer Module (DTM-CO) inserted in the HD03 Monitor, press the [Measure Patient] icon. Select the Flow-QC Tubing icon on the [Select Tubing] screen. Then press the Cardiac Output button to initiate the cardiac output measurement sequence. Enter parameters in the required fields and follow on-screen directions for the 6-7 second injection of 30 mL warmed saline. Measurement results including a CO dilution curve, calculated CO, CI and CBV values will display on the monitor.

Fig. 3b.4: Monitor display of measurement results.

Notes:
- If two measurements are within 15% of each other, do not make a third measurement. If a Repeat Measurement message displays, repeat injection.
- Cardiac Output can only be measured in patients with access flow and no access recirculation. Cardiac Output cannot be measured in patients with a central venous catheter.

C. Central Hemodynamic Profiling (CHP)

Central Hemodynamic Profiling identifies low CI and offers the physician the opportunity to improve CI by adjusting dry weight medication and length of dialysis.[1,11]

Effective cardiac function management depends on a routine screening program such as Central Hemodynamic Profiling Fig. 3b.5) that identifies patients who leave hemodialysis sessions with dange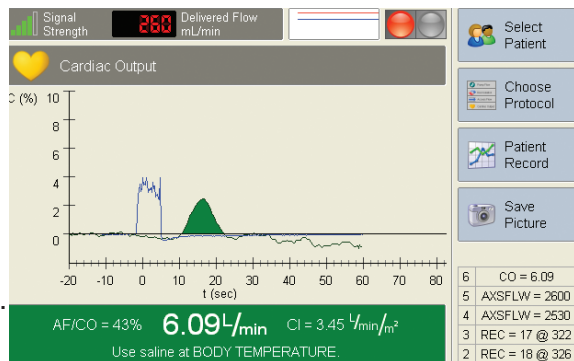rously low cardiac indices (CI ≤ 2.0), thereby increasing their risk for death, stroke or myocardial infarction. CHP is the periodic assessment of cardiac function during hemodialysis in order to track the heart's response to the stress of a dialysis treatment. CHP identifies:

- Prolonged high levels of access flow (>1,600-2,000 mL/min) that can lead to cardiomegaly and high output cardiac failure identified by an access flow to cardiac output ratio (AVF/CO) exceeding 25-30% (Fig. 3b.6).
- Cardiac Index of <2 L/min/m².
- Dramatic 20-30% drop in cardiac output during dialysis due to inaccurate dry weight estimation and/or medication that places patients at high risk for cardiovascular complications and sudden death following a dialysis session (Figs. 3b.6-7).
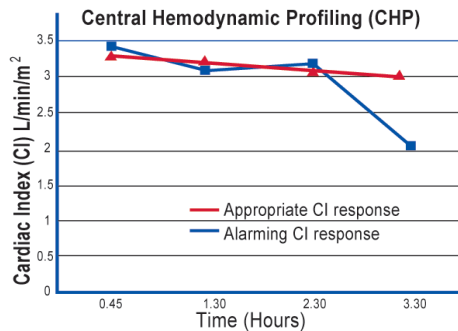

Fig. 3b.5: Central Hemodynamic Profiling (CHP): four measurements taken during a single hemodialysis session shows Cardiac Index responses to the hemodialysis treatment. Acceptable CI results range between 2.5 - 4.2 L/min/m².[37,38]
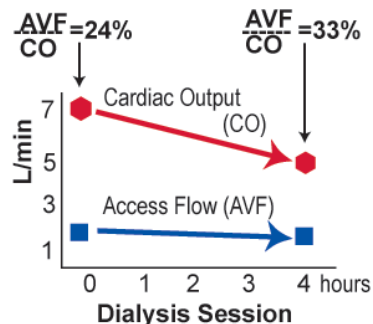

Fig. 3b.6: One third of CO is redirected from the systemic circulation to the AV fistula placing patients at cardiac risk.

IIIb. Cardiac Function Assessment cont.

D. Cardiac Function Study Protocol

A Cardiac Hemodynamic Profile Study (Flow Chart, page 58) consists of hourly cardiac output measurements throughout the hemodialysis treatment. Transonic® Flow-QC cardiac output software automatically calculates Cardiac Index. If Cardiac Index drops below 2 L/min/m^2 during treatment, the hemodialysis prescription should be reviewed and adjusted immediately. After adjustments are made, another Central Hemodynamic Profiling Study should be performed during the next dialysis session. If this profile is stable and in the appropriate range, the patient's cardiac status can then be monitored as usual.
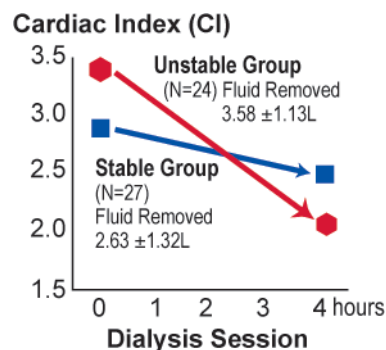

Fig. 3b.7: Inadequate dry weight estimation increases the risk of cardiac failure.[1,11]

Flow-QC Cardiac Function Study Program

1. Initial Cardiac Stability Assessment

For new patients, patients who have had interventions, and patients with suspected cardiac complications. Transonic Flow-QC Protocol begins with a Tucker Central Hemodynamic Profiling (CHP) study consisting of hourly cardiac output measurements during the hemodialysis session. If a patient is stable (CI > 2.5), the measurements serve as the first data point for the patient's cardiac function baseline (see 2. below).

2. Three-part Baseline Cardiac Function Study

The Baseline Cardiac Function Study established reliable average cardiac function parameters for the patient and consists of:
1) The first baseline CHP study performed on a stable patient (see above).
2) A second CHP study performed shortly after the first. (One baseline study should following a two-day dialysis break, another, after a three-day break.)
3) A third CHP study one month later, after a weekend dialysis break, to confirm a patient's stability and serve as the third data point for the patient's cardiac function baseline.

The nephrologist reviews the baseline study results, assesses the patient's status and prescribes a follow-up monitoring program.

3. Follow-up Cardiac Studies

Follow-up studies serve to monitor any progression of cardiovascular disease. A follow-up study consists of periodic CHP, preferably after a weekend break. The Flow-QC Protocol recommends quarterly testing for ESRD patients whose cardiovascular condition is stable and more frequent testing for patients with cardiovascular complications.

IIIb. Cardiac Function Assessment cont.

Flow-QC® Cardiac Function Study Protocol

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        ┌─────────────────────────────────────────────┐
        │      Initial Cardiac Function Study          │
        │  Hourly CO tests (CHP Study) performed during │
        │  hemodialysis when cardiac complications are  │
        │              suspected.                       │
        └─────────────────────────────────────────────┘
                              │
                              ▼
  Prescription Concern  ┌──────────────────┐  Cardiovascular
     ◄───────────────── │ Nephrologist     │     Concern
                        │ Review           │  ─────────────►
                        └──────────────────┘
                              │ Acceptable
                              ▼
              ┌─────────────────────────────┐
              │   Baseline Cardiac Studies  │
              │  A second CHP study and     │
              │  third, one month later,    │
              │  establishes reliable       │
              │  average cardiac function   │        ┌──────────┐
              │  parameters for the patient.│        │ Further  │
              └─────────────────────────────┘        │ Studies, │
                              │                       │ Treat-   │
                              ▼                       │ ments    │
              ┌─────────────────────────────┐         └──────────┘
              │   Nephrologist Analysis     │ Cardiovascular
              │  Set cardiac baseline values,│    Concern
              │  warning levels, testing     │ ────────────►
              │  schedule.                   │
              └─────────────────────────────┘
                              │ Acceptable
                              ▼
          ┌─────────────────────────────────┐
          │ Follow-up Cardiac Function Study │
          │  CHP study performed after a     │
          │  weekend break.                  │
          └─────────────────────────────────┘
                              │
                              ▼
   Acceptable         ┌──────────────────┐  Cardiovascular
     ◄─────────────── │ Nephrologist     │     Concern
                      │ Review           │  ─────────────►
                      └──────────────────┘
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E. Cardiac Function Case Studies

1. High Access Flow & Potential Cardiac Overload

A patient complaining of chest pains had 3630 mL/min AV fistula flow (Fig. 3b.8) which prompted a cardiac output measurement. Cardiac Output was 10.8 L/min (Fig. 3b.9). The vascular access was briefly occluded by a finger tip, and the patient's pulse rate dropped from 112 to 88 beats per min. An x-ray identified cardiomegaly. The vascular access was banded. Following the revision, access flow measured 1700 mL/min and Cardiac Output dropped to 7-8 L/min. The patient exhibited fewer post-dialysis hypotensive episodes, his dry weight decreased, his chest x-ray cleared and he reported significant improvement in his previous symptoms.
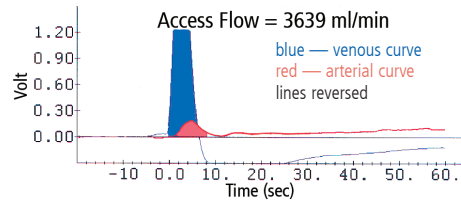

Fig. 3b.8: Access flow measured over 3.6 L/min which prompted a CO measurement.
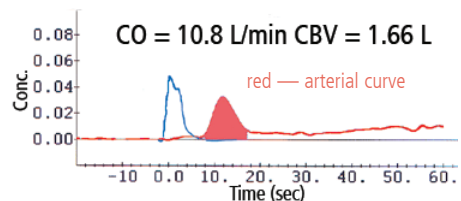
Fig. 3b.9: A 10.8L/min CO measurement corroborated cardiac overload.

2. Deterioration of Cardiac Output & Cardiac Index during Hemodialysis

Routine Flow-QC® Cardiac Function screening commenced 40 minutes into the hemodialysis session for a patient with ischemic heart disease. The first Cardiac Output measurement was 4.3 L/min with a Cardiac Index of 2.5 (Fig. 3b.10). When the cardiac function test was repeated two hours later, the patient's Cardiac Output had dropped to 2.7 L/min and his Cardiac Index was 1.6. The nephrologist was alerted, the patient's hemodialysis prescription was adjusted, and his cardiac condition was closely monitored.
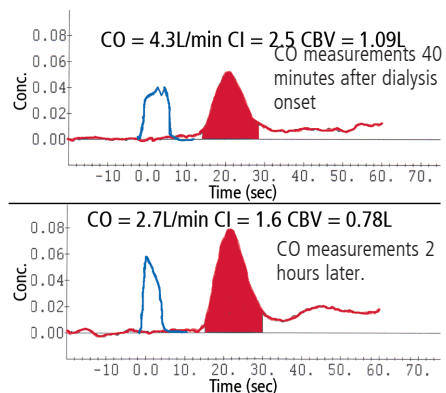

Fig. 3b.10: Flow-QC® software screens showing deterioration of cardiac function during the course of the hemodialysis session.

