Short- and Long-Term Functional Effects of Percutaneous Transluminal Angioplasty in Hemodialysis Vascular Access

JOKE VAN DER LINDEN,* JOHANNES H. M. SMITS,† JAN H. ASSINK,‡ DERK W. WOLTERBEEK,§ JAN J. ZIJLSTRA,‖ ¶ GIJS H. T. DE JONG,‡ MARINUS A. VAN DEN DORPEL,* and PETER J. BLANKESTIJN†

*Departments of *Internal Medicine and §Radiology, Rijnmond-Zuid Medical Center, Clara Location, Rotterdam, The Netherlands; Departments of †Nephrology and ‖Radiology, University Medical Center, Utrecht, The Netherlands; and Departments of ‡Internal Medicine and ¶Radiology, Albert Schweitzer Hospital, Dordrecht, The Netherlands.*

Abstract. The efficacy of percutaneous transluminal angioplasty (PTA) is usually expressed as the angiographic result. Access flow (Qa) measurements offer a means to quantify the functional effects. This study was performed to evaluate the short-term functional and angiographic effects of PTA and to determine the longevity of the functional effects during the follow-up period. Patients with an arteriovenous graft (AVG) or an arteriovenous fistula (AVF) who were eligible for PTA (Qa values of <600 ml/min) were included. Ultrasound-dilution Qa measurements were obtained shortly before PTA and periodically after PTA, beginning 1 wk after the procedure. The short-term effects were expressed as the increase in Qa and the reduction of stenosis. The long-term effects were expressed as patency and the decrease in Qa after PTA. Ninety-eight PTA procedures for 60 patients (65 AVG and 33 AVF) were analyzed. Qa improved from 371 ± 17 to 674 ± 30 ml/min for AVG and from 304 ± 24 to 638 ± 51 ml/min for AVF (both $P < 0.0001$). In 66% (AVG) and 50% (AVF) of cases, Qa increased to levels of >600 ml/min. The degree of stenosis decreased from 65 ± 3 to 17 ± 2% for AVG and from 72 ± 5 to 23 ± 7% for AVF (both $P < 0.005$). The reduction of stenosis was not correlated with ΔQa ($r^2 = 0.066$). Six-month unassisted patency rates after PTA were 25% for AVG and 50% for AVF. The decreases in Qa were 3.7 ± 0.8 ml/min per d for AVG and 1.8 ± 0.9 ml/min per d for AVF. Qa values before PTA and ΔQa were correlated with the subsequent decrease in Qa ($P < 0.005$). In conclusion, Qa increases after PTA but, in a substantial percentage of cases, not to levels of >600 ml/min. Qa values before PTA and the increase in Qa were correlated with long-term outcomes, whereas angiographic results were not. These data, combined with literature data, suggest that there is optimal timing for PTA.

Vascular access complications account for considerable morbidity and deaths among hemodialysis patients. In the United States, these complications are responsible for up to 25% of all hospitalizations among dialysis patients (1–3). The European Dialysis and Transplant Association does not collect data on this issue, but it is likely that data for Europe and elsewhere would be comparable.

Thrombosis is the leading cause of vascular access complications. Thrombosis is almost always associated with the presence of stenosis. Percutaneous transluminal angioplasty (PTA) is an accepted treatment for stenotic lesions (3). Routine surveillance programs for the early detection of stenoses, followed by angioplasty, have been demonstrated to substantially reduce the number of thromboses per patient-year (4–7). However, repeated PTA treatment is often necessary, because restenosis occurs frequently. Although the short-term success rates for PTA range from 85 to 98% (8), patency rates at 6-mo follow-up assessments vary from 38 to 63% (4,9–11).

Several studies have demonstrated that the angiographic extent of stenotic lesions before and after PTA is poorly correlated with subsequent patency (9,11–14). Recently, the Society of Cardiovascular and Interventional Radiology (SCVIR) Technology Assessment Committee recommended that PTA efficacy should be expressed by both angiographic and functional parameters (15). In particular, access flow (Qa) measurements offer the opportunity to quantify and monitor the functional effects of PTA.

