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### Sentinel Vascular Access Monitoring After Endovascular Intervention Predicts Access Outcome

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# Sentinel vascular access monitoring after endovascular intervention predicts access outcome

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## Abstract

**Background and objectives:** The vascular access pressure ratio test identifies dialysis vascular access dysfunction when three consecutive vascular access pressure ratios are  $>0.55$ . We tested whether the magnitude of the decline in vascular access pressure ratio 1-week post-intervention could alert of subsequent access failure.

**Design, setting, participants, and measurements:** The retrospective study included all vascular access procedures at one institution from March 2014 to June 2016. Data included demographics, comorbidities, vascular access features,  $\% \Delta \text{VAPR} = ((\text{Pre-Post})/\text{Pre}] \times 100\%$  assessed within the first 2 weeks post-percutaneous transluminal balloon angioplasty, time-to-next procedure, and patency. The log-rank test compared the area under the curve, receiver operating curve, Kaplan–Meier arteriovenous graft and arteriovenous fistula survival curves. A multivariable Cox proportional hazard (CP) model was used to determine the association of  $\% \Delta \text{VAPR}$  with access patency.

**Results:** Analysis of 138 subjects (females 51%; Black 87%) included 64 arteriovenous fistulas with 104 angioplasties and 74 arteriovenous grafts with 134 angioplasties. The area under the receiver operating characteristic curve for fistula failure at 3 months was 0.59, with optimal screening characteristics of 33.3%, sensitivity of 56.1%, and specificity of 63.2%. Arteriovenous fistula with  $<33.3\%$  decline compared to  $>33.3\%$  required earlier subsequent procedure (136 vs 231 days), lower survival on Kaplan–Meier analysis ( $P=0.01$ ), and twofold greater risk of failure ( $P=.006$ ). Area under the receiver operating characteristic for arteriovenous graft failure at 3 months had a sensitivity of 52.3% and specificity of 67.4%. Arteriovenous graft with a post-intervention vascular access pressure ratio decline of  $<28.8\%$  also required earlier subsequent procedure (144 vs 189 days), lower survival on Kaplan–Meier ( $P=0.04$ ), and a 59% higher risk for failure. The area under the receiver operating characteristic curve for combined access failure (arteriovenous fistula + arteriovenous graft) at 3 months had an optimal cut-point value of 31.2%, a sensitivity of 54.6%, and a specificity of 63.1%. Access with a  $<31.2\%$  drop had a 62% increase in the risk of failure (hazard ratio 1.62; confidence interval 1.16, 2.27;  $P=0.005$ ).

**Conclusion:** The magnitude of post-intervention reduction in vascular access pressure ratio provides a novel predictive measure of access outcomes.

## Keywords

Arteriovenous fistula, angioplasty, surveillance, outcome measure, access failure, procedure efficacy, predictive measure

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## Introduction

Vascular accesses (VAs) are considered to be the “Achilles heel” of hemodialysis.<sup>1</sup> Arteriovenous fistulas (AVFs) and arteriovenous grafts (AVGs) are the preferred long-term VA options for patients on hemodialysis. Access dysfunction is caused by “neointimal hyperplasia.”<sup>2,3</sup> Stenosis is the inward remodeling process of a vessel wall that produces luminal narrowing, which in turn affects blood flow and intra-access pressures. VA surveillance leads to the early identification of stenosis, providing sufficient lead time for intervention before thrombosis.<sup>4</sup> Surveillance methods are mainly based on blood flow or intra-access pressure.<sup>5,6</sup> Invasive tests such as angiography are performed based on surveillance alerts combined with clinical symptoms. Percutaneous transluminal balloon angioplasty (PTA) is the initial therapy of choice in the management of VA dysfunction.<sup>7</sup> Selection of the angioplasty balloon size and the residual stenosis estimation is operator dependent. Residual stenosis <30% indicates a “successful” angioplasty procedure.