Case studies courtesy of Dr. T.A. Depner, University of CA at Davis

F. Cardiac Function Frequently Asked Questions

Q. *I am seeing congestive heart failure (CHF) in patients with borderline cardiac function and excellent fistulas. We have done compression studies on these patients during a cardiac cath by measuring the ejection fractions, then compressing the fistula with a blood pressure cuff and remeasuring the ejection fraction. The ejection fraction increases and the patient becomes less symptomatic. There was a Transplant International article (France, 2008) stating that they are tying off fistulas in post-transplant patients to decrease left ventricular hypertrophy (LVH). Is anyone else seeing this?[40]*

A. In fact, high-output cardiac failure and also pulmonary hypertension are well known complications of high-flow HD access. Although "high flow" is subjective, since every patient has a threshold of access flow that will induce such failure (as well as distal extremity ischemia), Fistula First uses a minimal threshold of 2 L/min flow to refer the patient for cardiac evaluation.

This is an often overlooked cause of LVH & CHF and any HD patient with a history of CHF or progressive LVH, should absolutely have access flow measured. When unrecognized, many of these patients with recurring CHF will die from their access-induced heart disease, since the cause was not recognized, and only gets worse.

The advent of accurate non-invasive measurement by ultrasound saline dilution has made it possible to measure access flow, which permitted a number of studies confirming the correlation between cardiac output and access flow. Access flow is usually approximately 20% of cardiac output. As access flow increases, so does cardiac output. The only reason that we do not see this problem in many patients, is because only a small proportion of patients have access flow approaching or greater than 2 L/min. Certainly, any patient developing LVH or CHF after starting HD should have the access flow measured. One reason I strongly urge use of access flow surveillance, is because it provides so much information. (Larry Spergel, MD, FACS)

Q. *How accurate are Transonic CO measurements?*

A. Transonic Cardiac Output measurements are the greater of 15% of true cardiac output, or ± 0.5 L/min.

Q. **Why should the pump be set at 200 ml/min during CO measurements?**

A. Injecting 30 ml of saline over 6 seconds increases the outflow rate of the venous blood line temporarily by 300 ml/min. Lowering the pump setting reduces the chance of pump stoppage during venous pressure elevation and also reduces the chance of the saline injection triggering recirculation.

Q. *Why must there be 0% recirculation during a CO measurement?*

IIIb. Cardiac Function Assessment cont.

A. For accurate Cardiac Output measurements, the full saline injection must reach the heart in a single bolus. The CO calculation is based on a bolus volume of 30 ml. If there is recirculation a part of the bolus will return back into the arterial bloodline and the lost saline would introduce a measurement error. Flow-QC® monitoring software will recognize recirculation during the CO measurement injection and will ask to repeat the measurement at a lower pump flow setting.

Q. *Why do I need to enter the patient's height and body weight?*

A. These values are used to calculate the patient's body surface area (BSA) from which Cardiac Index (CI) is derived. The Cardiac Output measurement protocol can be executed without these values, but the software would not calculate the CI and Central Blood Volume Index (CBVI). If pressures are not entered, the monitor's software will not calculate Peripheral Resistance (PR).

Q. *Why must the saline be pre-warmed for the injection?*

A. The transit-time of ultrasound changes with temperature. When CO is measured, the saline bolus travels through the cardiovascular circuit before returning to the arterial line flow/dilution sensor. Saline must be pre-warmed to body temperature so there will be no additional thermal changes to the saline indicator bolus as it passes through the body. A Transonic Fluid Bag Warmer is provided to warm and maintain the saline at a temperature of 33-38ºC. Never use a microwave to warm the saline!

Q. *How should I inject the 30 mL?*

A. The 30 ml injection is made into the injection port on the venous side of the Flow-QC tubing. It must be injected in one single pass fairly rapidly (4 to 7 seconds). Software automatically identifies and reports injection errors (direct recirculation, micro-bubble, incorrect saline temperature).

Q. *Why do two consecutive CO measurements differ?*

A. The repeatability of Transonic® indicator dilution technology is ± 4%. This means that two consecutive measurements may vary an average of 4% from their mean. Also, CO varies during the course of a respiratory cycle, over the course of the hemodialysis treatment, and with the patient's level of activity.

Q. *Why aren't CO measurements possible with Central Venous Catheters?*

A. Cardiac Output measurements require recording of a arterial dilution curve after introduction of an intravenous indicator (saline). If the indicator were to be injected through a central venous catheter, the indicator would not have the proper mixing conditions to dilute with the entire cardiac flow.

IIIb. Cardiac Function Assessment cont.

Q. *How often should Cardiac Function parameters be measured?*

A. Patient profiling is performed to establish and confirm the adequacy of medication dosages and the hemodialysis prescription. A patient's cardiovascular baseline consisting of monthly measurements over two consecutive months, can then be established by measuring Cardiac Output. This baseline should be established when a patient first enters into the Transonic® monitoring program and repeated when the patient returns from a hospitalization. After the baseline period, the nephrologist determines a measurement regimen for each patient including a prescribed testing interval (i.e., quarterly, monthly), whether an analysis of fluctuations in cardiovascular parameters induced by hemodialysis should continue, and the threshold at which changes in critical cardiac parameters should be brought to the attention of the nephrologist.

Q. *What is an AF/CO ratio and will I get an AF/CO value every time I do an access flow measurement and CO measurement?*

A. The AF/CO value is the percentage ratio of the patient's access flow to the patient's cardiac output. For example an AF/CO value of 22% would mean that 22% of the patient's cardiac output is being shunted through the patient's access. However, when access flow exceeds 25% of cardiac output, a potential cardiac problem may exist. The AF/CO ratio is calculated by the HD03 Flow-QC® Hemodialysis Monitor when access flow and cardiac output measurements are performed during the same hemodialysis session.

IIIb. Cardiac Function Assessment cont.

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39 Cordtz J1, Sternby J, "An experimental, simplified method for intradialytic cardiac output measurement," Artif Organs 2012; 36(3): E71-7

40 http://www.fistulafirst.org/Professionals/ FrequentlyAskedQuestions.aspx#Q5

IVa. Flow-based Angioplasty

Routine Transonic Flow-QC® surveillance during hemodialysis trends declining vascular access flows in order to detect the presence of hemodynamically significant stenoses or to identify high flows that threaten cardiac overload.[1-2] When a significant stenosis has been identified, a variety of techniques are used to restore access flow to an acceptable level for hemodialysis delivery. An optimal choice takes into account the type of access, its anticipated durability, the severity of symptoms and disease, and the availability of a venous conduit.

This section presents the use of flow measurement with two established treatment modalities for repairing a vascular acccess in danger of failing. The first treatment modality presented in Section IVa is Percutaneous Transluminal Angioplasty (PTA); the second presented in Section IVb is Surgical Revision.[3]

A. Measuring Intragraft Flow during Angioplasty

When AV fistulas or grafts fall below a critical threshold, percutaneous transluminal angioplasty (PTA) is the front line treatment modality for repairing the access.[4-6] Elective rather than emergent, less invasive than surgery, angioplasty both conserves the current access site and preserves future access sites. During angioplasty, on-the-spot intragraft flow measurements with the Transonic ReoCath® Flow Catheter and HVT100 Endovascular Flowmeter are used as a problem solving tool for interventional radiologists as they seek to restore access patency.

At the University of Pennsylvania where direct intra-access flow measurements with the HVT100 Endovascular Flowmeter and ReoCath Flow Catheter are used selectively as a problem solving tool used to obtain supplemental information when there is a discrepancy between angiography and physical examination (PE) findings, measurements are considered especially relevant to support a decision not to intervene (see abstract on page 80).

IVa. Flow-based Angiography cont.

In one third of patients that have had apparently successful angioplasties, access blood flow sometimes fails to normalize.[7-8] Vesely attributes these poor outcomes to the presence of an arterial inflow stenosis, failure to identify multiple lesions within the access, elastic recoil immediately following the angioplasty and/or poor cardiac output. On-the-spot measurements of intragraft blood flows during the angioplasty procedure (Fig. 4a.1) inform the interventionalist about the entire vascular circuit.[5,9,16]

McCarley et al reported that, when surveillance was combined with expedient angioplasty, the rate of graft thrombosis decreased almost fourfold, overall costs dropped by approximately 50% and catheter use decreased dramatically.[11] During angioplasty, intragraft flow measurements provide quantitative data at three points of the intervention: at its outset, during the intervention, and/or at its conclusion.[13]

1. At the Outset of the Intervention

At the procedure's outset, an intragraft flow measurement confirms, first of all, that the procedure is indeed necessary and blood flows are lower than 600 ml/min KDOQI-recommended threshold.
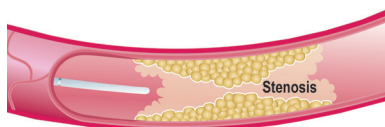

Fig. 4a.1: ReoCath® antegrade flow catheter measuring intragraft flow before angioplasty.

Studies have demonstrated that when a static pressure ratio is used for access surveillance, a high flow access can be erroneously targeted for an intervention.[14] It has also been shown that angiographic findings alone do not correlate with blood flow.[7] Vesely addresses this failure of angiography by advising that the intervention should not be performed unless clinical or hemodynamic abnormalities correlate with angiographic findings.[5]

A flow measurement at the beginning of the intervention also provides a flow baseline from which a target flow goal for the procedure can be set. In essence, each individual then serves as his or her own control as the goal of the intervention is to improve flow through the access. Intragraft blood flow measurements at the onset of angioplasty both confirm the need for the intervention and provide a baseline from which flow should improve.

IVa. Flow-based Angiography cont.

2. During the Intervention

As the intervention proceeds, intragraft ReoCath® flow measurements provide objective functional data to guide the interventionalist to achieve the target flow goal (see "How the ReoCath System Works," page 69).

Since Fistula First has urged the increased use of native fistula in lieu of prosthetic grafts, the interventionalist can no longer assume that the cause for declining vascular access flow is a single venous outflow stenosis common in grafts, and correcting it endovascularly will solve the access flow problem. The 2006 KDOQI Update states, "Inflow stenosis is more common than previously believed. ...Access inflow stenosis occurs in one third of patients referred to interventional facilities with clinical evidence of venous stenosis or thrombosis."[16] Vesely concurs, "Arterial anastomotic stenoses are the single most important flow determinant of the entire vascular access."[15]

When a ReoCath intragraft flow measurement demonstrates that the flow target has been attained, the intervention can be safely concluded. However, if, after angioplasty, flow remains below expected levels, the interventionalist is immediately alerted that another problem within the circuit exists that needs to be addressed.

3. At the Conclusion of the Intervention

Fig. 4a.2: ReoCath® antegrade flow catheter measuring intragraft flow after angioplasty.