The purpose of this study was to assess access function among patients undergoing PTA. We quantified the short-term functional and angiographic effects of PTA. In addition, we determined the longevity of the functional effects during the follow-up period. Finally, we addressed the question of whether functional variables are predictive of long-term outcomes.

Materials and Methods

Patients

This prospective, observational, intervention study was performed in nine Dutch hemodialysis centers, in which a well defined surveil-

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Correspondence to Dr. Peter J. Blankestijn, Department of Nephrology, Room F.03.226, University Medical Center, Heidelberglaan 100, 3584 CX Utrecht, The Netherlands. Phone: +31-30-250-73-26; Fax: +31-30-254-34-92; E-mail: P.J.Blankestijn@digd.azu.nl

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lance protocol was instituted as part of routine patient care. All chronic hemodialysis patients with permanent arteriovenous grafts (AVG) or arteriovenous fistulae (AVF) who were referred for angiography because predetermined Qa threshold levels had been reached were eligible to enter the study. The surveillance protocol included periodic Qa measurements and angiography with PTA for patients thus selected.

Qa Surveillance Protocol

Qa was measured at least every 8 wk, using the ultrasound-hemodilution technique (Transonic Systems Inc., Ithaca, NY). Bench and clinical validations are presented elsewhere (16,17).

The surveillance protocol was discussed in detail previously (7). In brief, Qa determinations consisted of the average of three single measurements made within the first 30 min of the dialysis session, at a fixed pump flow rate (>200 ml/min). If Qa levels reached values between 600 and 800 ml/min, then measurements were repeated at least every 4 wk. Patients were referred for angiography whenever Qa values were <600 ml/min. Patients referred for angiography on the basis of other criteria, *e.g.*, frequent miscannulation, swelling of the arm, or high venous pressure, were excluded. Patients with a history of allergy to iodinated contrast agents were also not included in the study.

Angiography and PTA

Angiography and PTA procedures were performed as soon as possible (usually <7 d) after detection of the low Qa level (<600 ml/min). Digital subtraction angiography was performed for observation of the complete vascular access and location of the stenosis. Any luminal reduction of ≥50% was treated with PTA during the same session. The same PTA technique was used for all patients. First, the stenotic lesion was crossed with a guide wire (Boston Scientific Corp., Watertown, MA). Then a sheath (Cordis Europe, Roden, The Netherlands) was introduced. The PTA balloon catheter was passed over the guide wire to the location of the stenosis. In general, the high-pressure balloons had a diameter of 6 mm, although larger balloons (up to 10 mm) could be used for large proximal veins (several brands of catheters were used). At the stenotic site, the balloon was inflated to at least 10 atmospheres of pressure and maintained for approximately 2 min. In resistant cases, pressures of up to 20 atmospheres were used and maintained for 10 min. No heparin, vasodilators, or local anesthetics were administered during the procedure. Immediately after PTA, angiograms were obtained for evaluation of the results of the procedure. The interventional radiologist considered PTA procedures successful when the residual diameter of the stenosis was <25%. After PTA, Qa measurements were performed within 1 wk and then at least at 4-wk intervals. If Qa decreased below 600 ml/min, then patients were referred for angiography and repeat PTA was performed if necessary.

Outcome Variables and Statistical Analyses

The short-term functional effect of PTA on Qa was evaluated by calculation of ΔQa, *i.e.*, the difference between Qa before (Qa_{pre}) and just after (Qa_{post}) PTA. The long-term functional effect was assessed as the time to the next intervention, if applicable. When there were three or more Qa measurements after the PTA, the decrease in Qa was determined (in milliliters per minute per day). Resistance was calculated as the mean arterial BP/Qa ratio.

Angiographic data were analyzed by an independent radiologist. Only cases for which adequate biplanar angiograms of the stenotic areas had been obtained both before and after PTA were included. The degree of stenosis was assessed before PTA (baseline) and after PTA (post-PTA) as the ratio of the maximal lumen reduction to an adjacent normal graft/vessel diameter (expressed as a percentage; 0% = no stenosis, 100% = occlusion). Stenosis reduction attributable to PTA was calculated as the difference between baseline stenosis and post-PTA stenosis.