Despite improved technical success in treating stenosis, recurrence rates are very high, with only 40%–50% of VAs maintaining patency without the need for subsequent procedures by 6 months.<sup>8</sup> Angioplasty failure may have disastrous consequences, requiring the use of endovascular stents or surgical revision and causing permanent access loss with intervening catheter use, thereby increasing cost, morbidity, and mortality. Failure to identify elastic recoil of treated stenosis and/or suboptimal treatment of the culprit lesion leads to persistence of clinical symptoms, worsening of stenosis, and eventual loss of patency. The actual frequency of delayed elastic lesion is unknown and may be as high as 15%.<sup>9</sup> This recoil may at times be seen after the angioplasty when performing repeat angiograms in 15-min intervals, but this is not practical and does not identify lesions that recoil more slowly.<sup>9</sup> Existing surveillance methodologies fall short in monitoring VA in the immediate post-procedure period. A functional outcome measure post-PTA would greatly help to identify accesses at higher risk for failure, assist in assessing the quality of the procedure, and might provide the lead time for the next course of the intervention, potentially altering the natural course of access dysfunction.

Functional effects of the angioplasty are not routinely monitored.<sup>10</sup> Distal radial artery pressure gradient, transluminal pressure ratio, and catheter-based flow studies are proposed to predict technical and patency outcomes in limited VA types and require additional resources.<sup>11–14</sup> These adjunctive methods are useful intraprocedure but have limited applicability across various access types and clinical settings.

Vasc-Alert™ (Vasc-Alert, LLC, Lafayette, IN) is an automated, noninvasive surveillance algorithm that monitors VA during every dialysis session.<sup>15</sup> Dialysis machine

data such as needle gauge, arterial and venous pressures, blood flow, dialysis time, and patient hematocrit are electronically captured and uploaded to a cloud-based database system. A patented algorithm calculates the venous intra-access pressure ratio (VAPR). The ratio is computed by dividing the calculated VA pressure by the mean arterial pressure (MAP). Vasc-Alert directly calculates the intra-access pressure ratio of hemodialysis access at least six times during each dialysis treatment. Pressure readings are obtained with every dialysis session, are not time-dependent, do not add material cost or additional staff time, and do not interfere with dialysis delivery. Three consecutive dialysis sessions with VAPRs that exceed the threshold of 0.55 trigger an electronic alert sent to designated personnel in dialysis units. Patients with electronic alert warnings in combination with clinical symptoms are referred for PTA. A decrease in access pressure post-successful PTA should be noted as early as the next dialysis session. The lack of this change after the PTA is likely due to elastic recoil, underestimated balloon size, misidentification of the culprit lesion, or, less likely, an unrecognized form of accelerated neointimal hyperplasia. The magnitude of pressure changes post-PTA is not explicit and might depend on access type. We aimed to study the degree of drop in VA pressure ratio after PTA to observe whether post-PTA VAPR drop correlates with procedure outcomes.

## Materials and methods

We conducted a retrospective review of all patients of an independent dialysis provider who were monitored using the Vasc-Alert surveillance program and had a successful PTA (alone or as part of successful thrombectomy). Procedures were performed by different specialties at one institution including interventional nephrology, vascular surgery, and interventional radiology. Procedural success was defined as <30% residual stenosis. The hospital-based electronic medical record (EMR) (Epic, Epic Systems Corp., Verona, WI) was used to identify patients with end-stage renal disease (ESRD) who received a PTA of VA from March 2014 to June 2016. Data collection included demographics, comorbidities, VA type, location, laterality, and access vintage (age of the access), mean of 3 VAPR values leading to the alert, mean of the first 3 VAPRs post-procedure, time-to-next intervention, years of ESRD, site of stenosis, and access patency. The percent of change ( $\Delta\%$ VAPR) derived from pre- and post-intervention VAPR was computed to measure the difference in the intra-access pressure post-procedure. Subsequent access failures were defined as undergoing access procedures or permanent loss. The time to access failure at 3 months was chosen for area under curve analysis, based on the Kidney Disease Outcomes Quality Initiative (KDOQI) guideline 6.6 and North American Vascular Access Consortium

