

Access Flow Surveillance – Major Criteria for Success

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Abstract.

Introduction. Since the introduction of access flow (AF) surveillance technology for routine patient screening in 1995, more than 26 clinical trials have been presented in peer reviewed journals. Despite overall positive outcomes, some trials failed to produce good results for access surveillance from authors point of view. The purpose of this study is to analyze published data to identify the major reasons for access surveillance failure in these trials. Three major factors are analyzed: technology for routine surveillance (access flow vs. intra access pressure), guidelines for referring patient for fistulography/PTA, and PTA outcomes. **Results.** The main reasons for non-successful surveillance outcomes in some randomized trials were: first, failure to use two flow thresholds to predict hemodynamically significant stenoses, and second, the failure of PTA interventions to improve access blood flow. **Summary:** Access flow measurement technology successfully identifies patients with hemodynamically significant stenosis and should be the technology of choice for surveillance. The sole use of static flow thresholds may lead to missing a patient's thrombosis event and/or late intervention on an identified access. Radiologists should use objective flow means for interventional evaluation during PTA.

Introduction

Since the introduction of access flow (AF) surveillance technology for routine patient screening in 1995 [1], more than 26 scientific papers pertaining to the diagnosis of stenoses, thromboses and survival of artificial grafts (AVG) and native fistulae (AVF) have been published in peer reviewed journals. Despite the overall positive outcomes for surveillance of the studies, in some

cases, surveillance outcomes were rated negative from the author's point of view. The purpose of this study is to analyze the factors that may lead to negative access surveillance outcomes and thus avoid future pitfalls.

Methodology

Two criteria are needed for inclusion in clinical trials. First, studies should be published in peer-reviewed journals. Second, studies should be performed by independent researchers, and therefore not include authors of the methods used. For PTA trials where access flow was measured just before/after intervention abstracts were included in addition to papers.

Results

A summary of independent studies (1990- 2006) including the author's opinion of the study's outcome, are presented in Table 1 [3-28]. According to the literature all the access flow clinical trials were performed using Transonic Systems Monitor (HD01 or HD02). The outcomes of 10 independent studies that were performed using one (static) flow threshold of 500 – 650 ml/min for referring patient to fistulography/PTAS are presented on Fig.1. The results of 14 independent studies that were performed using static and dynamic flow thresholds for referring patient to fistulography/PTA are presented on Fig.2. A summary of the results of PTA in 21 clinics where AF was measured in the hemodialysis unit before and after PTA are presented in Fig. 3 (average flow change) and Fig. 4 (absolute flow dynamic) [30-48].

Analysis.

Three major factors influence surveillance outcomes:

- a) Technology used for routine surveillance (access flow, intra access pressure).
- b) Guidelines for referring patient for fistulography/PTA
- c) Outcomes of PTA

Surveillance Technology Choice. There is common agreement in the guidelines that intra access flow is the best tool to predict a hemodynamically significant stenosis. A recent publication [2] reports the first large multi-center independent study to address the question: are static venous pressure ratio VP/MAP (venous pressure (VP) divided by mean arterial pressure (MAP)) and also dynamic venous pressure surrogates or related in any way to access flow in AVF or AVG? The paper concludes that intra access venous pressure in all its modifications is not a surrogate for access flow, nor does it bear any relation to it. Based on a large amount of clinical data and theoretical considerations, the study concluded that the current K/DOQI guidelines related to intra access pressure (i.e., threshold for referral $VP/MAP=0.5$) are misleading and should be abandoned. For example, if in the AV access VP/MAP is in the order of 0.6, the blood flow in this access may be anything from 300 ml/min to 3000 ml/min [2]. The same may be true if VP/MAP is 0.25, the blood flow in this access may be anything from 300 ml/min to 3000 ml/min [2]. This means that, not only is the absolute intra-access pressure threshold recommended by K/DOQI erroneous, but that development of a referral algorithm based on dynamic intra-access change is irrelevant. For example, if pressure surveillance records an increase in VP/MAP of 20%, it could apply to a patient with 3000 ml/min flow or to a patient with 300 ml/min flow. What should the algorithm be for sending a patient to angiography

without knowledge of actual access flow? It is therefore no surprise that a majority of independent studies related to pressure surveillance have negative outcomes (Table 1).