Although improvement in blood flow following angioplasty should be obvious, Beathard warns, "Elasticity of venous stenotic lesions appears to be a much more serious problem than has been previously recognized ... Recoil of an elastic lesion can be easily missed."[5] To this end, a follow-up intragraft flow measurement several minutes after completion of the intervention will confirm continuing good flow and the absence of elastic recoil (Fig. 4a.2). Conversely, it will alert the interventionalist if recoil has occurred. Flows can then be documented for the patient record and compared with vascular access flows obtained during subsequent access surveillance in the hemodialysis unit with the Flow-QC® Monitor
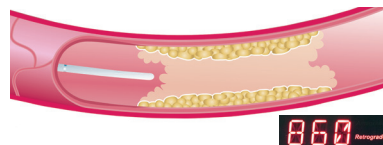
4. Angioplasty Success

It has been reported that post-PTA access flow should ideally return to or be higher than former optimum access flow levels; the literature reports the average flow increase to be about 300 ml/min. Krivitski reports that patients whose blood flow increased more than 300 ml/min during angioplasty also showed significant increases in flow measured during subsequent hemodialysis. In his review of 17 studies, the post angioplasty weighted mean flow increase was 309 ml/min for AV grafts and 329 ml/min for AV fistulas respectively.[19] Murray and colleagues also have reported that

Fig. 4a.3: Murray B et al: "Access Flow after Angioplasty Predicts Subsequent Arteriovenous Graft Survival."[17]

blood flow achieved after angioplasty is predictive of subsequent graft patency (Fig. 4a.3) and asserts that grafts with post-angioplasty access flows of less than 1L/min are more likely to require repeat intervention, to exhibit thrombosis within the first six months, and have a lower one-year survival compared with those with access blood flow rates greater than 1L/min.[18]
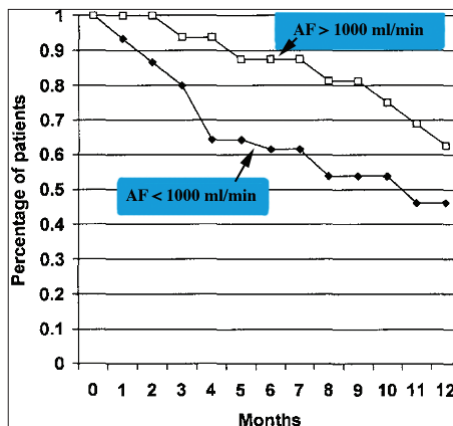
Successful Angioplasty

KDOQI defines successful angioplasty as one where the residual stenosis is less than 30% of the diameter of the access. Ahya *et al* dispute this anatomic measure, "Visual assessment of the lesion following angioplasty fails to predict the hemodynamic success of the procedure."[7] Another study in which flow actually decreased after angioplasty in four grafts also supports the conclusion that anatomic assessment by angiography does not correlate with flow. Although residual stenoses were visualized in the grafts, none was greater than 30% of the diameter of the access. Beathard calls for total elimination of the stenosis and cites a Lilly study of 330 cases in which the median primary patency for a graft was longer (6.9 months) when there was no residual stenosis than if there was any degree of residual stenosis (4.6 months).[5-6]

IVa. Flow-based Angiography cont.

B. How the ReoCath® System Works

The ReoCath® Flow Catheter System consists of single-use catheters (antegrade and retrograde), a ReoCath extension cable and the Transonic® HVT100 Flowmeter (Fig. 4a.4). The 6 French antegrade and retrograde flow catheters each have an external injection port connected to a central lumen (Figs. 4a.5, 4a.6) through which saline is released into the access during angioplasty.

Each catheter has two temperature sensors (thermistors). When room temperature saline is injected into the access, a thermister located close to the proximal end of the catheter records the temperature of the injected saline solution. The second thermister located close to the distal tip of the catheter records the thermodilution within the access.

A 2-meter extension cable connects the catheter to the HVT100 Flowmeter. The Flowmeter automatically calculates and displays intra-graft blood flow in milliliters per minute (see Theory sidebar on next page).

Antegrade Catheter

Fig. 4a.5: Antegrade catheter (6 F, 35 cm length) is inserted in the same direction as blood flow. Saline is released proximal to the catheter tip and then is measured downstream by the dilution thermister.

Retrograde Catheter

Fig. 4a.6: Retrograde catheter (6 F, 48 cm length) is inserted against the direction of blood flow. Saline is released at the catheter tip and is then is measured downstream by the dilution thermister.
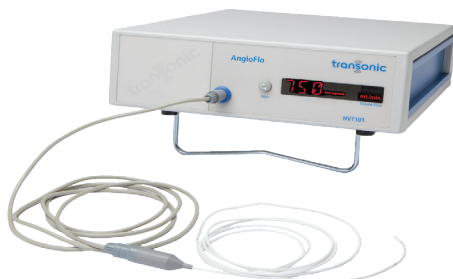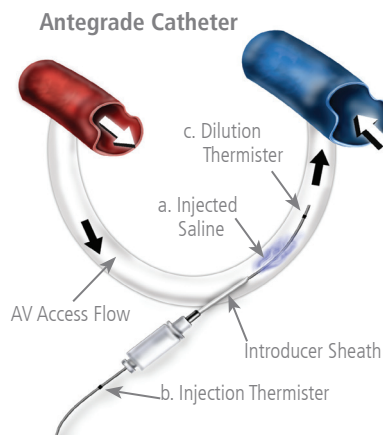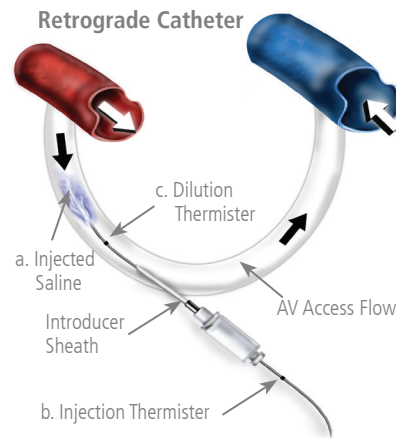
Fig. 4a.4: HVT100 Endovascular Flowmeter measures intragraft blood flow in the arteriovenous (AV) vascular access to provide quantitative information about access functionality during angioplasty.

IVa. Flow-based Angiography cont.

With the ReoCath® Flow Catheter system, the interventional radiologist introduces a 10cc bolus of room temperature, isotonic saline into the access while performing the endovascular procedure (see Procedure on next page). The system calculates intragraft blood flow from the change in temperature of the injected saline. The Flow Measurement Protocols (Flow Charts, pages 72-73) recommend that these intragraft flows be measured before and after balloon insertion. By comparing the post-angioplasty value to the pre-angioplasty baseline flow value, the interventional radiologist has immediate feedback on the procedure's success. If intragraft blood flow has not increased to satisfactory levels, the balloon can be re-inserted until flow is optimized.

Principle of Operation

For flow measurements within the AV vascular access, the HVT100 Endovascular Flowmeter and ReoCath® Flow Catheter use classical dilution-based equations adapted to the unique hemodynamic conditions that exist within the access. Intra-access blood flow measurements are based upon the following equation:

$$Q = k\,(T_b - T_i)\,V/S - 0.5\,V/\tau$$

Where:

Q = intra-access blood flow;
k = a coefficient related to the thermal properties of blood, saline = 1.08
T_b = temperature of the blood prior to injection;
T_i = temperature of injected saline;
V = volume of injected saline (10ml);
S = the area under the temperature-time dilution curve resulting from the mixing of blood and injected saline;
τ = width of the dilution curve at 50% height (Figure).

The expression $(0.5V/\tau)$ is an average expected increase in blood flow as a result of the saline injection.
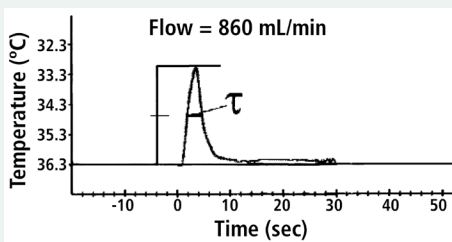
Thermal dilution curve generated by the change in temperature between the isotonic saline injected into the AV access and the diluted temperature registered by the catheter thermistor within the access.

IVa. Flow-based Angiography cont.

C. Intragraft Flow Measurements Protocols

1. Connect HVT100 Endovascular Flowmeter to grounded power receptacle.
2. Select a sterile antegrade or retrograde ReoCath® Flow Catheter. Open its pouch and pass the connector of the ReoCath Flow Catheter to the non-sterile field.
3. Remove the distal cap, curve retainer, and tag from the ReoCath Flow Catheter.
4. Have someone outside the sterile field attach the connector of the ReoCath Flow Catheter to the extension cable. Connect extension cable to the HVT100 Endovascular Flowmeter.

    Note: The system will not identify the type of catheter (antegrade or retrograde) until it is inserted into the introducer sheath.
5. Open stopcock on the ReoCath Flow Catheter and prime the catheter with isotonic saline. Close the stopcock.
6. Insert the ReoCath Flow Catheter through the 6F or larger introducer sheath until the marker band is visible outside the sheath.
7. Press the start button on the front of the HVT100 Flowmeter.
8. The HVT100 Flowmeter will display "Wait". The catheter indicator light will display the type of ReoCath connected, either antegrade or retrograde.
9. After 15-20 seconds, the HVT100 Flowmeter will display "Ready". Open the ReoCath stopcock and inject about 10 ml of room temperature saline (20-25°C) as a 2-3 second bolus in a smooth, continuous motion. (Small deviations in the injection volume do not affect measurement accuracy.)
10. Close the stopcock.
11. The HVT100 Flowmeter display will change to "PROC. 21" and countdown to "PROC. 00" and will then change to "CALC. 10" (at this point the Flowmeter has begun to calculate flow) The countdown will continue to "CALC 00".
    Note: at some point during the CALC. process, the display may pause momentarily (this is normal).
12. The Flowmeter will display blood flow in ml/min. If there was a problem with the injection, the display will read "REPEAT" instead. Return to Step 7.
14. Repeat Steps 7-11 once or twice more to ensure measurement reproducibility.
15. Remove the ReoCath from the introducer sheath and keep it in the sterile field for possible additional measurements later in the procedure.
16. Dispose of the ReoCath according to standard infection control procedures.
17. The extension cable and HVT100 Flowmeter can be cleaned with alcohol wipes.

