Vascular Access Monitoring

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Vascular Access Monitoring

- 1. Why is it important?; the human and financial cost of access thrombosis.
- 2. What are current recommendations?; the 2001 K/DOQI Guidelines.
- 3. How are we doing?; Implementation of guidelines.
- 4. What are the techniques and technologies available?; Benefits and limitations.
- 5. What are barriers to implementing guidelines?; Reimbursement and system issues.

Vascular Access Monitoring

- 1. Why is it important?; the human and financial cost of access thrombosis.
- 2. What are current recommendations?; the 2001 K/DOQI Guidelines.
- 3. What data supports monitoring and intervening?
- 4. Are newer methods superior?

Why might this be important?

- Access related admissions are 17-25% of all hospitalizations for hemodialysis patients
  - early detection of access stenosis can allow elective outpatient intervention.
- Vascular access costs more than $8000 per patient-year at risk, representing approximately 15% of total Medicare expenditures for ESRD patients annually
  - prior to 1989!
- ....more recent data suggests that access-related morbidity accounts for at least 25% of all hospital stays and in the first year of dialysis may constitute up to 50% of all patient care costs (Feldman 1996).

Impact of vascular access blood flow monitoring (VABFM) program on patient care indexes and cost

Patients & events	No monitoring	VABFM
Patients	72	59
Grafts	78	62
Thromboses/patient/year	0.71	0.16*
Missed treatment/patient-year	0.98	0.26*
New access + revisions/patient-year	0.20	0.14
Declots/patient-year	0.51	0.05*
Hospital days/patient-year	1.8	0.4*
Angioplasties/patient-year	0.09	0.54*
Adjusted yearly costs	$307,966	$158,532

*Significantly improved clinical outcome.

McCarley PB, Wingard RL, Shyr Y, Pettus W, Ikizler TA: Monthly vascular access blood flow monitoring (VABFM) reduces A-V graft thrombosis rate and associated costs [abstract]. J Am Soc Nephrol 10:211A, 1999

Adjusted yearly charges for thrombosis-related access care for patients with grafts and fistulas

	Grafts			Fistulae		
	I	II	III	I	II	III
Hospitalization	$87,275	$82,000	$20,400	$21,820	$16,000	$3,600
Missed treatments	9,600	9,000	2,650	2,400	1,800	480
Catheters	10,650	6,750	2,700	4,090	1,500	0
New access/revisions	62,170	101,312	38,000	41,450	50,656	15,200
Thrombectomy	125,450	95,000	12,000	0	0	0
Angioplasty	13,100	51,000	82,800	0	9,000	21,600
Adjusted yearly cost	$308,245	$345,062	$158,550	$69,760	$78,956	$40,880

I – no monthly monitoring
II – monthly dynamic venous pressure monitoring
III – access flow monitoring with Transonic device

McCarley, KI 2001

Cost / Benefit

- Cost of one access flow measurement $20-$30, the annual cost of the surveillance program on 59 patients would be from $14,160 to $21,240. Adding this cost to $158,532, the annual cost of the vascular access program is still less than 60% of the cost without monitoring, $307,966. Currently the cost of monitoring can be [partially] compensated to hemodialysis units by a decrease in missed patient treatments (approximately $10,000) with no reimbursement to health care providers.
  - From Krivitski (of Transonic).
- He is discussing AVG, and doesn't make same calculations for AVF, although data to do so was in same paper.
- 43 AVF x 360$/year = $15,480
- Still a cost savings: $69,760/year vs. $40,880 + $15,480 = $56,360.

2001 K/DOQI Guidelines- summarized; #10 AV grafts, #11 AV fistulae, and #12 Recirculation.

- Examine each AV graft or fistula.
- Collect, and have available to all staff, data on clinical parameters and adequacy.
- Monitor access flow monthly

Am J Kidney Dis Vol 37, No 1, Suppl 1 (January), 2001: pp S150-S156.