One Verses Two Access Flow Thresholds for Fistulography/PTA Referral

American and Canadian guidelines and European publications have adopted two types of flow thresholds, static and dynamic, for sending patients to fistulography. The static threshold for AVG, common to all guidelines, is 600 ml/min. This threshold may vary for the AVF guideline of 600 ml/min in the USA to 400 – 500 ml/min in Canada and Europe. The dynamic flow threshold recommends that if blood flow declines by more than 25% within 4 months and is less than 1000 ml/min, the patient should be also referred to fistulography /PTA. While there is, as yet, no common agreement about what the dynamic thresholds should be (could be 30 -40% for AVF), all guidelines agree that there should be one universal dynamic guideline.

Without exception, all 26 flow publications (Table 1) suggest that if a patient is referred for fistulography based on small blood flow or decreased blood flow, there is a hemodynamically significant stenosis (more than 50% of the main lumen of the access) in these AVG or AVF with a probability of (positive predictive value) 92 – 100%. While we may agree that there is always a high prevalence of 50% stenosis in AVG and also in AVF, the actual definition of a hemodynamically significant stenosis is, in fact, a decrease in blood flow.

One Flow Threshold Trials Out of 10 independent trials (Fig. 2) that were performed using the threshold of 500 – 650 ml/min, three failed. This also included a randomized trial [16]. The fact that some researchers intentionally used only one threshold is puzzling. Ignoring a dramatic flow decline will obviously increase the probability of missing a thrombosis event. Hypothetically, in these trials, if graft blood flow fell from 1200 ml/min to 700 ml/min within a month, the patient would NOT be sent to fistulography/PTA. Because surveillance is usually performed once a month, such a decrease dramatically increases the probability of a graft thrombosis before the next evaluation. It would therefore have been surprising if such trials did not periodically fail.

Two Flow Threshold Trials Out of 14 independent studies that were performed using two thresholds, three failed (Fig.3). While some trial results [29] are disputed in the literature, one remarkable failure is definitely the failure of a Canadian perspective randomized double blind trial [5]. This trial included referring patients to fistulography based on Transonic flow measurements. In a later analysis of their results, the authors conclude that while > 50% stenosis was identified correctly in 87 % of the cases, PTA treatment of these stenoses did not improve the blood flow in half of the cases. In other words, the surveillance trial failed due to inadequate PTA treatment.

PTA Outcomes The body of literature on PTA interventions is controversial from the radiological versus nephrology point of view. While radiologists usually report a near 95-100% successful intervention based on a criteria of residual lumen reduction to the level of <25 - 30%,

nephrologists report that more than 20% of angioplasty procedures in AVG are not immediately successful and nearly 50% of shunt flow returns to a pre-angioplasty level within 3 months [7, 38]. Two publications related to AVG and AVF clearly represent this situation. The first is the previously mentioned Canadian AVG study [5] in which a radiologist reported reduction of the stenosis to less than 30% of the lumen diameter achieved in 85% of the cases. Flow measurement after PTA in a hemodialysis unit showed that a 20% increase in access flow was achieved in 60% of the cases. A simple analysis of the data suggest that a blood flow increase in the order of 300 - 400 ml/min was actually achieved in less than 50% of the cases. Analogous was an AVF and AVG European [20] study. In all cases, PTA was reported to be successful, *i.e.* residual luminal reduction of < 25%. Judging by a criteria for flow exceeding the AVF threshold of 500 ml/min (measured in the hemodialysis unit after intervention), only 42% were successful. For grafts, only 46% exceeded the 600 ml/min threshold that was the original reason they were sent for intervention.