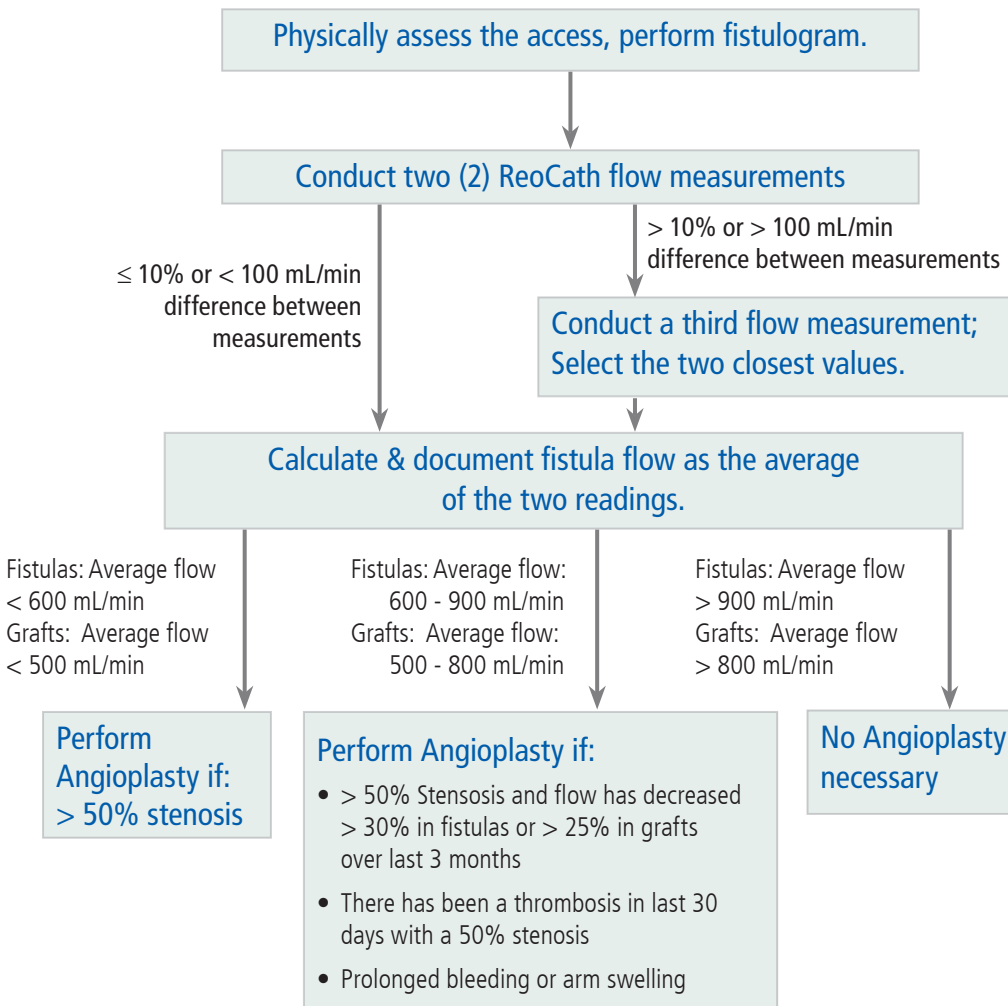   *Note: The same ReoCath can be used several times during the same procedure.*

IVa. Flow-based Angiography cont.

ReoCath® Flow Catheter Measurement Protocol
PRE-INTERVENTION

Pre-intervention Notes:
1. Do not cross a stenosis with the catheter.
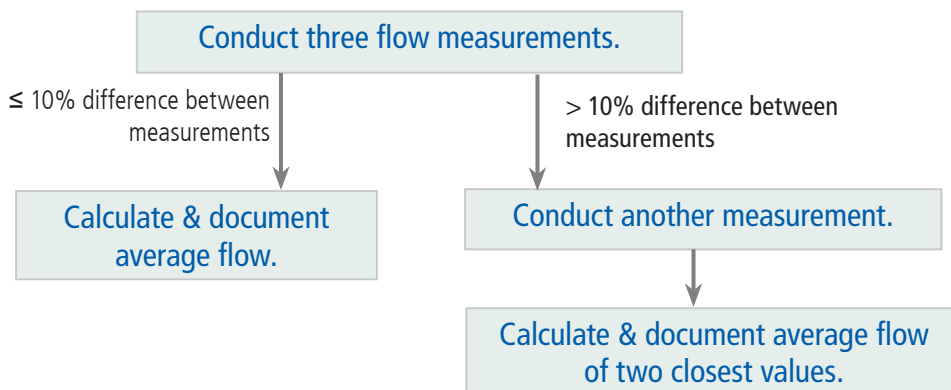2. Avoid catheter tip placement near side branches or within an aneurysm.

Physically assess the access, perform fistulogram.

↓

Conduct two (2) ReoCath flow measurements

> 10% or > 100 mL/min difference between measurements

≤ 10% or < 100 mL/min difference between measurements

Conduct a third flow measurement; Select the two closest values.

↓

Calculate & document fistula flow as the average of the two readings.

Fistulas: Average flow
< 600 mL/min
Grafts: Average flow
< 500 mL/min

Fistulas: Average flow:
600 - 900 mL/min
Grafts: Average flow:
500 - 800 mL/min

Fistulas: Average flow
> 900 mL/min
Grafts: Average flow
> 800 mL/min

Perform Angioplasty if:
> 50% stenosis

Perform Angioplasty if:

- > 50% Stensosis and flow has decreased > 30% in fistulas or > 25% in grafts over last 3 months
- There has been a thrombosis in last 30 days with a 50% stenosis
- Prolonged bleeding or arm swelling

No Angioplasty necessary

IVa. Flow-based Angiography cont.

ReoCath® Flow Catheter Measurement Protocol cont.

POST-INTERVENTION

Conduct three flow measurements.

≤ 10% difference between measurements

> 10% difference between measurements

Calculate & document average flow.

Conduct another measurement.

Calculate & document average flow of two closest values.

Post-intervention Notes:
1. A progressive decline in observed blood flow values may be due to elastic recoil of the stenosis. Wait 5 minutes and repeat the fistulogram.
2. A progressive increase in blood flow values may be due to relaxation of spasm. Wait 2-3 minutes and repeat blood flow measurement.

Is This Vascular Access Patent?

An angiography of the vascular access on the right revealed what appeared to be a kink or stenosis (at the arrow). However, when access flow was measured with the ReoCath® Flow Catheter and HVT100 Endovascular Flowmeter, access flow actually measured 1600 mL/min, which negated the need for a corrective intervention.
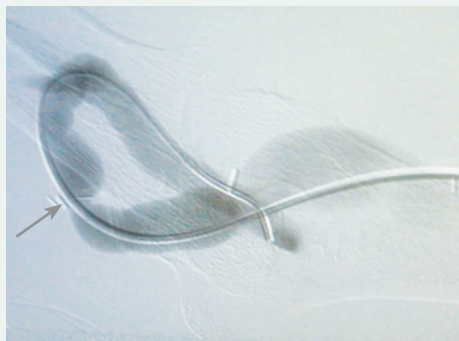
Minimally Invasive Limited Ligation Endoluminal-assisted Revision[20]

MILLER Banding Protocol courtesy of GA Miller, MD, American Vascular Access, Brooklyn, NY

Two conditions dictate the need to increase venous outflow resistance in an AVF used to deliver hemodialysis.

- ### Ischemic Steal Syndrome (ISS)
  Clinically significant ISS, associated with severe hand pain, neurological defects and distal finger gangrene, is a potentially devastating complication of an AV access.

- ### High Flow Fistula Access
  As an AV matures, high flow (~>2L/min) can develop, which can lead to bleeding, increased venous pressures and cardiac overload.

Fistula Banding

In both cases, a high resistance band is used to restore sufficient distal flow and perfusion to the extremity and to correct the symptoms of steal or high flow access. Successful treatment of ISS presents a clinical challenge of balancing the demand of maintaining the access with restoration of sufficient flow to reduce steal symptoms. In instances of high flow access, the diameter of the band must also be precisely controlled as not to induce thrombosis.

Although fistula banding has been used for over 30 years to reduce fistula flow, all previous techniques have relied on measurements of the outside of the fistula to change the size of the lumen (inner diameter) of the fistula. By using an endoluminal balloon as a sizing dowel, the MILLER technique refines the banding procedure so that a fistula's inner diameter is shrunk to a perfect predictable size.

MILLER Procedure

Performed in an outpatient hemodialysis vascular access (radiology) clinic, the MILLER procedure uses an inflated endoluminal balloon as a sizing dowel within a fistula as a ligature is tightened around its exterior. The band around the fistula redirects flow to improve distal perfusion and alleviate symptoms. MILLER Steps include:

Pre-intervention Assessment: Patients are categorized as "Steal" or "High Flow" according to their symptoms and a physical examination.

1. Fistula Access: The skin is anesthetized with 1% lidocaine with epinephrine. A 21-g microaccess needle with a 5F vascular sheath, guide wire and Bern Catheter is used to enter the access in both antegrade and retrograde directions.

2. Imaging to Identify Obstructions: Fluoroscopy with intravenous high contrast material introduced through a catheter into the access identifies any venous outflow obstruction and images the arterial circulation. With the catheter in the feeding artery, extremity imaging is performed. Steal patients also undergo an upper extremity arteriogram.

IVa. Flow-based Angiography cont.

MILLER Steps cont

3. **Initial Flow Measurement:** An initial flow measurement is performed with an antegrade flow catheter and Endovascular Flowmeter (Transonic Systems Inc.).

4. **Banding Site Identified:** The arm is palpated to find a banding site as close to the AV anastomosis as possible (1-3 cm), yet superficial enough to allow for easy dissection.

5. **Dissection:** Once a site is identified, the first of two parallel horizontal 0.5 cm incisions is made. A pocket is created and a Kelly clamp is used to tunnel around the fistula. Dissection continues until the clamp emerges and the top of the clamp is palpable through the superficial tissue. The site is marked. A second incision and pocket are made at this site.

6. **Band Positioned:** A clean 2-0 monofilament Prolene ligature is pulled over the body of the fistula from pocket one to pocket two and then looped over the access (under the skin) using a Kelly clamp. A second ligature is also introduced to use if the first band is not successful.

7. **Banding:** Fluoroscopy is used to ensure that the endoluminal balloon is positioned over the dissection plane. The balloon is then inflated to 18 atmospheres of pressure. *Notes: The sizing of the balloon is critical to the procedure's success. In steal patients, the band should be equal or smaller than the size of the downstream artery to ensure that the resistance of the access is significantly increased with respect to the resistance of the downstream artery. In high flow patients, the diameter of the access lumen must be reduced by 60-80% in order to significantly affect flow, (per Murray).*
The ligature is then tightened around the balloon until there is no flow in the access. The ligature is then secured and the knot is rotated down so that it will not poke the skin. The balloon is deflated and flow is restored. Angiography confirms successful banding.

8. **Post-procedure Measurements:** Flow measurements with the flow catheter and Endovascular Flowmeter confirm appropriate flow reduction. Flow will be reduced 40-50% with a 3-4 mm band.

9. **Completion/Modifications:** The wound is closed with a set of superficial sutures. The entire site is cleaned up and bandaged for recovery. The access is palpated to determine flow. If flow is too sluggish, a balloon with a diameter 1 mm larger is used to stretch the band. If a patient reports no symptomatic improvement and angiographic evidence of steal persists, the procedure is repeated with a second ligature using a balloon with a diameter 1 mm less than the first. See Transonic's MILLER Banding Procedure Medical Note (IR-622-mn) for more details.