2001 K/DOQI Guidelines- summarized; #10 AV grafts, #11 AV fistulae, and #12 Recirculation.

Surveillance techniques for AV grafts:

- Preferred:
  - intra-access flow (E) *
  - Static venous dialysis pressure (E) *
- Acceptable:
  - Dynamic venous pressures (E) *

Surveillance techniques for AV fistulae:

- Direct flow measurement preferred
- Dynamic or Static venous pressure measurements are not as accurate in AVF as in AVG.

* per protocol defined in guidelines

Am J Kidney Dis Vol 37, No 1, Suppl 1 (January), 2001: pp S150-S156.

2001 K/DOQI Guidelines- summarized; #10 AV grafts, #11 AV fistulae, and #12 Recirculation.

Surveillance techniques, continued:

- Other studies:
  - Recirculation using [urea]
  - Recirculation using dilution techniques (non-urea)
  - Unexplained decreases in URR or Kt/V
  - Physical findings – persistent arm swelling, graft clotting, prolonged bleeding, altered pulse or thrill
  - Elevated negative arterial pressures; inability to obtain goal blood flow.
  - Doppler ultrasound

Am J Kidney Dis Vol 37, No 1, Suppl 1 (January), 2001: pp S150-S156.

2001 K/DOQI Guidelines- summarized; #10 AV grafts, #11 AV fistulae, and #12 Recirculation.

- Diagnostic Testing for AVG:
  - Trend of decreasing access flow is more significant than any single measurement of access flow.
  - Re-assessment after intervention; Qa should increase by at least 20%; otherwise reflects failure of intervention
  - Doppler flow, ultrasound dilution, magnetic resonance are best studied methods of measuring access flow:
    - Doppler – significant inter-observer variability
    - Magnetic resonance – accurate but expensive
    - Both difficult to perform during dialysis
  - Venous pressure monitoring is least expensive method; both static and dynamic venous dialysis pressures have acceptable sensitivity and specificity
  - Increases in urea recirculation is predictive, but is a relatively late predictor of access dysfunction

2001 K/DOQI Guidelines- summarized; #10 AV grafts, #11 AV fistulae, and #12 Recirculation.

- Diagnostic Testing for AVF:
  - Direct flow measurement preferred
  - Static and dynamic pressures not as accurate. Because stenoses can occur more centrally, collateral veins can develop preventing marked increased pressures. (E)
  - Recirculation is more useful in AVF than AVG, because flow can be less than blood pump speeds while remaining patent. (O)
  - Because pressure measurement and recirculation may be late indicators, Doppler u/s may be useful despite cost (O).

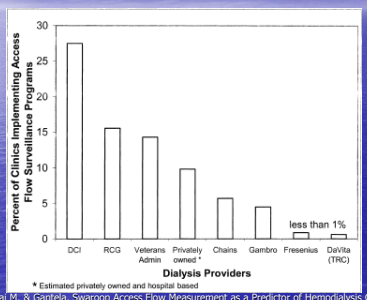
(E) Evidence (O) Opinion

2001 K/DOQI Guidelines- summarized; #10 AV grafts, #11 AV fistulae, and #12 Recirculation.

- Recirculation
  - Should be measured with nonurea-based dilutional method, or two-needle urea method
  - Should not use three-needle peripheral vein method (E)
  - Values > 5% (non-urea) or > 10% (urea-based) require evaluation, but if access recirculation > 20%, confirm needle placement before sending patient for access studies.

(E) Evidence (O) Opinion

Implementation of Access Flow Testing



Krivitski, Nikolai M. & Gantela, Swaroop Access Flow Measurement as a Predictor of Hemodialysis Graft Thrombosis: Making Clinical Decisions. Seminars in Dialysis May 2001. 14 (3), 181-185.

What is natural history of AVF, without intervention? (Do we need to monitor access flow?)