**Table 1.** Baseline characteristics of the study population by the access type.

Variable	Response	Overall	Fistula	Graft	P-value
Age (years)	N; mean (SD)	138; 64.16 (12.23)	64; 63.07 (11.98)	74; 65.09 (12.45)	0.335
Dialysis vintage (years)	N; mean (SD)	138; 6.00 (4.38)	64; 4.28 (2.93)	74; 7.49 (4.87)	<0.001
Access vintage (years)	N; mean (SD)	138; 2.57 (62.05)	64; 2.34 (1.96)	74; 2.77 (2.28)	0.222
Sex	Female	70 (50.7%)	28 (43.8%)	42 (56.8%)	0.128
Race	A	3 (2.2%)	2 (3.1%)	1 (1.4%)	0.46
	B	120 (87%)	53 (82.8%)	67 (90.5%)	
	H	1 (0.7%)	1 (1.6%)	0	
	NA	2 (1.4%)	1 (1.6%)	1 (1.4%)	
	W	12 (8.7%)	7 (10.9%)	5 (6.8%)	
DM	Yes	89 (64.5%)	44 (68.8%)	45 (60.8%)	0.331
HTN	Yes	125 (90.6%)	59 (92.2%)	66 (89.2%)	0.548
PAD	Yes	21 (15.2%)	11 (17.2%)	10 (13.5%)	0.549

SD: standard deviation; A: Asian; B: Black; H: Hispanic; NA: unknown; W: White; DM: diabetes mellitus; HTN: hypertension; PAD: peripheral arterial disease.

guidelines on standardized definitions for hemodialysis VA months.<sup>16,17</sup> The Institutional Review Board (IRB) approved the study protocol with an exemption from informed consent (IRB #9682).

### Statistical methodology

All analyses were done using SAS version 9.4 (SAS Institute, Inc., Cary, NC). A generalized estimating equation approach was used to model the repeated measures per individual. The receiver operating characteristic (ROC) curve was generated as a plot of sensitivity versus 1-specificity where the screening characteristics were produced for each possible cut-point (change in VAPR;  $\Delta\%$ ). An optimal cut-point was designed as the value that maximized the sum of sensitivity and specificity which treats false-positive and false-negative values as equally important in deciding a cut-point. Follow-up analyses assessed how well the best cut-point predicted survival using a cluster data approach to both the Kaplan–Meier estimate and a multivariate Cox model using the robust sandwich covariance matrix estimate which evaluates the effect of  $\Delta\%$ VAPR adjusting for significant covariates.

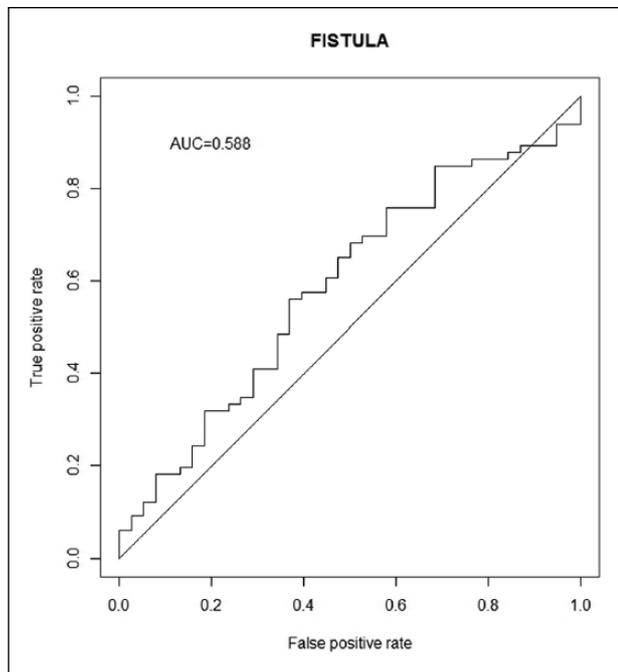
### Results

Over a 27-month period, PTA was performed in 138 subjects (Black 87%, diabetes mellitus 65%, hypertension 91%, and peripheral arterial disease 15%) that included 64 AVFs with 104 angioplasties (1.63 angioplasties/access) and 74 AVGs with 134 angioplasties (1.81 angioplasties/access) (Table 1). Two-thirds of AVF angioplasties were in brachiocephalic fistula (n=66, 67%) while AVG angioplasties were predominantly of C-shape configuration (n=54, 63%). Only one procedure had a stent placement along with angioplasty. High-pressure angioplasty balloons were employed in 49 procedures. Patients with AVF

