Vasc-Alert Efficacy

How Accurate is Vasc-Alert as an Indicator for Significant Stenosis?

This paper will present summaries of studies and other documents that speak to the accuracy of Vasc-Alert as an indicator of stenosis. The highlighted documents can be accessed over the Internet if this document is viewed on-line.

There have been a number of studies published and presented at various meetings on the efficacy of Vasc-Alert as a tool for access site surveillance. These studies are summarized in the following table:

	# of Patients	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	False Positive Rate	False Negative Rate
AJKD published study 2002 - results @ 6 months (1)	120	74%	92%	84%	92%	4%	
Use with Fistulas 2004 - results @ 6 months (2)	79	94%	86%	65%	98%	14%	6%
University of Chicago study 2006 (3)	234	90%	90%	93%	88%	10%	
Ball Memorial Hospital Case Study (4)	126	94%				6%	
Arterial Pressure Ratio Test for grafts @ 6 months (5)	98	100%	96.7%	70%	100%	3.3%	
Arterial Pressure Ratio Test for fistulas @ 6 months (5)	66	100%	94.9%	70%	100%	5.1%	
Average	120	92%	91.9%	76.4%	95.6%	7.1%	6%

1. Frinak S, Zasuwa G, Dunfee T, Besarab A, Yee J. Dynamic venous access pressure ratio test for hemodialysis access monitoring. Am J Kidney Dis. 2002;40(4):760-8. 90%This was the original study on the efficacy of this method was published in the American Journal of Kidney Disease in October of 2002. AJKD published study
2. Frinak S, Zasuwa G, Besarab A, Yee J, Dynamic Venous Access Pressure Surveillance in Arterio-Venous (AV) Fistula, unpublished data from 2004 study required for FDA approval of Vasc-Alert use for patients with fistulas.

3. Hammes M, Funaki B, Hirschman K, Kennedy J, Aneziokoro O, Vasc-Alert is an Effective Tool to Predict Venous Stenosis, ASN Poster 2006 University of Chicago study
4. Stewart G, Vasc-Alert Statistics, Presentation at Network 9/10 Meeting 2007, Chicago
5. Frinak S, Zasuwa G, Besarab A, Yee J, Arterial Pressure Ratio Test for Hemodialysis Access Monitoring of Arteriovenous Grafts and Fistulas, unpublished data from 2004 study required for FDA approval of Vasc-Alert use for arterial surveillance.

Vasc-Alert Compared to Flow-Based Methods

Vasc-Alert is often compared to flow-based technologies such as the Transonic device and Fresenius On-Line Flow as incorporated in the K machine. While all three methods are deemed acceptable by the latest K/DOQI report on access site maintenance, (http://www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/index.htm), there are indications that Vasc-Alert is both more sensitive to changes in the growth of stenosis than flow based technologies, and seems to identify issues earlier than flow based technologies:

An independent study compared Vasc-Alert and Transonic and published at ASN in 2006.

> This paper examines the sensitivity of both Vasc-Alert and Transonic to detect a change in stenosis. It examines 529 interventions and compares the readings taken before to the readings taken after an intervention. The ability to detect change is a marker for the growth of stenosis. Since the fact that an intervention creates a big change in the occlusion of the stenosis (decreasing the blockage), by presumption, the device that is more sensitive here, will also be more sensitive to detecting the growth of stenosis.
>
> The conclusion is that Vasc-Alert is more sensitive to change in stenosis growth than Transonic. It also suggests that the performance of Transonic might be improved with more frequent measurements than once a month. A simple explanation of the study is also available.

An analysis of Transonic and Vasc-Alert results on the same patient population.

> This analysis was internally derived from data provided by a dialysis center, which used both the Vasc-Alert and Transonic devices for a year. While this analysis does not have the same controls as a study, it does support the conclusions that Vasc-Alert:
>
> - Vasc-Alert identifies more patients with issues, (74% vs. 52%)
> - Vasc-Alert identifies patients with issues earlier, (74% vs. 18%)
> - When Vasc-Alert alerts earlier, it does so with a longer lead-time. (38 vs. 26 days)

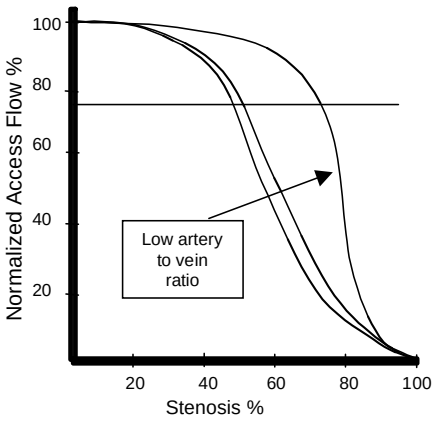
One of the reasons that Vasc-Alert may be more sensitive to changes in stenosis is that it tests the access with each session rather than once a month. The following paper suggests that for certain patients, more frequent testing is important.

A Physiological Basis for Testing More than Once a Month

A published paper by Dr. William Paulson suggests that there is a physical basis for the need for more frequent testing than once month.

This paper looks at the relative diameters of the artery supplying the access and draining vein and their influence on the use of flow-based technology to detect stenosis. His findings:

- For patients with very low artery to vein diameter ratios, adequate flow is maintained while stenosis is growing until it



reaches a critical point and then it drops very quickly, see graph. A greater than 70+% stenosis goes undetected because the reduction in access flow is not greater than 25%.

- This helps to explain why “monthly measurements often fail to warn of thrombosis”. *Page 3, column 2, second to last paragraph.*
- The study concludes that flow measurements should be done “at least weekly” in order to catch stenosis that is progressing at a constant rate.

Most centers using flow-based technologies test the access once a month. Vasc-Alert tests the access with every session.

Implication: If a center compares Vasc-Alert results to the tests derived using flow-based methods, it is likely that Vasc-Alert will report potential issues for certain patients before the results from a flow based technology identify that a patient is at risk for clotting. If the center does not send patients for intervention because the flow-based technology does not indicate an issue, the impression that would be developed will be that Vasc-Alert is generating a lot of false positives because the flow-based system says there is adequate blood flow.