- 52 randomly selected adult Caucasian prevalent hemodialysis patients, with radiocephalic wrist AVFs.
- Prospective, observational study to follow the natural history of their AVFs for 4 years.
- No surgical or interventional radiological procedures until access failure (AVF thrombosis or a vascular access not assuring a single-pool Kt/V > or =1.2).
- Annual assessments of vascular access blood flow rate by saline ultrasound dilution method.

Nephrol Dial Transplant. 2004 May;19(5):1231-6. Basile C, et al.

Natural History Study –Patient Characteristics:

Age (years) 66.6±11.5
Dialysis vintage (months) 53.1±56.6
Females (%) 42.3
Comorbid conditions (%)
- Atherosclerotic vascular disease 49.8
- Diabetes mellitus 11.5
- Arrythmia 2.6
- Arterial hypertension 76.3
- Congestive heart failure 6.7

RC wrist AVFs 100%
Blood flow rate (ml/min) 1056.9±776.9
Time interval between AVF placement and start of the study (months) 64.5±53.4
Time interval between AVF placement and first venipuncture (months) 4.4±1.2
Prior number of AVF failures/patient 0.4±0.6

What is natural history, without intervention? (cont.)

- RESULTS:
  - –21 patients with initial blood flow < 700 ml/min; 7 thrombosed, 7 died, 2 transplanted.
  - –31 patients with initial blood flow > 700 ml/min; 2 thrombosed, 7 died, 3 transplanted.

What is natural history, without intervention? (cont.)

- RESULTS:
  - All failures (9) were due to AVF thrombosis; none due to an inadequacy. Rate of 0.043 AVF thrombosis per patient-year at risk.
  - The value of vascular access blood flow rate, identified as a predictor of AVF failure, was <700 ml/min with an 88.9% sensitivity and 68.6% specificity.
  - Two of nine thromboses occurred among AVFs with baseline blood flow rates >700 ml/min (n = 31),
  - Five AVFs remained patent throughout the study with a blood flow rate consistently < or =500 ml/min.
  - 24 AVFs that remained patent at the end of the 4 years maintained a median blood flow rate > or =900 ml/min at all time points studied.
- COMMENTS:
  - Study authors questioned need for frequent monitoring, while acknowledging they had a prevalent, non-diabetic population with optimal access.

VABF measurement technique

- Access flow by ultrasound velocity dilution technique:
- Two ultrasonic sensors are attached to the lines of the hemodialysis tubing, one to the arterial and another to the venous line, approximately two to six inches distant from the connection of tubing to dialysis needles.
- Initially, blood recirculation is checked in the vascular access while the blood lines are in the normal position.
- Blood lines are reversed and ultrafiltration is turned off.
- The blood pump flow is set at 300 mL/min.
- A bolus of saline (approximately 10 mL) is released into the venous line, diluting the flow of blood in the access and resulting in changes of sound velocity, which is measured by the transducers on the lines.
- This change is calculated by the Transonic® software, giving the VABF in mL/min.

Int J Artif Organs. 2003 Dec;26(12):1056-63. Comparison of different techniques of hemodialysis vascular access flow evaluation. Lopot F, Nejedly B, Sulkova S, Blaha J.

- Measurement of vascular access flow (QVA) has been suggested as a method of choice for vascular access quality (VAQ) monitoring. Besides traditional duplex Doppler, a number of bedside methods based mostly on the Krivitski principle of QVA evaluation from recirculation at reversed needles (RX), have been developed.
- 1). ultrasonic dilution (UD), taken as a reference, HD01, Transonic Systems;
- 2). duplex Doppler (DD);
- 3). thermodilution (TD), BTM, Fresenius;
- 4). optodilutional RX measurement (ORX), Critline III, R-mode, HemaMetrics;
- 5). direct optodilutional QVA evaluation from jumpwise changes in ultrafiltration rate at both normal and reversed needles connection (OABF), Critline III, ABF-mode;
- 6). direct transcutaneous optodilutional QVA evaluation (TQA), Critline III TQA.