IVa. Flow-based Angiography cont.

D. Intragraft Flow Studies

1. Validation Studies

Transonic ReoCath® Flow Catheter technology has been rigorously validated on the bench, *in vivo* and in clinical studies.[9-10]

a. Bench Test

In the bench test model, catheter flow was measured 397 times while water flow in a graft model was varied from 150 - 1,700 ml/min. Measurements between the ReoCath® Flow Catheter system and the Transonic® HT109 Volume Tubing Flowmeter demonstrated excellent correlation (r = .98). More than 60% of the ReoCath® measurements were within 5% of true flow as measured by the Flowmeter and 95% of the measurements were within 15% of the true flow.

b. *In Vivo* Testing

In vivo testing in two adult ewes followed. Eleven intragraft blood flow measurements, obtained with the ReoCath® Flow Catheter system, were compared to values measured with a Transonic Perivascular volume Flowprobe. Again, the two measurement methodologies demonstrated excellent correlation (r = .99).
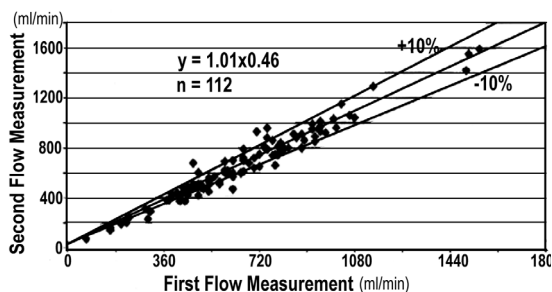

Fig. 4a.7: Reproducibility of sequential blood flow measurements made by the ReoCath® Flow Catheter system during the clinical validation study of 24 patients.
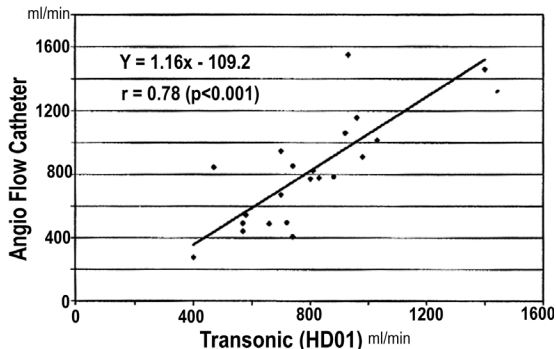
$$y = 1.01x0.46$$
$$n = 112$$

Fig. 4a.8: Correlation of post-angioplasty blood flow measurements (HD01 Hemodialysis Monitor) with those obtained with the ReoCath® Flow Catheter system.

$$Y = 1.16x - 109.2$$
$$r = 0.78 \ (p<0.001)$$

IVa. Flow-based Angiography cont.

c. Clinical Study

In a prospective clinical study, intragraft measurements in 25 patients with the ReoCath® Flow Catheter system were compared to pre- and post-angiography measurements with the Transonic® HD01 Hemodialysis Monitor.[19] All patients had PTFE loop grafts, 20 of which were located in the forearm and five were in the upper arm. Fistulograms identified 40 hemodynamically significant stenoses in 24 patients. In each of those patients, angioplasty was performed. Prior to the balloon insertion the ReoCath Flow Catheter was inserted through a vascular sheath so that the side holes in the catheter were within the graft, but had not entered its stenotic segment. For each measurement, 10 ml of sterile room temperature, isotonic saline was injected into the catheter's injection port over 3-4 seconds. Two consecutive intragraft blood flow measurements were taken and the results averaged. If the two measurements differed by more than 10%, a third measurement was taken. Sequential measurements were highly reproducible (Fig. 4a.7). Measurements were performed both before and immediately after angioplasty.

On an average of 11.9 days before angioplasty, the mean vascular access blood flow measured by the HD01 Monitor in the 24 subjects was 463±154 ml/min. When intragraft flow was measured just prior to balloon insertion with the ReoCath Flow Catheter system, the mean flow was 495±180 ml/min. Post-angioplasty correlation between the ReoCath flows and HD01 flow measurements were 779±331 ml/min and 781±221 ml/min respectively (Fig. 4a.8). The mean increase in vascular access blood flow following angioplasty measured by the ReoCath system was 324±267 ml/min and 319±256 ml/min measured by the HD01 Monitor 4.9 days (average) following angioplasty.

d. Conclusion

The ReoCath system provides a quantitative flow assessment of the entire vascular circuit: its arterial inflow segment, mid-access segment and venous outflow segment.[9-11] This data alerts the interventional radiologist to lesions wherever they are located within the circuit to ensure success of the intervention and avert an immediate return of the patient to the radiology suite or to surgery for another intervention.[21]

2. Other Studies

Publication Briefs of three studies using the ReoCath® Flow Catheter follow.

Endpoints for Hemodialysis Access Procedures: Correlation between Fistulography and Intraaccess Blood Flow Measurements[23]

Goyal A et al, "Endpoints for hemodialysis access procedures: correlation between fistulography and intraaccess blood flow measurements." J Vasc Interv Radiol. 2011; 22(12): 1733-9. (Transonic Reference # IR9604V)

OBJECTIVE

To compare angiographic vessel diameter of stenotic hemodialysis prosthetic grafts and autogenous fistulas, the traditional measure of percutaneous intervention success, and pre and post intervention real-time intra-access blood flow rates (IBF) and access blood flow (ABF) measurements during hemodialysis.

STUDY

- Radiologic images and IBF measurements of 35 patients with 76 procedures were analyzed retrospectively. ABF rates were also included if they took place within five weeks after the intervention. The study population included 19 autologous fistulas and 16 prosthetic grafts.
- In first-time patients, time to failure of treatment was modeled.

RESULTS

- Significant correlations included:
- Initial ABF (during hemodialysis) and pre-intervention Intra-access Flow Measurements (p = 675);
- Initial ABF (during hemodialysis) and fistulography (p = 781);
- Post-intervention Intra-access Flow Measurements and ABF (during hemodialysis) (p = 798);
- The final intra-access flow measurements and ABF correlated better than final fistulography and ABF (difference = 0.418, 95%)
- There was no significant correlation between access survival after the intervention and Intra-access flow values.

STUDY'S CONCLUSIONS

- Post-intervention, IBF measurements correlate more strongly than fistulography with ABF rates performed during hemodialysis with flow/dilution measurements.
- More studies are needed to determine the optimum target flow value to be achieved by a percutaneous intervention.

TAKE HOME POINTS

- The Endovascular Flowmeter and ReoCath® Flow Catheters calculate real-time blood flow through access circuits.
- These measurements provide functional and therefore more physiologically relevant data in the interventional suite than qualitative fistulography.

IVa. Flow-based Angiography cont.

Can Catheter-Based Blood Flow Measurement after Hemodialysis Access Intervention Predict Long-Term Patency?[24]

Itkin M, Trerotola SO et al, "Can Catheter-Based Blood Flow Measurement after Hemodialysis Access Intervention Predict Long-Term Patency?" J of Vasc Intervent Radio 2008; 19(2): S37 Abstr 92. (Transonic Reference # IR7568AH)

INTRODUCTION
This study was designed to determine if blood flow measured at the end of interventional procedures using a thermodilution catheter could predict post-intervention patency.

STUDY
- Pre-and post-angioplasty flows were recorded in 45 patients in the dialysis clinic and with thermodilution catheter before and after the intervention.
- Patients were followed until access failed, death or end of the two and one-half year study.

RESULTS
- Flows increased 37% after angioplasty.
- Flows measured with Hemodialysis Monitor and thermodilution catheters agreed.

Mean Vascular Access Flows: Pre & Post Angioplasty (ml/min)			
Time	Mean (n = 45)	Graft (n = 45)	Fistula (n = 45)
Pre-intervention	786	772	849
Post-intervention	1,077	1,035	1,249

STUDY'S CONCLUSIONS
There was a statistically significant difference in graft survival at one year ($p < .05$, Kaplan-Meier) between patients with blood flow > 600 mL/min post-procedure compared with flow < 600 mL/min.

STUDY'S LIMITATION
Small fistula sample size (n=8) precluded any conclusions for fistulas.

TAKE HOME POINTS
- Pre-and post-angioplasty flows record flow improvements as a result of intervention.
- Corroborates KDOQI Guideline recommendation of a lower threshold of 600 mL/min or more for acceptable flow in prosthetic grafts.
- Endovascular Flowmeter and flow catheter measurements during an intervention closely agree with measurements with "Gold Standard" Hemodialysis Monitor during dialysis.

IVa. Flow-based Angiography cont.

Direct Intra-Access Flow Measurement as a Problem Solving Tool in Hemodialysis Access Interventions[25]

Leontiev O, Trerotola SO, "Direct Intra-Access Flow Measurement as a Problem Solving Tool in Hemodialysis Access Interventions," Society of Interventional Radiology 2012; Dialysis Interventions Abstr 95. (Transonic Reference # IR9666AH)

INTRODUCTION
At the University of Pennsylvania direct intra-access flow measurements with the HVT100 Endovascular Flowmeter and ReoCath® Flow Catheter are used selectively by the treating interventionalist as a problem solving tool used to obtain supplemental information when there is a discrepancy between angiography and physical examination (PE) findings.

PURPOSE
1) To identify specific scenarios in which flow measurements were performed;
2) To determine how flow measurement affected the chosen course of action.

STUDY
- All PTAs in malfunctioning (n=118) or thrombosed (n=21) hemodialysis access circuits in which direct intravascular flow measurement was used during an 32 month period
- Demographic information was collected and procedural outcomes were determined.

Angioplasty Study			
Interventions	Qualifying	Excluded	Study
1540	139	33	106 (9%)
Fistulas: 72; Grafts: 34			

RESULTS
1) High-flow related cardiac risk was examined in 20 patients with aneurysmal fistulae;
2) The remaining 86 patients were indicated for direct flow measurement to problem solve the following: No lesion to explain failure of access (n=17); decision for further PTA (n=6); place covered stent (n=4); terminate the procedure (n=21);
   - Indecisive physical exam results (n=5);
   - Inflow problems (n=33) with subsequent intervention: (PTA n=3)(clot aspiration n=1);
3) In 16% of patients (14/86), flow measurements directly led to a decision for further treatment.
4) In 84% of patients (72/86), flow measurements directly led to a decision to not treat any further.

CONCLUSIONS
1) Endovascular flow measurements with the ReoCath® Flow Catheter may be used as a problem solving tool during hemodialysis access intervention.
2) Direct flow measurements are considered especially relevant to support a decision not to intervene.