The data in Fig.3 underscores the significant difference in PTA outcomes in different radiology units. The extent of this difference is threefold, ranging from 150 ml/min in one unit to 400 ml/min in another. As these increases represent average increases, this means that there was no improvement in flow in many patients. Recently introduced blood flow measurement [49, 50] technology that assesses the flow during PTA intervention may give quick and immediate feedback to the radiologist about the outcome of intervention and may be helpful in improving PTA results.

Fig. 4 illustrates a very important point. It is obvious that most lines are parallel, indicating that the smaller the flow to begin with the lower the resulting flow after PTA. In other words the earlier an intervention is performed (with higher initial flow), the higher final blood flow will be. It confirms the importance of the dynamic flow threshold that identifies hemodynamically significant stenosis early. It was shown that a higher flow in AVG after intervention leads to longer survival [24]. Dr. Tessitore et al in randomized trials[18, 28] reported that if intervention is performed on higher flow AVF, the stenosis is more treatable by PTA and the accesses have a better rate of survival.

Summary: The analysis of success and failure in flow surveillance clinical trials suggests:

1. Access flow methodology successfully identifies patients with hemodynamically significant stenoses.
2. Both static and dynamic access flow thresholds should be used for successful surveillance. Using only a static flow threshold may lead to missing a patient's thrombosis event and/or to late intervention on identified accesses.
3. Radiologists should use objective flow means for interventional evaluation during PTA.

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Table.1 Summary of Independent Vascular Access Surveillance Trials (Papers) 1990 - 2005

Surveillance	Papers	Number of accesses	Authors' conclusion + positive – negative			Problems with some studies
			Investigated	+ / -		
Dynamic venous pressure	10	748 AVG 150 AVF	stenosis	4	1	<i>Technical details and wrong basic theoretical assumption</i>
			thrombosis	4	6	
Static venous pressure ratio	7	353 AVG 84 AVF	stenosis	3	0	
			thrombosis	2	4	
Intra-access blood flow during HD	26	1501 AVG 1380 AVF	stenosis	12	0	<i>Not following K/DOQI; PTA failure; incorrect statistic. analysis</i>
			thrombosis	13	5	
			economics	3	0	

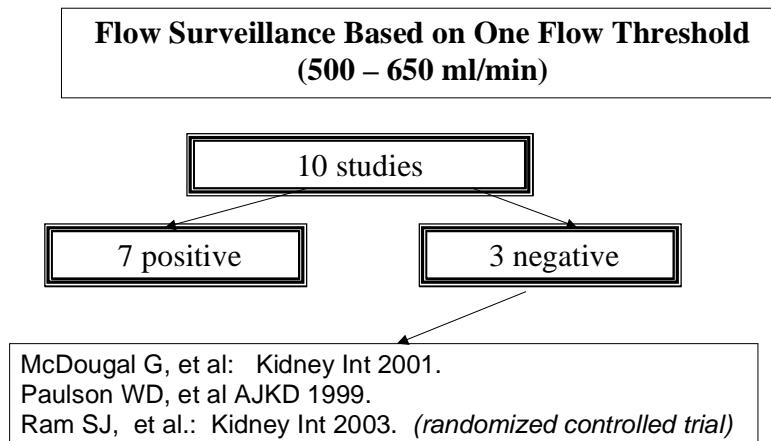


Fig.1. Results of flow surveillance based on one flow threshold.