(44% women) had a mean age of 63.1 years, a mean of 4.3 years on dialysis, and an access vintage of 2.3 years. Patients with AVG (57% women) had a mean age of 65 years with a mean of 7.5 years on dialysis and an access vintage of 2.8 years. Solitary stenosis was noted in 67% of procedures. Stenosis distribution (solitary or in combination with other sites) was predominantly in downstream direction (cephalic arch: n=40, swing segment: n=18, vein graft anastomosis: n=105, intra-stent lesions: n=9, central veins: n=14, intra-access: n=87). There were no significant associations between site of stenosis and  $\Delta\%$ VAPR in both AVF and AVG. There were no significant differences in the prevalence of diabetes, hypertension, peripheral arterial disease, use of high-pressure PTA balloon, or the number of angioplasties per access except for the AVG group, which had a longer dialysis vintage compared to the AVF group (7.5 vs 4.3 years,  $P < 0.001$ ). The area under the ROC curve for access failure (AVF + AVG) at 3 months was 0.569, with an optimal cut-off value of 31.2%, sensitivity of 54.6%, and specificity of 63.1%. Access with a  $<31.2\%$  drop had a 62% increase in the risk of failure (hazard ratio (HR) 1.62; 95% confidence interval (CI) 1.16, 2.27;  $P = 0.005$ ). The distribution of the  $\Delta\%$ VAPR variable was not normally distributed, as noted with the Shapiro–Wilk test ( $P < 0.001$ ), and had several large outliers. Of 238 observations, 38 (18 AVF and 20 AVG) had a directional increase in the post-procedure venous intra-access pressure ratio test (VAPRT). Of these 38 observations, 13 in the AVF group and 12 in the AVG group failed by 3 months. Compared to the accesses with a change of 0%–31%, the directional increase in post-procedure VAPRT did not enhance the risk of access failure ( $P = 0.43$ ).

### Predictive value of $\Delta\%$ VAPR in AVF

Among the 104 procedures in the fistula group, the mean post-procedure change in VAPR ( $\Delta\%$ ) was  $32.5 \pm 36.1$