J Nephrol. 2003 Nov-Dec; 16(6):908-13. A comparison of methods for the measurement of hemodialysis access recirculation. Basile C, Ruggieri G, Vernaglione L, Montanaro A, Giordano R.
NEED to see article again..

- A non-urea based method has been developed (ultrasound dilution Transonics Hemodialysis Monitor--USM) which is considered the gold standard together with the two needle revised slow-stop-flow BUN recirculation method (S/SF). Furthermore, some other indicator dilution techniques, utilizing the dilution of serum potassium (K), glucose, hematocrit (Hct) and hemoglobin (Hb) have been recently described.
- METHODS: compare some of these tests with the gold standards (the USM and the revised S/SF methods). One hundred-five adult HD patients, all with radiocephalic wrist AVF.
- Studies included the assessment of AR by means of:
  - A. non-urea based methods: 1. at the start of HD a blood sample was obtained from the arterial needle at the time of needle insertion for the measurement of serum K, Hb and Hct (respectively K1, Hb1 and Hct1). The blood circuit was connected and the pumping of blood was started at 200 mL/min. After 18 seconds, blood samples were drawn from the arterial line sampling port (K2, Hb2, Hct2). At this time, if AR is present, part of the saline entering the blood stream will dilute K2, Hb2, Hct2. AR (%) is =100 x (1 - Hb2/Hb1) in the case of

Need this reference!

- Contrib Nephrol. 2004;142:350-62. Systemic barriers to vascular access care: implications for clinical outcomes. Sands JJ, Montis AL, Etheredge GD. Fresenius Medical Care NA, Celebration, Fla., USA. Jeffrey.Sands@fmc-na.com
- Contrib Nephrol. 2004;142:269-84. Arteriovenous vascular access flow measurement: accuracy and clinical implications. Krivitski N, Schneditz D. Transonic Systems, Inc., Ithaca, N.Y., USA. nikolai.krivitski@transonic.com
- Contrib Nephrol. 2004;142:254-68. Vascular access recirculation: measurement and clinical implications. Schneditz D, Krivitski N.
- Contrib Nephrol. 2004;142:238-53. Hemodynamics of the hemodialysis access: implications for clinical management. Paulson WD, Jones SA. Interventional Nephrology Section, Division of Nephrology and Hypertension, Department of Medicine, Louisiana State University Health Sciences Center, Shreveport, La., USA. wpauls@lsuhsc.edu
- Contrib Nephrol. 2004;142:228-37. Hematocrit-based measurements of vascular access flow rate. Bell DA, Zhang S. HemaMetrics, Kaysville, Utah, USA. dbell@hemametrics.com
- Contrib Nephrol. 2004;142:216-27. Monitoring techniques of vascular access. Segal JH, Weitzel WF. Department of Internal Medicine, University of Michigan Health System, Ann Arbor, Mich., USA.

Semin Dial. 2003 Nov-Dec;16(6):498-501. Effect of time on sensitivity and specificity of access flow in predicting thrombosis. Weitzel WF, Segal JH, Leavey SF, Saran R, Swartz RD, Messana JM. Department of Internal Medicine, Division of Nephrology, University of Michigan, Ann Arbor, Michigan, USA. weitzel@umich.edu

Is elective intervention beneficial? (Yes)

Patients with total of 56 fistulas and 97 PTFE grafts were followed from placement to see if elective intervention prolonged access survival. The mean follow-up was 772 days (minimum 14 days, maximum 2755 days.

	access life (days)	recurrent clots per patient-year	interventions per patient-year
Initial elective intervention			
PTFE	1023	1.1	1.8
AVF	999	0.5	1.2
intervention after initial thrombosis			
PTFE	689	3.6	3.7
AVF	358	4.8	5.3

Clin Nephrol. 1995 Nov;44(5):329-33. Prolongation of hemodialysis access survival with elective revision. Sands JJ, Miranda CL. Renal Consultants of Wyoming Valley, P.C., Wilkes-Barre, Pennsylvania, USA.

