



Introduction to Vasc-Alert

This paper is an overview of Vasc-Alert, a new solution for proactive surveillance of arteriovenous fistulas and grafts in hemodialysis patients. Vasc-Alert works by taking routinely collected dialysis treatment data and using it to detect an increase in pressure in the access due to stenosis. Once the pressure in the access exceeds a preset threshold, Vasc-Alert issues a report to the center staff, prompting a referral.

There are several advantages to this approach. First, minimal staff time is required. Surveillance is performed with each treatment, rather than just once a month, so stenosis that develops quickly can be detected. And since Vasc-Alert is monitoring for an increase in pressure, rather than a decrease in blood flow, it can detect the growth of stenosis at an early stage.

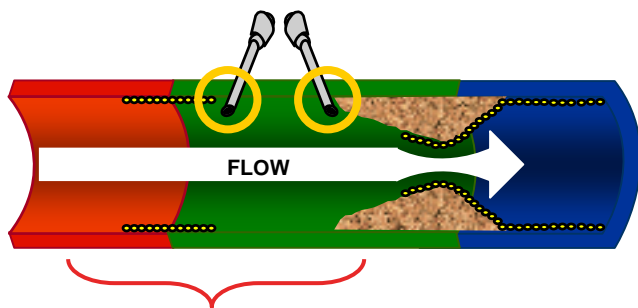
The reason for performing proactive surveillance of access sites is as follows:

Avoidance of catheter-related infections in hemodialysis patients begins with the preservation of the vascular access that each patient receives. Therefore, avoidance of arteriovenous graft or fistula complications is paramount. Graft or fistula loss from whichever cause is associated with a reduction in survival and even recovery from a vascular access complication is associated with significant morbidity.

Prevention of vascular access complications requires continual surveillance by knowledgeable and dedicated individuals. Until recently, the intensive labor required to achieve continual surveillance was cost prohibitive, which is why we developed Vasc-Alert. Vascular access surveillance remains the optimal method by which a given hemodialysis unit may decrease its vascular access complication rate.

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Description of the Vascular Access Pressure Ratio Test



Pressure builds up in front of the lesion as stenosis grows

Studies have shown that the early detection of vascular access stenotic lesions, followed by timely corrective procedures, reduces the thrombosis rate and prolongs access survival¹.

It is widely held that surveillance for an elevation in venous line pressure, which increases as a stenosis develops, would have clear diagnostic value².

¹ Besarab, et al. "Utility of intra-access pressure monitoring in detecting and correcting venous outlet stenosis prior to thrombosis" *Kidney International*. 1995