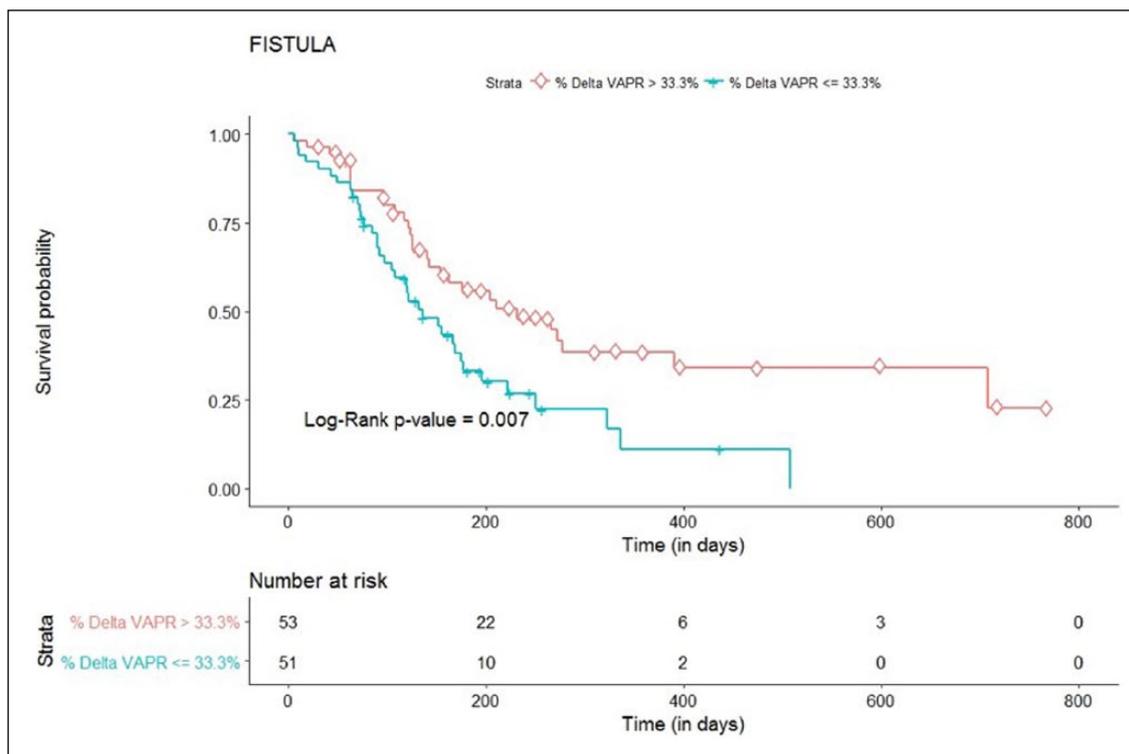


**Figure 1.** ROC curve for percent delta VAPR for fistulas, predicting failure at 3 months. In the ROC curve, sensitivity is on the vertical axis and 1-specificity on the horizontal axis.

(standard deviation (SD)). The area under the ROC curve for fistula failure at 3 months was 0.59, with an optimal cut-point of 33.3%, a sensitivity of 56.1%, and a specificity of 63.2% (Figure 1). Generalized estimating equation survival analysis for time to fistula failure is shown in Figure 2, with lower survival rates for fistula with <33.3% drop post-angioplasty. Table 2 provides adjusted HRs and 95% CIs from a multivariable Cox proportional hazards model, modeled with multiple time-points per individual as clusters modeling time to fistula failure. Each effect is interpreted as the effect while controlling for all other variables presented in the model. Nearly half of AVFs (n=51) had a <33.3% drop in VAPR post-PTA. Fistula with <33.3% drop had a 99% increase in the risk of failure (HR 1.99 (CI 1.14, 3.89), P=0.016) with a lower median survival of AVF (136 vs 231 days, P=0.01). There was no evidence that the other variables in the multivariable model had unique associations with time to fistula failure.

**Predictive value of  $\Delta\%$ VAPR in AVG**

Among the 134 procedures in the AVG group, the mean post-procedure change in  $\Delta\%$ VAPR was  $32.3 \pm 33.6$  SD. The area under the ROC curve for graft failure at 3 months

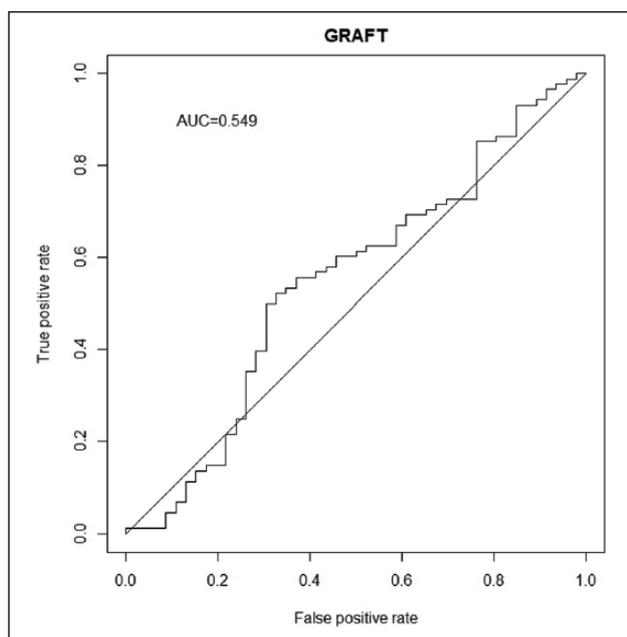


**Figure 2.** Kaplan–Meier survival curve estimates for time to fistula failure, stratified by percent delta VAPR dichotomized at 33.3. Access survival was significantly better for AVF with >33.3% drop in VAPR post-angioplasty than AVF with <33.3% drop in VAPR (log-rank test, P=0.007).