E. Flow-based Angiography References

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IVb. Flow-based AV Access Surgical Revision

An arteriovenous access sends oxygenated arterial blood that usually flows through a complex high resistance system of arterioles and capillaries before it reaches the venous system, immediately to a low resistance vein. This precipitous drop in resistance makes AV accesses (prosthetic grafts, in particular) susceptible to myointimal hyperplasia that can eventually lead to stenosis, thrombosis and ultimately, access failure.

To deliver the prescribed dialysis prescription, a patient must have a healthy access that produces sufficient flow. When access flow is too high, heart function might be jeopardized or dialysis access-induced steal syndrome (DASS) could result. If access flow is blocked by a stenosis or thrombosis, hemodialysis can be compromised. Surgical treatment options to correct or salvage a problematic access include one or more of the following[1]:

1) High Flow Accesses: access flow reduction
    a) Banding or vein tapering at inflow
    b) Distalization of anastomosis (RUDI) with revision to proximal radial artery (PRA or other distal branch artery)
2) Normal/Low Flow Access: restoration of extremity blood flow
    a) Proximalization of anastomosis (PAI)
    b) Distal Revascularization/Interval Ligation (DRIL)

When any of these surgical options is selected, intraoperative flow measurements prove invaluable during the revision procedure. Flow measurements provide quantitative data to assist in making surgical decisions during a procedure and in documenting flow changes for the patient record. This section presents the use of flow measurements during these corrective AV access procedures.

IVb. Flow-based AV Access Surgical Revision cont.

A. High Access Flow

1. Cardiac Overload

The unique hemodynamics produced by AV fistula creation may cause AV fistulas to mature to more than 2 L/min. Prolonged high access flow rates can over stress the heart and lead to cardiomegaly or congestive heart failure. When AV access flows exceed 2 L/min, Flow-QC® Cardiac Output measurements coupled with Central Hemodynamic Profiling inform whether the heart is being overworked (pages 44-48).

When cardiac overload occurs, a traditional approach has been to band the fistula to increase resistance and reduce cardiac overload. When this surgical strategy is chosen to reduce fistula flow, intraoperative flow measurements help guide the procedure and confirm that "banding" has reduced flow to an acceptable level. Flow measurements essentially take the "guesswork" out of fistula banding. [2-3]

2. Dialysis Access-Induced Steal Syndrome (DASS)[4]

Ischemic steal syndrome (ISS) following hemodialysis access creation is a devastating complication that can occur when an AV access that shunts arterial inflow into the low-pressure venous circulation effectively "steals" arterial flow from perfusing the lower arm and hand. Referred to by van Hoek as Hemodialysis Access-Induced Distal Ischemia (HAIDI)[6], some level of "steal' is an almost universal "physiologic" result of vascular access creation, but it is usually asymptomatic. However, clinically significant DASS or HAIDI, develops in 1.6 - 8 percent of primarily diabetic patients, whose inherent compensatory mechanisms for collateral circulation and vasodilatation cannot meet metabolic demands.

ISS treatment challenges the clinician to walk the fine line between relieving the distal ischemia while maintaining a functional access. Traditional approaches have included banding or lengthening the fistula to increase fistula resistance, without allowing the resulting decrease in blood flow to lead to access stenosis or thrombosis.

Both cardiac overload and/or DASS or HAIDI create the need to increase venous outflow resistance in the vascular access that must deliver hemodialysis.

3. Flow-Guided Fistula Banding

One strategy to relieve cardiac overload or DASS is to band an AV fistula to increase flow resistance. This subsequently reduces AV fistula flow and increases flow to the distal extremities. Three techniques use Transonic® intraoperative flow measurements to guide their banding procedure.

a. Continuous Intraoperative Flow Measurements to Guide Banding

Dr. M.R. Scheltinga of Máxima Medical Center, Veldhoven, the Netherlands, pioneered continuous intraoperative flow measurements during fistula banding to achieve a pre-set flow goal (see pages 86-87).[6-12] He begins with a pre-operative AV fistula flow level (determined by a Transonic Flow-QC® Hemodialysis Monitor in the dialysis clinic) and sets a percent decrease in AV fistula flow to be achieved by banding. As the band is tightened, AV fistula venous outflow is measured by an OptiMax® Flowprobe and Transonic Flowmeter (see page 88).

b. Flow-Guided Artegraft® Banding

Dr. Jose U. Zamora II, from the Balboa Transplant Institute in San Diego pioneered banding using an Artegraft® bovine carotid artery grafts with hemoclips (see pages 90-91).[13]

c. MILLER Banding

Dr. Gregg A. Miller, an interventional nephrologist with American Access Care, Brooklyn, NY, treats dialysis associated steal syndrome or high-flow access problems with his Minimally Invasive Limited Ligation Endoluminal-Assisted Revision (MILLER) banding procedure.[14] He uses the Endovascular HVT100 Flowmeter and ReoCath® Flow Catheter for pre-and post-measurements of flow that guide and document his procedure (see pages 74-75).
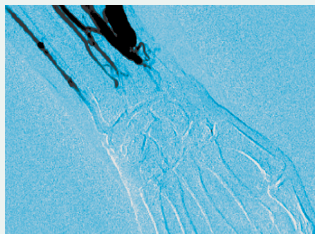
"During banding of AVGs, it is very difficult to reduce access flow without causing a thrombosis. Therefore, one must measure flow to quantify the reduction."
From presentation, "Banding (How I do it)," I. Davidson, MD,CIDA, 2011.

Flow-Guided AV Fistula Banding

*Banding protocol photo essay courtesy of M. R. Scheltinga, M.D.,
www.vascularprocedures.com/html/algemeen/home.php*

Step 1: An inability to see hand arteries in a pre-op angiography of a patient with a radiocephalic AVF indicates HAIDI.


Step 2: Tissue necrosis in the hand also indicates presense of HAIDI.

Flowprobe
Banding site

Step 3: Banding: Minimally invasive application of a Transonic volumetric Flowprobe guides the degree of tightening of a 5 mm Dacron band during this procedure.

Dacron Band
Sutures
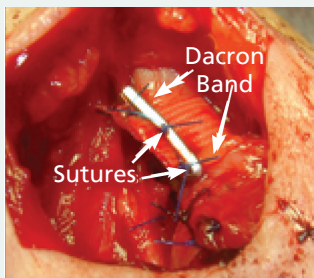
Step 4: A 5 mm Dacron band is fixed using a clip and stitches. In this patient, AVF thrill was maintained and radial arterial pulses returned.
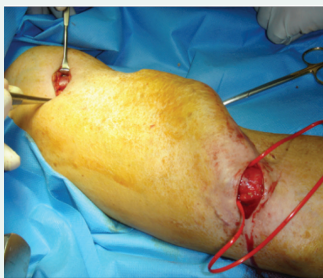
Step 5: Banding may also be performed for a high flow AV fistula (HFA) > 2L/min. This patient suffered from fatigue in the presence of a 3.7 L/min upper arm AVF.

Step 6: In high flow accesses, finger pressure measurement is also used to attain an optimal coupling of access flow with finger pressure (>50 mmHg) before the band is fixed.

Flow-Guided AV Fistula Banding cont

Banding protocol photo essay courtesy of M. R. Scheltinga, M.D., www.vascularprocedures.com/html/algemeen/home.php

INTRODUCTION

Banding of an AV fistula (AVF) may be indicated for hemodialysis access induced distal ischemia (HAIDI).

MEASUREMENT STEPS OVERVIEW FOR FISTULA BANDING OR INFLOW REDUCTION SURGERY

1) **Establish Flow Goal**
   Before surgery, set an AV access flow goal, considering the type and location of the access, the patient's size, weight, gender, medical and access flow histories.

2) **Measure Pre-Revision Flow**
   Measure flow through the AV access before the revision per selected protocol.

3) **Measure Post-Revision Flow. Compare Flows**
   Measure AV access venous outflow after revision. Compare and document the pre and post flows. Evaluate the flow measurement after repair or revision against the desired AV access flow target.

Flow Measurement Protocol

0. Pre-operative: Determine % fistula flow decrease to be achieved by banding.

↓

1. Expose AV fistula and its venous outflow (2 incisions).

↓

2. Expose venous outflow diameter and select Flowprobe size.

↓

3. Apply Flowprobe to venous outflow.

↓

4. Measure baseline flow. Calculate target flow (baseline flow times % decrease).
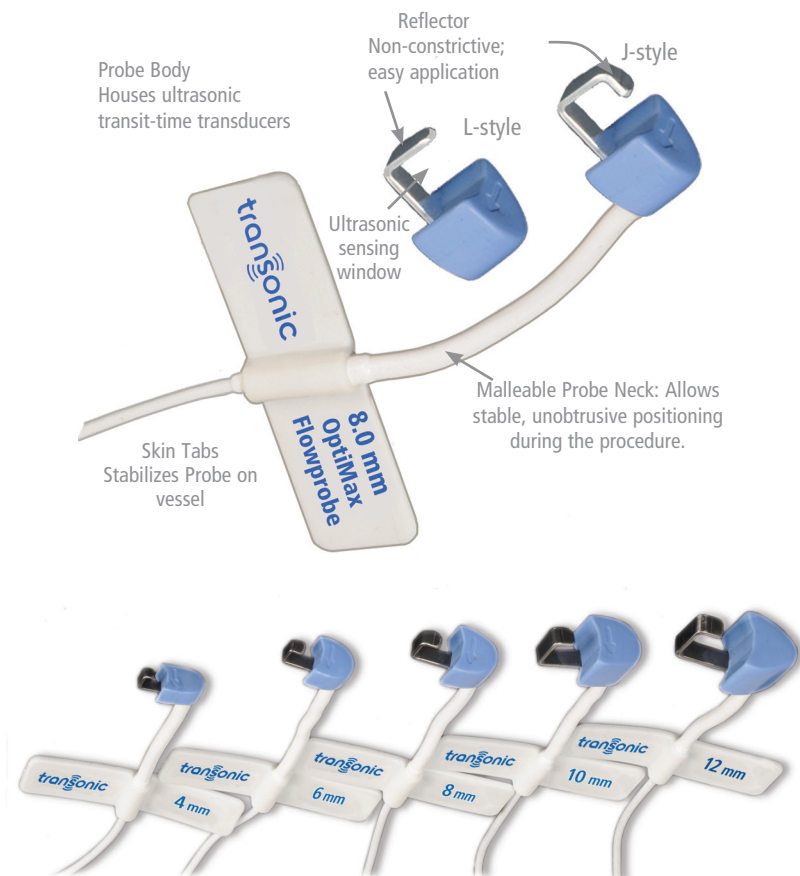
↓

5. Tighten band. Remeasure flow.

↓

6. Repeat step 5 until flow reaches intraoperative target flow.

IVb. Flow-based AV Access Surgical Revision cont.

