

Vasc-Alert Defined

Vasc-Alert® System

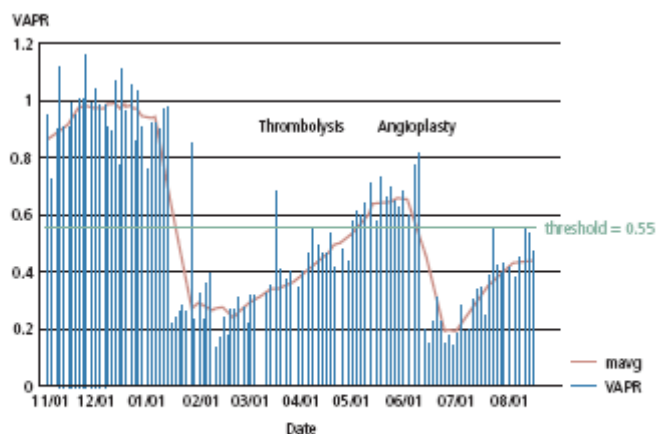
The Vasc-Alert® computer algorithm identifies persistent VAPR elevations that may signify that an access requires additional evaluation. This algorithm calculates VAPR from the venous drip chamber (VDP), measurements by the dialysis machine, and blood pump flow data that are routinely collected during dialysis and determine persistent increases of VAPR. The program extracts the most recent hematocrit (an index of viscosity effects) and individual treatment data from the dialysis database, and VAPR is calculated each time blood pressure is measured during dialysis. Data from the last 60 minutes of dialysis is excluded to eliminate the effect of ultrafiltration on hematocrit, blood pressure, and changes in systemic and vascular access resistances. The algorithm calculates mean VAPR for each dialysis session. Readings are considered abnormal if the VAPR exceeds 0.55 during three consecutive treatments. The dialysis treatment is never interrupted to take a reading.

The Vasc-Alert system also obtains the machine pre-pump arterial pressure recorded during dialysis. The ratio of the absolute value of the pre-pump arterial pressure divided by machine blood flow is calculated. An arterial pressure ratio (APR) greater than 0.6 in grafts and 0.65 in fistulae during three consecutive treatments indicates that the patient has an obstruction in the arterial inflow.

Figure 1a and Figure 1b show VAPR data from Vasc-Alert example reports where VAPR values are plotted for each dialysis treatment; following thrombolysis or angioplasty, VAPR values are reduced below the threshold level of 0.55. The data in Figure 1a are typical for a patient who has undergone thrombolysis; VAPR values are again above threshold in approximately four months.

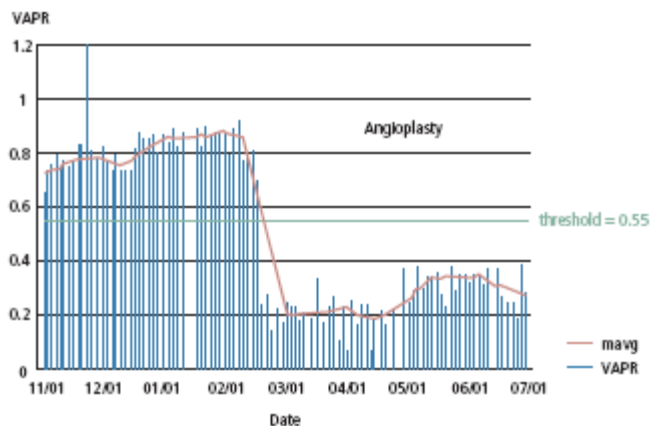
For all surveillance techniques, trend analysis is more useful than any single measurement. Trend analysis requires a computerized database for data storage and presentation of the individual patient data. The VAPR measurements in *Figure 1a* and *Figure 1b* demonstrate the advantage of having surveillance measurements from each dialysis treatment; it is very easy to determine the trend in the patient's data.

Figure 1a: Venous Access Pressure Ratio (VAPR) Data Using the Vasc-Alert System for a Patient That Was Allowed to Clot



Following thrombolysis, VAPR values remain low for about one month then show a relatively rapid increase that exceeds 0.55 in four months. This rapidly increasing trend in VAPR values is typical following access thrombolysis.

Figure 1b: Venous Access Pressure Ratio (VAPR) Data Using the Vasc-Alert System for a Patient That Underwent Angioplasty Before Clotting



VAPR values remained low during the four-month period following angioplasty.