RCT – Monthly monitoring with Access Flow and with Static Venous Pressure, vs no Monthly Monitoring.

- 103 patients (68 AVF, 35 PTFE grafts; mean follow-up 197 days)
- Patients with access flow <750 cc/min or with static venous pressure > or =0.5 were electively referred for angiography and angioplasty of stenotic lesions > or =50%.
- Access thrombosis 9.7% vs 22% 6/62 and 9/41
- AVF thrombosis 2.4% vs 15.4% 2/42 and 4/26
  - Monthly monitoring vs. standard care
- Measurement of access flow tended to result in lower thrombosis rates than measurement of static venous pressure.

ASAIO J. 1999 May-Jun;45(3):147-50. Intervention based on monthly monitoring decreases hemodialysis access thrombosis. Sands JJ, Jabyac PA, Miranda CL, Kapsick BJ. Renal Consultants of Wyoming Valley, P.C., USA.

Monthly Access Blood Flow Monitoring is Beneficial, compared to Historic Controls.

- Compared access flow monitoring (Transonic) to historic controls using venous dialysis pressure, with screening criteria for interventions similar to K/DOQI;
- Overall thrombosis rates improved from 25 to 16% per patient year; AVF thrombosis rates improved from 16 to 7% per patient year.
- Eight of 10 thrombosis episodes were predicted based on inability to improve access flow.
  - 14% of AVF and 21% of AVG PTA attempts did not improve Qa by at least 20%.
- PTA was required on average 5.8 month intervals for AVG.
  - AVF flow was restored for a much longer period of time after PTA (11.4 month follow-up at end of study).
- COMMENT – how much improvement would there have been simply from rigorous application of standard venous pressure monitoing?

Kidney Int. 2001 Jan;59(1):358-62. Hemodialysis arteriovenous access: detection of stenosis and response to treatment by vascular access blood flow. Schwab SJ, Oliver MJ, Sunocki P, McCann R. Duke University Medical Center.

On-line Blood Temperature Monitor, to evaluate for AVF stenosis based on recirculation.

Recirculation in native AVF was measured with every treatment in 80 patients over a period of 6 months.

- Nine of 11 interventions performed during the entire observation period were triggered by a BTM recirculation above the threshold of 15%.
  - Two fistulas thrombosed despite BTM recirculation below the threshold.
- BTM recirculation to detect fistulas for revision is sensitive (81.8%) and specific (98.6%).

Semin Dial. 2003 Nov-Dec;16(6):483-7. Surveillance of access function by the blood temperature monitor. Schneditz D, Kaufman AM, Levin N. Renal Research Institute, New York City, New York, USA.

Nephrol Dial Transplant. 2004 May 25 [Epub ahead of print]. Clinical validation of glucose pump test (GPT) compared with ultrasound dilution technology in graft surveillance.Magnasco A, Bacchini G, Cappello A, La Milia V, Brezzi B, Messa P, Locatelli F.

- Comparison of 3 Access Flow Measurements;
  - glucose pump test (GPT), based on dilution of a constant glucose infusion, pre-dialysis.
  - ultrasound dilution technique (HD01 device Transonic Systems Inc., USA), during dialysis
  - color Doppler ultrasonography study (CDU) was reference standard for the diagnosis of stenosis

Clinical validation of glucose pump test (GPT) compared with ultrasound dilution technology … cont'd:

- 30 chronic hemodialysis patients with AVG; monthly comparison of sequential Qa measurements performed with GPT in pre-dialysis and the ultrasound dilution technique (HD01 device Transonic Systems Inc., USA) during dialysis.
- Color Doppler ultrasonography study (CDU) was reference standard for diagnosis of stenosis.
- Endpoints were graft thrombosis or PTA treatment.