² Schwab. "Vascular Access for hemodialysis." *Nephrology Forum*. 1999

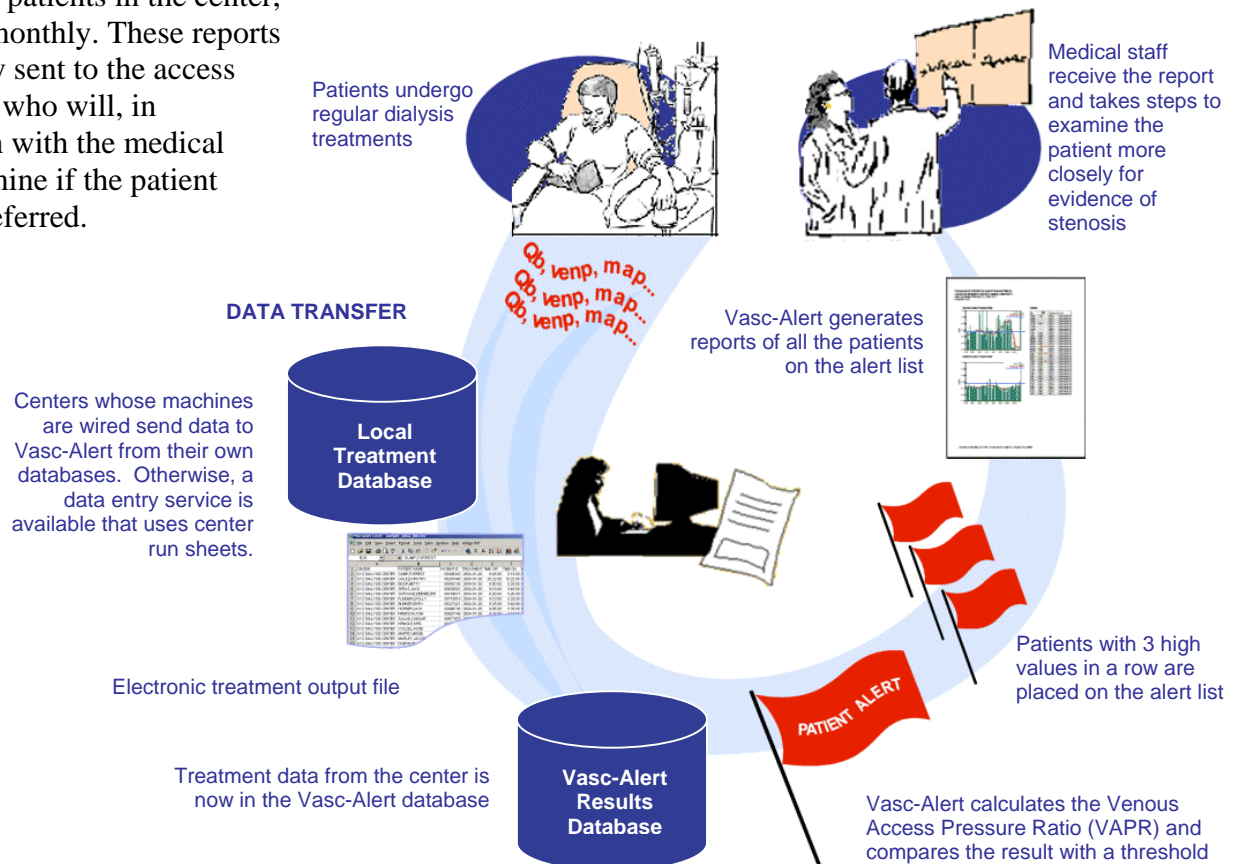


Vasc-Alert uses data collected during the dialysis session to predict the growth of stenosis. The algorithm takes into consideration the average of all the observations recorded during the treatment, (Qb, venous drip chamber pressure and the arterial pressure). It corrects for the type of dialysis machine, the needle/tubing set being used, the height of access relative to the drip chamber, and the patient's hematocrit to determine the actual pressure in the access site. This is then compared to the patient's mean arterial pressure, which nullifies changes caused by variations in the patient's blood pressure, to develop a ratio. If the ratio is above .55 for the venous side for three consecutive treatments, it is an indication of stenosis and a basis for evaluating the patient for referral to an interventionalist. An additional calculation is done on the arterial side.

The Vasc-Alert Data Flow

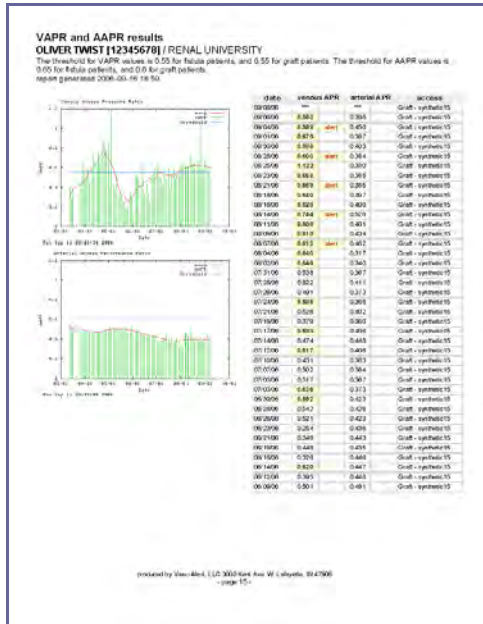
Vasc-Alert functions as a cycle of information, starting with treatment information that is recorded at your center, and returned to your center in the form of reports. The diagram below shows this cycle. In many dialysis centers, key treatment information is already being collected directly from the dialysis machines and stored in a local database, often as part of a clinical management system. In this case, it is very easy to generate a simple report with the treatment data and send it to us weekly. In centers where there is no local database, clerical staff can enter the required data into a Vasc-Alert data program.

If three consecutive sessions are above the threshold limit, Vasc-Alert generates an alert report. These reports are sent to you via a secure connection on a weekly basis. A summary report, covering all patients in the center, is sent out monthly. These reports are typically sent to the access coordinator who will, in consultation with the medical staff, determine if the patient should be referred.

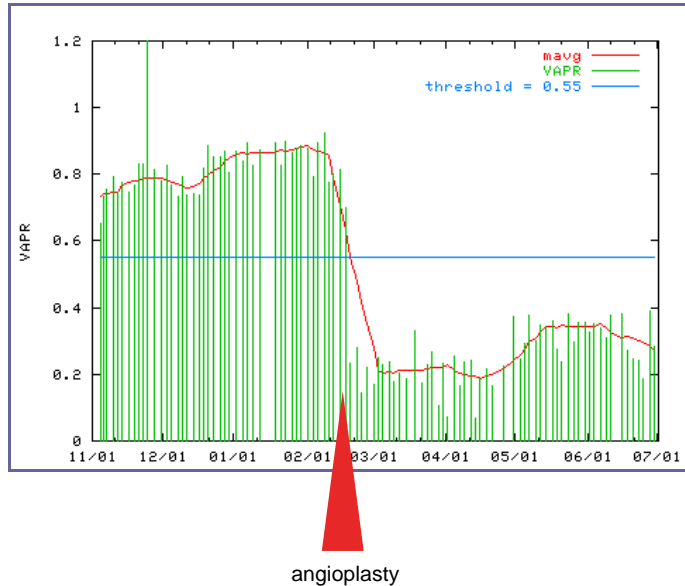


How does a patient get included in a Vasc-Alert report?

Vasc-Alert compares patient VAPR values to a threshold value. Since individual calculations can be high for a variety of reasons, Vasc-Alert introduces an element of trend analysis. Three high readings in a row are called an **alert**. When an alert occurs for a given patient, Vasc-Alert includes the patient in the next report. Vasc-Alert then starts the counting for that patient over again.



Example of a report for a patient on alert



VAPR graph showing thrombosis followed by angioplasty

What are the benefits of proactive surveillance?

- Center Revenue will Increase
- Patient Care will Improve
- Disruptions to Normal Center Operations will Decrease

Why use Vasc-Alert for your surveillance program?

- Minimal Staff Involvement
- Test with each Treatment
- Flags Stenosis Issues Earlier