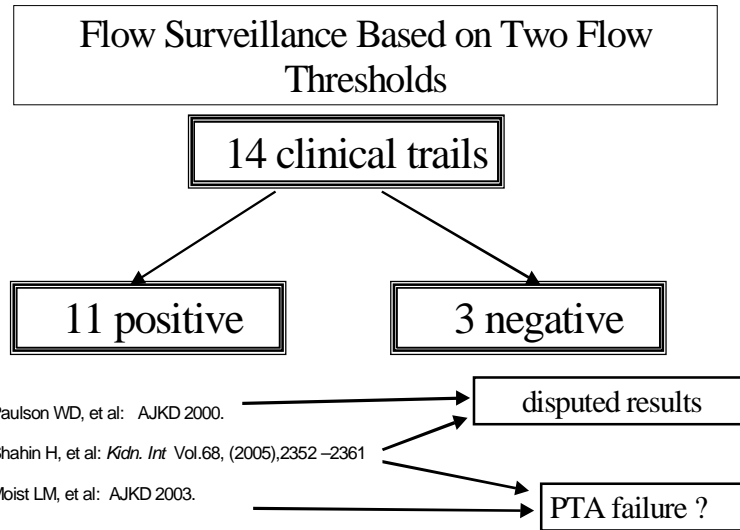


Fig.2. Results of flow surveillance based on two flow thresholds.

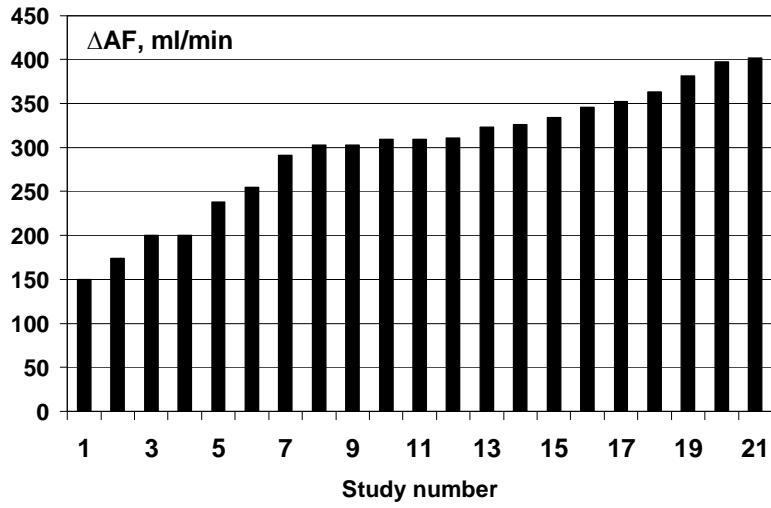


Fig.3. Average increase in access flow Δ AF in hemodialysis unit measured after PTA (21 studies).

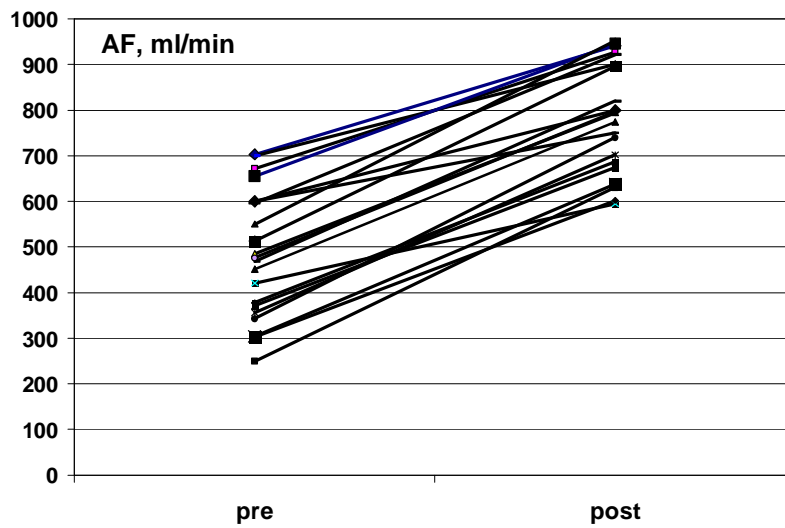


Fig.4. Average access flow (AF) in hemodialysis unit measured before PTA (pre) and after PTA (post 21 studies).