**Table 2.** Summary of multivariable Cox regression analysis for time to fistula failure.

Variables	HR (95% CI)	P-value
$\Delta\%VAPR < 33.3\%$	2.06 (1.19, 3.57)	0.010
Male	0.64 (0.34, 1.18)	0.15
Age	1.00 (0.97, 1.02)	0.849
Access vintage	0.91 (0.77, 1.08)	0.302
Diabetes mellitus	1.32 (0.73, 2.40)	0.361

HR: hazard ratio; CI: confidence interval; VAPR: venous access pressure ratio.

**Figure 3.** ROC curve for percent delta VAPR ( $\Delta\%$ ) for grafts, predicting failure at 3 months.

In the ROC curve,  $\Delta\%$  levels are plotted for their ability to predict graft failure at 3 months with sensitivity on the vertical axis and 1-specificity on the horizontal axis.

was 0.55, with a cut-point of 28.8% giving a sensitivity of 52.3% and specificity of 67.4% (Figure 3). A generalized estimation equation analysis for time to graft failure is shown in Figure 4 with a lower survival for the graft with a  $<28.8\%$  decline. Table 3 provides adjusted HRs and 95% CIs from a multivariable Cox proportional hazards model for clustered data, modeling time-to-graft failure. Exactly 46% AVG ( $n=61$ ) had a  $<28.8\%$  drop in VAPR post-PTA. Graft, which had a  $<28.8\%$  drop in VAPR within the first week post-angioplasty, had a 59% higher risk of failure (HR 1.59 (CI 1.07, 2.36),  $P=0.02$ ) with lower median survival (144 vs 189 days,  $P=0.04$ ). There was no evidence that the other variables, including age of access in the multivariable model, had unique associations with time-to-graft failure.

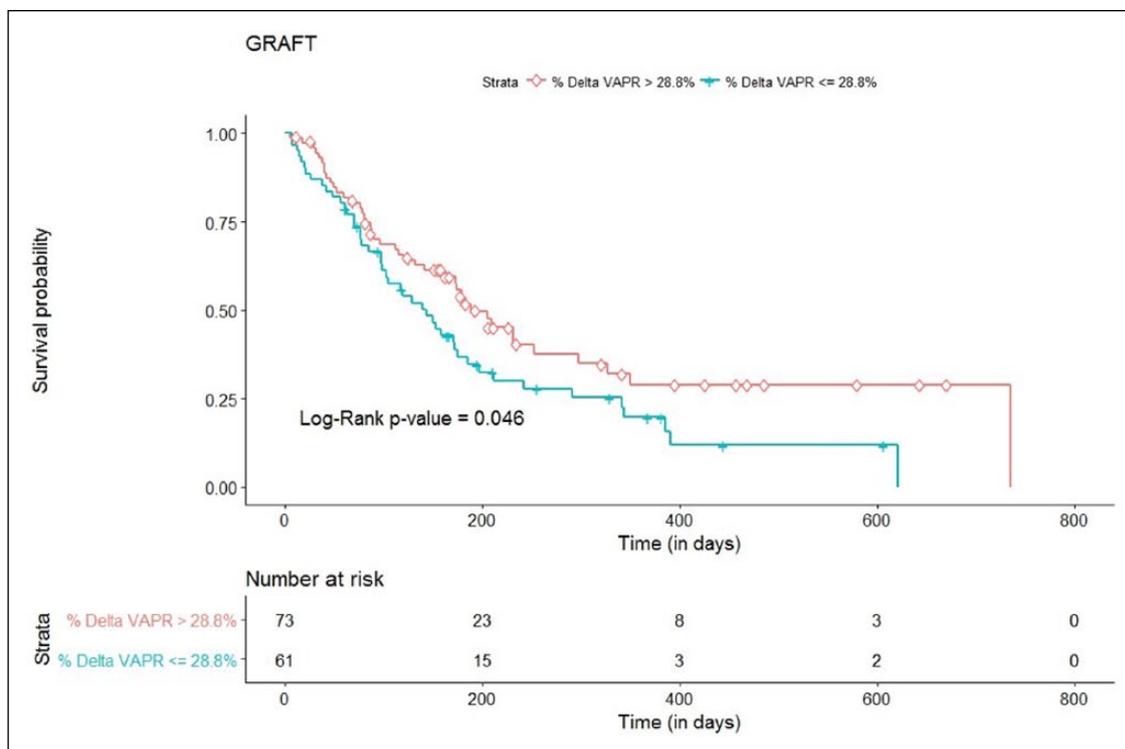
## Discussion

This study evaluated the interval change in pressure of AVFs and AVGs after the PTA to assess outcome and survivability. The principal finding of this study indicates that PTA post-pressure changes can predict subsequent access patency and survival. We report automated VA pressure-based predictive measures to evaluate post-procedure outcomes.