OptiMax® Vascular Hands-Free Flowprobes

Reflector
Non-constrictive;
easy application

J-style

Probe Body
Houses ultrasonic
transit-time transducers

L-style

Ultrasonic
sensing
window

transonic

8.0 mm
OptiMax
Flowprobe

Malleable Probe Neck: Allows
stable, unobtrusive positioning
during the procedure.

Skin Tabs
Stabilizes Probe on
vessel

transonic 4 mm   *transonic* 6 mm   *transonic* 8 mm   *transonic* 10 mm   12 mm

OptiMax® Continuous Measurements Guide Fistula Banding
OptiMax Flowprobes allow continuous volumetric flow measurements
to guide vascular access construction, banding or revision procedures.
The Flowprobe can be easily slipped around a vessel and left there for
extended periods. It can then be quickly removed after the target flow is
reached and the procedure is completed.

IVb. Flow-based AV Access Surgical Revision cont.

AV Fistula Banding: Flow Measurement Steps

a. Preoperative
From preoperative surveillance in the hemodialysis clinic, determine % drop in flow to be achieved during banding surgery.

b. Identify Vessel to be Measured
Expose and identify the venous outflow of the AVF.

c. Select Flowprobe Size (FTV-Series)
Measure the vein's diameter. Select a Probe so that the vein will fill between 65% - 100% of the flowsensing window of the Probe (Fig. 4b.1).

PROBE SIZE	NONRESTRICTIVE VESSEL RANGE
4 mm	3.2 - 5.3 mm
6 mm	4.5 - 7.5 mm
8 mm	6.0 - 9.5 mm
10 mm	7.5 - 12.0 mm
12 mm	9.0 - 14.0 mm

d. Measure Venous Outflow
a) Confirm that the outflow site is wide enough to accommodate the Probe's acoustic reflector.
b) Apply sterile gel inside the Flowprobe's sensing window to ensure good ultrasound coupling.
c) Apply the Flowprobe to the vein, bending the Probe's flexible neck so that the entire vein lies within the sensing window of the Probe.
d) Check the Signal Quality Indicator on the AureFlo® display or Flowmeter's front panel to verify good acoustic contact.
e) Listen to the pitch of FlowSound®. The higher the pitch, the greater the flow.

e. Document Flows

After applying a Flowprobe to a vein, wait ~ 10-15 seconds for mean readings to stabilize before capturing a snapshot on the AureFlo® display or printing the flow waveform on the Flowmeter. If flow is negative, press the [INVERT] button to change the polarity before printing the waveform.

Press the [PRINT] button on the Flowmeter to document the venous flow patterns for the case record.
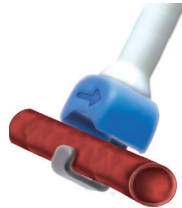
IVb. Flow-based AV Access Surgical Revision cont.

Flow-Guided Artegraft® Banding[13]
Zamora JU II, MD, Balboa Transplant Institute, San Diego, CA

INTRODUCTION

Clinically significant steal syndrome is a potentially devastating complication of an arteriovenous (AV) fistula or graft and is often characterized by negative (reversed) flow in the distal artery. The challenge for the surgeon is to relieve the distal ischemia, but maintain a functional AV access with sufficient flow to deliver dialysis. One strategy is to band the access to increase flow resistance, thereby reducing access flow and increasing distal arterial flow.

Traditional banding methods modify the arterial or venous ends of a graft. This can compromise both the efficacy of hemodialysis and/or the life of the AV access. The Zamora Method™ is a novel banding procedure that uses hemoclips on collagen AV Artegrafts® and intraoperative flow measurements with Transonic perivascular Flowprobes to guide the banding procedure. One advantage of the Zamora banding procedure is that the hemoclips can be adjusted and/or removed during angioplasty. Traditional banding methods do not allow modification or reversal without surgical intervention.

METHOD

Pre-operative AV access flow is measured during dialysis with a Transonic Hemodialysis Monitor. The surgeon then determines the percent decrease in access flow to be achieved by the banding procedure. Medium hemoclips are then placed on the midsegment of an Artegraft®.

Upper arm site marked for Artegraft

Artegraft flow is decreased by the depth of the hemoclip position on the graft and the distance between the clips. The clips are generally placed 10 mm apart (range: 8 - 20 mm) depending on the "length" of band desired. The angle of placement varies from 30 to 90 degrees varying the "depth" into the graft needed. A medium hemoclip placed at 90 degrees occludes to a 3.5 - 3.7 mm opening. As the clips are applied, Artegraft flow is measured at the venous end of the graft with a 6 mm Transonic® Flowprobe.

A 3 or 4 mm Flowprobe measures distal arterial flow.

IVb. Flow-based AV Access Surgical Revision cont.

Flow-Guided Artegraft Banding cont

RESULTS

This method was utilized in over 250 patients over the past eight years with excellent results in both graft patency and correction of Steal Syndrome. The method maintains **both** a "maximal" inflow and outflow of the Artegraft® at the time of hemodialysis. Optimally, the arterial (inflow) needle is placed on the arterial ½ of the graft, and the venous (outflow) needle is placed on the venous ½ of the graft. During dialysis, the flows both into and out of the dialysis machine are maximized. Clips (banding) can be "reversed/removed" with an angioplasty balloon at the time of the first graft thrombectomy, if necessary. Often in older, diabetic patients with peripheral artery disease, banding reversal will not be tolerated. Steal syndrome returns, and a more permanent banding method can still be utilized to maintain optimal, long-term, lower Artegraft® flow.

CONCLUSIONS

Transonic Flowprobes provide on-the-spot measurements of volume flow within an Artegraft as the graft is banded to treat steal syndrome.

Reference: Zamora JU II, "A Novel, Adjustable and Reversible Banding Procedure for Artegraft," 13th Biennial VASA Dialysis Access Symposium, May 9-11 2012, Orlando, FL

Hemoclips are applied to the Artegraft mid-segment.

Artegraft outflow is measured with a 6 mm Flowprobe as the hemoclips are applied.

Artegraft inflow and outflow marked for hemodialysis needle cannulation.

Artegraft® is a bovine carotid artery graft processed into a biological fibrous matrix to enhance long-term patency and to provide a flexible and compliant tightly woven conduit for hemodialysis cannulation.
www.artegraft.com

4. Alternative Strategies for DASS Relief

a. Inflow Reduction

Banding of a fistula, however, can at times be counter-productive. Although fistula flow is reduced and less stress is placed on the heart, the reduction in blood flow within the access might accelerate stenosis and subsequent thrombosis. Recognition of this danger has led to the use of alternative methods to reduce flow through an high access bypass.

Distal Revascularization-Interval Ligation (DRIL) has become an accepted alternative strategy for managing DASS. DRIL eliminates a potential pathway for steal syndrome by ligating the artery distal to the origin of the AV fistula, and revascularizes the extremity through creation of a bypass (saphenous vein, bovine or PTFE graft) from above the AV fistula to below the AV fistula (Fig. 4b.2).[15-35] However, because the DRIL technique calls for ligating the artery, it is not universally accepted.

In 2004, Wayne Gradman and colleagues from Los Angeles' Cedars Sinai Medical Center reported on the mathematical models and intraoperative flow measurements they used to investigate several options for mitigating ischemic steal syndrome. He and others have proposed alternative procedures for alleviating ischemic steal syndrome.[26-29]

Fig. 4b.2: DRIL includes distal artery ligation and bypass construction to an extremity.

b. Revision Using Distal Inflow (RUDI)[28-29]

Introduced in 2005 by David J. Minion and colleagues at the University of Kentucky the RUDI technique calls for ligation of the fistula at a location slightly proximal to its origin and then re-established via a bypass from a more distal arterial source to the venous limb of the fistula.

c. Proximalization of Arterial Inflow (PAI)[30-33]

This procedure converts the arterial supply of the arteriovenous access to a more proximal artery with higher capacity by using a small-caliber polytetrafluoroethylene graft as a feeder.
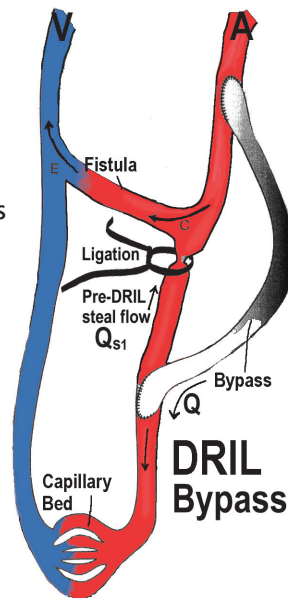
IVb. Flow-based AV Access Surgical Revision cont.

"Flow reduction using intraoperative access flow monitoring is an effective and durable technique allowing for the correction of distal ischemia and cardiac insufficiency in patients with a high-flow autogenous access."[34]

FLOW MEASUREMENT STEPS FOR INFLOW REDUCTION TO RELIEVE DASS

1) **Expose Arterial Segment for Pre-Bypass Flow**
   Expose arterial inflow segment distal to the fistula origin. Select an optimum site (wide enough to accommodate the Probe's acoustic reflector) for applying the Probe, and clean the site of fat and excess tissue.

2) **Select Flowprobe Sizes**
   Estimate the diameter of vessel with a gauge. Select a Probe size so that the vessel diameter will fill 75 - 100% of the sensing window.

SITE	PROBE SIZE	NONRESTRICTIVE VESSEL RANGE
Radial Artery	2 mm	1.5 - 2.7 mm
	3 mm	2.4 - 3.7 mm

3) **Apply Flowprobe and Measure Flow**
   - Apply sterile Aquasonic Gel 100 to the Flowprobe to provide ultrasound coupling between the Probe body and Probe reflector.
   - Apply the Flowprobe to the site bending the Probe's flexible neck segment, as necessary, so that the entire vessel lies within the Flowprobe window and aligns with the Probe body.
   - Listen to the pitch of FlowSound® as the Flowprobe is applied to the vessel. The higher the pitch, the greater the flow. Note if flow is traveling antegrade or retrograde. Retrograde flow indicates the presense of DASS.
   - Check the Signal Quality Indicator on the Flowmeter's front panel or on the AureFlo® display to ensure good acoustic contact.

4) **Construct the Bypass**

5) **Measure and Evaluate Bypass Flow**

"Accurate flow measurements can be of great assistance during vascular reconstructive surgery. The primary aim with these intraoperative measurements is to obtain information on the immediate result of the reconstruction, where a technical failure may jeopardize an otherwise successful operation."[37]

IVb. Flow-based AV Access Surgical Revision cont.

5. Inflow Reduction Case Reports

ISS on a High Inflow Brachiocephalic Fistula: Management by Inflow Reduction Using a Bovine Bypass Graft from the Radial Artery[35-36]

Study courtesy of Eric S. Chemla, MD, consultant surgeon and honorary senior lecturer, Renal Transplant and Vascular Surgery, St. George's Healthcare NHS Trust, London, UK

INTRODUCTION
A female patient with a mature brachio-cephalic fistula presented with ischemic steal syndrome (ISS) as she awaited a second nephrectomy. The fistula had not been cannulated. Surgery was undertaken to alleviate ISS symptoms before the nephrectomy.