Results – Glucose Pump Test vs. Transonic (HD01)

- HD01 yielded 27 of 112 high-risk Qa measurements (21 Qa <600 ml/min; mean 406+/-145 ml/min; 6 DeltaQa >25%; mean 43+/-7%).
- In 12 of 27 cases the CDU control did not show hemodynamically significant stenoses (false positive);
- 15 of 27 cases were confirmed high-risk accesses by CDU and did PTAs (HD01 specificity 86%).
- GPT yielded 14 of 112 high-risk Qa measurements (8 Qa <600 ml/min; mean 404+/-135 ml/min; 6 DeltaQa >25%; mean 38+/-8%) and all had severe stenoses and underwent PTA treatments showing a GPT specificity of 100%.
- The CDU study allowed us to correctly assess the Qa negative cases.
- HD01 method had 10 false negative cases (treated or clotted grafts with a Qa >600 ml/min and DeltaQa <25%) with a sensitivity of 60%, while GPT had 11 false negative cases with a sensitivity of 56%.

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- HD01 method had 10 false negative cases (treated or clotted grafts with a Qa >600 ml/min and DeltaQa <25%) with a sensitivity of 60%, while GPT had 11 false negative cases with a sensitivity of 56%.
- The diagnostic accuracy tested with the ROC curves was similar with both tests (area under the curve was 0.762 and 0.752 with GPT and ultrasound dilution, respectively; P = 0.985).
- The diagnostic efficiency (percentage of grafts with agreement between test result and factual situation) was 90 and 80% (P = 0.056) for GPT and HD01, respectively.

Clinical validation of glucose pump test (GPT) compared with ultrasound dilution technology … cont'd:

- CONCLUSION: Compared with HD01, the GPT had a lower false positive rate and similar diagnostic accuracy and efficiency.
- Smaller number of unnecessary, invasive procedures (angiographies or PTAs), without increasing the thrombosis risk.
- "GPT is an accurate, quick and economic test for Qa monitoring."
- [PROBLEMS – IS CDU really the standard? Or does it have false negative!?]

3 yr prospective study comparing Duplex US to Transonic.

Single unit with a change in monitoring strategy.

Accesses were monitored using Duplex ultrasonography in year 1, while (Transonic) flow monitoring was used in year 3 (year 2 was transitional).

A total of 303656 access days at risk were assessed, with 344, 385 and 425 accesses monitored in years 1, 2 and 3, respectively.

Total thrombosis rate was 1.01/1000 access days in year 1 vs 0.66/1000 access days in year 3.

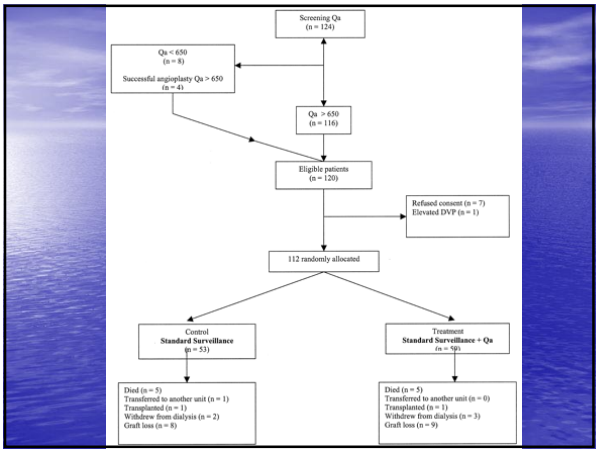
Reduction in procedure rates of 55% for angiograms, 13% for angioplasties and 31% for thrombolysis.