Post-PTA residual stenosis is frequently used to express the efficiency of PTA procedures. Outcomes of access dysfunction treated predominantly with PTA are influenced by accuracy in the identification of the culprit stenosis and the use of appropriate balloon type and size. The quantification of stenosis<sup>18</sup> and the choice of the balloon are operator-dependent with inventory limitations. Treated stenosis has the potential to recoil or recur in a short time after the procedure. Unlike access blood flow, post-PTA fluoroscopic changes are not shown to be predictors of functional outcome measures. Delayed elastic recoil is a frequent finding post-angioplasty with a prevalence as high as 10% at 5 min after a technically successful angioplasty.<sup>9</sup> Elastic recoil has not been shown to influence access survivability but still is used as an indication for implantation of endovascular stents emphasizing further the need for functional markers.<sup>9</sup> Notwithstanding these limitations, the lack of alternative measures has led to angiographic imaging being the principal marker of procedural efficiency. Considering that elastic recoil does not have any influence on access survivability, the effect of the VAPRT changes within the first week after PTA in our study likely indicates procedural efficiency.

In our study, we demonstrated that the changes in pressure profiles post-PTA could be used to predict access outcomes. Identifying a single methodology as an outcome measure in two biologically different access types with a diverse natural course but with a common etiology for dysfunction is a significant challenge. The combined access analysis provides a cut-point of a 31.2% drop as a single predictive measure. The lack of adequate pressure improvement post PTA could either be due to suboptimal interventions or the biological nature of the stenosis. The  $\Delta\%VAPR$  provides a single, clinically relevant, pragmatic, and objective measure assessing responses to PTA in fistulas and grafts.

Objective parameters reported in the literature to date can be broadly classified into flow-based and pressure-based measures.<sup>19,20</sup> Intraprocedure pressure-based settings are meant to identify hemodynamically significant stenosis missed by angiography. Asif et al.<sup>10</sup> described the intra-access static pressure ratio measured during angioplasty for 70 AVGs, demonstrating a decline of 38% post-intervention and nearly doubling the access flow at



**Figure 4.** Kaplan–Meier survival curve estimates for time to graft failure, stratified by percent delta VAPR dichotomized at 28.8. Access survival was significantly better for AVG with >28.8% drop in VAPR post-angioplasty than AVG with <28.8% drop in VAPR (log-rank test,  $P=0.046$ ).

**Table 3.** Summary of multivariable Cox regression analysis for time to graft failure.

Variables	HR (95% CI)	P-value
$\Delta\%VAPR < 28.8\%$	1.54 (1.03, 2.31)	0.036
Male	0.63 (0.34, 1.17)	0.146
Age	0.99 (0.97, 1.01)	0.388
Access vintage	1.02 (0.91, 1.15)	0.700
Diabetes mellitus	1.33 (0.81, 2.27)	0.252

HR: hazard ratio; CI: confidence interval; VAPR: venous access pressure ratio.

2 weeks. Funaki et al.<sup>21</sup> described trans-stenotic pressure gradient post-PTA as an intraprocedural adjunct to angiography to evaluate the results of PTA in grafts. Lin et al.<sup>12</sup> determined the trans-stenotic gradient across central venous stenosis angioplasty to be better than residual stenosis. Lai et al.<sup>22</sup> reported intra-graft pressure (IGP) as an intraprocedural objective measure for angioplasty of AVG. Pre-PTA IGP and post-PTA IGP were shown to be predictive of 1-year patency. The study also had nearly 60% procedure failure and residual stenosis of >60% reinforcing angiography's weakness as a marker of efficiency. Lai et al.<sup>11</sup> also reported distal radial artery pressure measured at the time of procedure as a marker of angiographic outcomes and 3-month primary access

patency. Reported studies to date are limited to intraprocedural measurements that require additional resources, adds to procedure times, cost, and specific access types. Although our study does not provide intraprocedural information, it includes information accrued in the post-procedural period without adding further cost and is applicable to both access types and practical in a community setting.