BASELINE FLOW MEASUREMENT
Fistula (cephalic vein) flow was measured with a Transonic® Perivascular Flowprobe. Flow measured 1600 ml/min - 1700 ml/min confirming a mature fistula.

FISTULA ANASTOMOSIS LIGATION
The anastomosis was ligated and the brachial artery repaired.

BYPASS GRAFT CONSTRUCTION
A bovine graft was constructed between the radial artery and the cephalic vein.

POST-BYPASS FLOW MEASUREMENTS
Cephalic vein flow after revascularization dropped to 600 ml/min. Bypass flow also measured approximately 600 ml/min.

Fistula flow is measured pre-revision.

After construction of a radial artery-cephalic vein graft, flow was remeasured.

CONCLUSION: After surgery, steal symptoms immediately began to improve as the brachial artery resumed full delivery of flow to the distal arm and hand circulation.

Flow Summary		
Conduit	Baseline	Post-revascularization
Cephalic Vein	1600 - 1700 ml/min	~ 600 ml/min
Bypass graft		~ 600 ml/min

Cephalic vein flow drop from 1600-1700 ml/min to 600 ml/min following inflow reduction surgery.

IVb. Flow-based AV Access Surgical Revision cont.

Inflow Reduction to Resolve High Cardiac Output[38]

Study courtesy of Eric S. Chemla, MD, consultant surgeon and honorary senior lecturer, Renal Transplant and Vascular Surgery, St. George's Healthcare NHS Trust, London, UK

INTRODUCTION

A 2007 study reported a novel inflow reduction through anastomotic distalization method was used to reduce inflow in the vascular access to treat high cardiac output in 17 hemodialysis patients (10 men, 7 women).

STUDY

Fifteen patients with brachialcephalic fisutlas and two with brachioaxillary bypass grafts presented with symptoms of heart failure. Their fistula inflow rates were > 1600 ml/min.

METHOD

The access inflow reduction procedure described in the study called for the fistula anastomosis to be exposed, dissected and tied off. The brachial artery was then reconstructed with either an end-to-end anastomosis or a patch. The radial artery was dissected at the wrist and a 6 mm expanded polytetrafluoroethylene (ePTFE) graft was implanted between the radial artery and the cephalic vein. Bypass outflow was then measured with an intraoperative Flowprobe.

ePTFE Bypass graft

Radial artery

Following construction of a bypass graft from the radial artery to the cephalic vein, outflow is measured.

RESULTS

Anastomotic distalization decreased access mean flow significantly and a resultant decrease in cardiac output and resolution of cardiac overload symptoms in all patients.

Inflow Reduction (n = 17)	Mean Flow (ml/min)	Cardiac Output (L/min)
Pre-surgery	3135 ± 692	8 ± 3.1
Post-surgery	1025 ± 551	5.6 ± 1.7

Mean pre- and post-inflow reduction surgery blood flows and cardiac outputs in 17 patients that presented with symptoms of cardiac overload.

B. Low Access Flow

If an access fails or a patient develops acute upper arm or extremity ischemia, the patient may have to use a catheter for long-term dialysis or the vascular surgeon must surgically correct the problem by either:
- rescuing the access or
- establishing another access.

During these corrective surgical proceduress, intraoperative flow measurements help guide the revision to a successful outcome.

When the more common arm AV access sites are exhausted, a vascular surgeon may turn to creative complex bypasses in order to establish a viable AV access for administration of hemodialysis.[37] Examples of complex expanded polytetrafluoroethylene (ePTFE) bypass grafts reported in the literature include:
- a necklace bypass (axillary artery to contralateral axillary vein);
- contralateral internal jugular vein (brachial artery to the internal jugular vein);
- femorofemoral crossover or "Bikini Bypass" (femoral artery to contralateral femoral vein);
- axillary artery to popliteal vein (axillary artery to superficial femoro-popliteal vein);
- femoral artery to right atrium.

When the ESRD patient returns to the dialysis unit for hemodialysis, ongoing quantitative surveillance of a revised access can then be resumed with ultrasound dilution monitoring of graft inflow rate, recirculation, access flow and cardiac output described in Chapters IIa and IIb of the handbook.

The following two case reports demonstrate creative surgical solutions and the use of intraoperative flow measurements when a surgeon has sought to create a viable access for his patient.

"Arterial insufficiency following the placement of a standard fistula does not preclude successful vascular access in the same extremity. Confirmation of adequate flow with intraoperative flow measurements allows safe placement of successful vascular access in these high-risk patients."[37]

1. Low Flow Access Case Reports

Brachiocephalic Fistula with Cephalic Arch Stenosis[38]

Case report courtesy of Eric S. Chemla, MD

INTRODUCTION

A 58-year-old male patient, on dialysis for 25 years, had had three transplants that had failed and was deemed unsuitable for another transplant. Attempts at peritoneal dialysis (PD) ended in peritonitis. He was being dialyzed through a precious 12-year-old right brachiocephalic arteriovenous fistula (AVF), but his access flow measurements continued to decline. A fistulogram showed a right cephalic arch stenosis which was dilated three times. Dilations intevals were shortening.

Clinically, the fistula was pulsatile with no thrill or bruit. Dialysis was painful and inefficient with very high venous pressures, low pump speed and poor inflow (200-250 ml/min). It was decided to correct the problem surgically through creation of a new arch, by ligating the cephalic vein just proximal to the stenosis, mobilizing it and swinging it over to anastomose with the axillary vein.
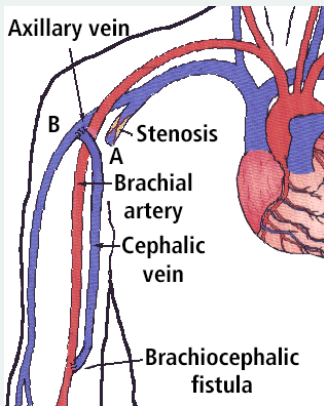
Cephalic vein is ligated (a). The stenosis is then mobilized & anastomosed to the axillary vein (b).

PROCEDURE

The fistula was dissected in the delto-pectoral groove and the axillary vein just below the pectoralis minor. Before reconstruction of the fistula, outflow on the cephalic vein measured 36 ml/min (range:18-114 ml/min). The fistula was clamped, as was the axillary vein which was opened. The distal part of the fistula was then tied off, and the vein was cut and trimmed to obtain a nice surface for an anastomosis. The vein was then mobilized and anastomosed, end to side, to the axillary vein. The diameters of the cephalic and axillary veins were 7 mm. The length of the anastomosis was 20 mm.

RESULTS

Post-procedure fistula flow measured 600 ml/min (range 359-1004 ml/min). Clinically, a thrill and a bruit were present and dialysis could be resumed through the fistula. Fistula flow increased significantly.

Fistula Outflow Summary			
Conduit	Size	Pre-correction	Post-correction
Cephalic vein	7 mm	36 ml/min	
Axillary vein	7 mm		600 ml/min

Fistula outflow improved from 36 ml/min to 600 ml/min as a result of anastomosing the cephalic vein to axillary vein.

Surgical Creation of a Left Axillary Vein to Right Internal Jugular Jump Graft Rescues Brachiocephalic Obstruction[36]

*Case report courtesy of Eric S. Chemla, MD*

A 55-year-old obese female patient with high blood pressure had been on dialysis for the 10 years. She was ineligible for transplant. Four previous accesses were functional at first, but had stenosed. For the previous 18 months, the patient has been dialyzed through a critically important left brachio-axillary bypass graft.

The patient came to the clinic with a very painful swollen arm and breast. A fistulogram revealed a complete left brachio-cephalic (central) obstruction. With no endo-vascular options remaining, the surgeons decided to rescue the graft surgically.

A venogram showed that the central veins on the right side all appeared patent, so the surgeons decided to perform a jump graft from the left axillary vein to the right internal jugular vein (IJV) with an 8 mm-60cm PTFE graft.

Flow was measured in the right internal jugular vein before and after completion of the bypass.

The surgeons were satisfied with the result and closed the wounds. Immediately post op, the swelling of both the arm and the breast diminished and dialysis was resumed through the new graft.
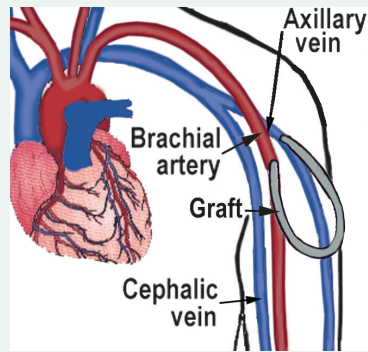
Left brachio-axillary bypass graft.
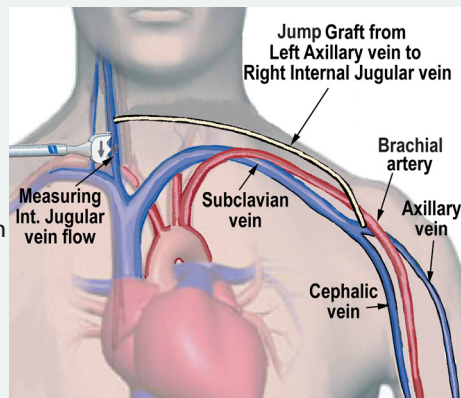
An 8 mm-60cm PTFE jump graft was created from the left axillary vein to the right internal jugular vein after a venogram revealed patent central veins on the right side.

Intraoperative Flow Summary		
Conduit	Pre-graft Construction	Post-graft Construction
Internal jugular vein	8 ml/min	600 ml/min

Internal jugular vein flow increased to 600 ml/min after creation of the jump graft.

C. Conclusion

A myriad of problems can result from the unique hemodynamics of an arteriovenous vascular access. In order to maintain a functioning access for hemodialysis delivery, these problems must be addressed. Treatment options depend on many factors and include the severity of symptoms, the type, site and expected life of the access along with the co-morbidities of the patient.

While PTA balloon angioplasty is an appropriate intervention for an arterial stenosis, a number of corrective surgical procedures can be used to improve access flow. These include access ligation, banding or vein tapering at inflow to limit access flow, distal revascularization with interval ligation (DRIL), revision using distal inflow (RUDI) and proximalization of arterial inflow (PAI).

Surgeons familiar with the various treatment options must judiciously select the best option for their patient. Whatever remedial surgical option is chosen, measurement of intraoperative flow is an invaluable tool in taking the guesswork out of the procedure and helping to achieve the pre-determined flow target.

To measure flow is to know flow! To know flow is to add another quantitative dimension to the surgeon's armamentarium that either clarifies and supports or challenges the clinical impression which, ultimately, ensures the best surgical outcome for the patient.

IVb. Flow-based AV Access Surgical Revision cont.

D. AV Access Surgical Revision References

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