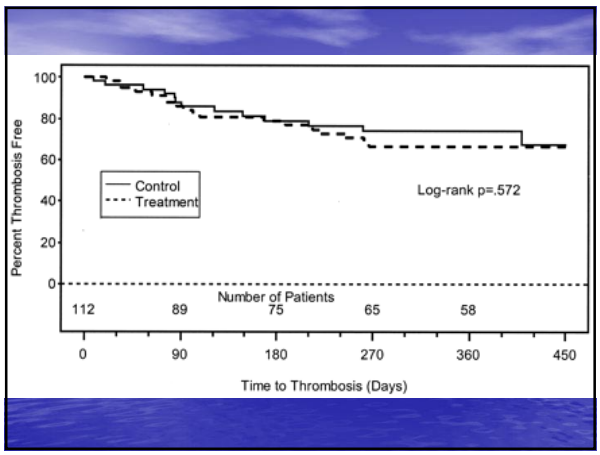
Nephrol Dial Transplant. 2003 Jun;18(6):1174-80. Reducing vascular access morbidity: a comparative trial of two vascular access monitoring strategies. Lok CE, Bhola C, Croxford R, Richardson RM. Toronto, Canada.

Does Monthly Access Monitoring Change Outcome?

- Blinded, randomized, controlled study.
- Compared three times weekly dynamic venous pressure (DVP) and physical exam plus monthly blood flow measurements (used Transonic device), vs. thrice weekly DVP with exam alone.
- Interventions made if Qa < 650 ml/min or 20% decrease in flow, in treatment group only, or if either DVP or exam indicated for both groups.

J Am Soc Nephrol. 2003 Oct;14(10):2645-2653. Regular Monitoring of Access Flow Compared with Monitoring of Venous Pressure Fails to Improve Graft Survival. Moist LM, et al. (McMaster)





Does Monthly Access Monitoring Change Outcome?

- Four findings
  - Qa and DVP detect venous stenosis, Qa more frequently.
  - No difference in time to thrombosis using monthly Qa plus thrice weekly DVP and exam vs. thrice weekly DVP and exam alone. Rates 0.51 and 0.41 per patient-year, consistent with other studies 0.5-2.5 events per patient year.
  - No difference in time to permanent graft loss.
  - Number of procedures to maintain patency was greater in treatment than control group; 51 PTA (0.93/patient-year risk) vs. 31 (0.61/patient-year).

Pearls

- Palpable thrill at arterial, mid-graft, and venous segments of AV graft correlates with blood flow > 450 ml/min.
- Aspirin (ASA) therapy at baseline was associated with an 84% reduction in risk of AV graft thrombosis.
- Graft thrombosis is usually due to neointimal hyperplasia at venous anastomosis.

Conclusions

- Access monitoring with elective intervention is beneficial, but additional benefits from newer techniques are still controversial; the best designed trials show least advantage, particularly for patients with AVF.
- Role for closely monitoring trends in venous pressures on dialysis (protocol in K/DOQI)
- Optimum strategy likely different for AVF and AVG
  - May need less than monthly flow monitoring for established stable AVF
  - Use of on-line methods promising, despite lower sensitivity.

Prevention of thrombosis – an RCT

- ASA 325 mg and Plavix 75 mg, vs. or double placebo
  - not a 2x2 study.
- Stopped after 200 patients for safety, due to increased bleeding in treatment group;
  - (hazard ratio, 1.98; 95% CI, 1.19 to 3.28; P = 0.007)
- Twenty-three participants in placebo group and 44 participants in active treatment group experienced a bleeding event (P = 0.006).
- No significant benefit of active treatment in the prevention of thrombosis (hazard ratio, 0.81; 95% CI, 0.47 to 1.40; P = 0.45),
- Trend toward benefit for participants who had no prior graft thrombosis (hazard ratio, 0.52; 95% CI, 0.22 to 1.26; P = 0.14).

J Am Soc Nephrol. 2003 Sep;14(9):2313-21. Randomized controlled trial of clopidogrel plus aspirin to prevent hemodialysis access graft thrombosis. Kaufman JS, et al.; Veterans Affairs Cooperative Study Group on Hemodialysis Access Graft Thrombosis.