Access flow (AF) measurements using ultrasound dilution or ionic dialysance have been well studied and widely used for access surveillance.<sup>23,24</sup> The effect of preemptive angioplasty on AF has been reported with mixed results. Post-angioplasty AF in AVG has been reported to nearly double from pre-procedure levels in the first month with subsequent progressive decline to reach pre-intervention levels by the third month.<sup>25</sup> In a study of 28 AVGs, almost 15% had thrombosed and were lost in the third month. AVGs that achieve less than 1 L/min of AF post-intervention tend to have higher failures by 6 months, and lower 1-year assisted patency.<sup>26</sup> Similar results have been reported by Van der Linden et al.<sup>27</sup> and Tessitore et al.<sup>28</sup> Post-intervention AF measurement using the delta H method was proposed for functional surveillance by Roca-Tey et al.<sup>29</sup> The significant hurdles in using AF as an efficiency marker are its inherent weaknesses. AF measurements are time dependent and vary during and between dialysis sessions. The study conducted by Polkinghorne

et al.<sup>30</sup> measured AF multiple times during the dialysis session for three consecutive sessions. Significant reductions in flow and MAP were progressively noted throughout the dialysis treatment. AF may decrease by 10%–30% during the last hour of dialysis.<sup>30</sup> Similar results were found by Huisman et al.<sup>31</sup> using a duplex Doppler ultrasound and Doppler ultrasound study methods. AFs are performed monthly. Frequent measurements of AF are cost-prohibitive, affect dialysis delivery, and remain impractical. Routine use of AF as a marker of procedural or access efficiency can be questionable at best.

Our study addresses many of these limitations of AF. Access pressure measurements are obtained during every dialysis session, are not time dependent, do not add cost, and do not interfere with dialysis delivery. Both delayed elastic recoil and suboptimal procedures can be accounted for in real-time automated settings using the mean VAPR of the first three sessions after intervention. The additional time obtained by our outcome measure could be utilized in planning salvage procedures or new access placement, avoiding interim catheter use.

The role of surveillance is still controversial,<sup>32</sup> and our study has several limitations inherent to any retrospective design. However, a definite signal can be detected for increased hazards from a lack of adequate change in intra-access pressure following PTA. A blinded interventionist review of the images for stenosis identification and severity was not performed, limiting analyses that compare pressure changes with residual stenosis. The external validation of this predictive model development dataset in a different practice pattern with varied demographic compositions would be needed. Low sensitivity and moderate specificity impede its utility as a diagnostic test. The flat area under the curve is most likely due to the skewed distribution of  $\Delta\%$ VAPR, as noted by the Shapiro–Wilkes test. The low specificity of  $\Delta\%$ VAPR is expected due to co-existence of more than one stenosis segment, and combining it with post-intervention clinical symptoms might improve its specificity. Our study also lacks an intraprocedural pressure profile and is unable to ascertain if the failure of VAPR decline was due to an intraprocedure or post-procedure event. Our study does not address the impact of endovascular stent placement and its effect on the pressure profile, as only one angioplasty with stent placement was included. The study does not discuss pressure changes in subsequent procedural outcomes in the same access. Our review also does not examine the effect of time from alert to procedure and its impact on the response. Despite limitations, our study provides a valuable prognostic parameter useful for assessing post-procedure access outcomes.

## Conclusion

We report for the first time an electronic VA pressure-based outcome measure that can evaluate procedure efficacy and

access outcomes. This simple tool can identify access failure earlier than traditional symptoms of VA dysfunction and can aid in developing value-based procedure outcome measures and/or identifying failing access. Prospective studies evaluating the incorporation of  $\Delta\%$ VAPR in access surveillance, its impact on access survival, and cost-benefit analysis are needed.

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## Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: On behalf of all co-authors and I being the corresponding author, I hereby state that results presented in this article have not been published previously in whole or part, except in abstract format.

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