Data are presented as mean ± SEM, unless indicated otherwise. Differences in Qa and ΔQa values for different time points and subgroups of patients were calculated with two-tailed *t* tests. Pearson analysis was used for correlation purposes. Post-PTA primary patency, *i.e.*, the period of time that elapsed after intervention until access thrombosis or reintervention (surgical and/or radiologic), was calculated using a life-table analysis. To compare post-PTA survival rates for AVF and AVG, a (two-sided) log-rank test was used. *P* values of <0.05 were considered significant.

Results

Patients

Sixty patients who were referred for angiography were included. A total of 98 PTA procedures were performed. For 35 patients with AVG, 65 PTA procedures were performed. For the remaining 25 patients with AVF, 33 PTA procedures were performed. Patient and graft characteristics are presented in Table 1.

Table 1. Patient and access characteristics[a]

	AVG	AVF	Total
No. of patients	35	25	60
Mean age (range) (yr)	62.7 (37.2 to 82.6)	66.8 (34.6 to 83.7)	64.4 (34.6 to 83.7)
Gender			
male	6	16	22
female	29	9	38
Diabetes mellitus	9 (26%)	4 (16%)	13 (22%)
Coumarin therapy	19 (54%)	10 (40%)	29 (48%)
Mean age of access (range) (d)	629 (2 to 1893)	1088 (30 to 2926)	806 (2 to 2926)
Lower arm/upper arm	31/4	21/4	52/8

[a] AVG, arteriovenous grafts; AVF, arteriovenous fistulae.

Functional Results

Short-Term Results. In all cases, the first Qa measurement was performed within 7 d after PTA, usually during the first dialysis session after PTA. For AVG, Qa improved from 371 ± 17 to 674 ± 30 ml/min ($P < 0.0001$). Mean arterial BP remained stable after PTA (97 ± 2 *versus* 96 ± 2 mmHg), indicating that the increase in Qa represented a decrease in resistance. Qa_{post} values of >600 ml/min were reached in 62% of cases (40 of 65 cases) (Figure 1A). A negative correlation was observed between Qa_{pre} and ΔQa ($P = 0.0019$, $r = -0.38$). Qa_{pre} values did not differ for diabetic patients *versus* nondiabetic patients (340 ± 32 *versus* 386 ± 19 ml/min, $P = 0.20$). PTA tended to be less effective for diabetic patients than for nondiabetic patients (ΔQa, 228 ± 50 and 337 ± 41 ml/min, respectively; $P = 0.06$). The ages of the AVG and of the patients were not correlated with ΔQa. Multiple procedures were performed for 15 patients (Table 2). For patients who were treated twice, ΔQa values were 355 ± 68 and 424 ± 79 ml/min after the first and second PTA procedures, respectively ($n = 15$, P = NS). For patients who were treated three times, ΔQa values were 315 ± 98, 484 ± 112, and 345 ± 51 ml/min after the first, second, and third PTA procedures, respectively ($n = 10$, P = NS). For 15 patients, the PTA procedure was the first intervention for the AVG. ΔQa values for those patients did not differ from the values for patients who underwent a second or later PTA (287 ± 61 *versus* 313 ± 41 ml/min, $P = 0.72$). Unassisted patency rates also did not differ.

For AVF, Qa improved from 304 ± 24 to 638 ± 51 ml/min ($P < 0.0001$) (Figure 1B); 52% of PTA procedures (17 of 33 cases) resulted in Qa_{post} levels of >600 ml/min. The ΔQa was not related to Qa_{pre} for AVF ($r = -0.06$). Diabetes mellitus or the ages of the AVF or patients did not significantly affect the results for AVF. Only four patients underwent two PTA procedures (Table 2), and those patients demonstrated ΔQa values of 541 ± 173 and 285 ± 144 ml/min after the first and second PTA procedures, respectively ($P = 0.09$).

Long-Term Results. For 35% of all patients (21 of 60 patients), multiple procedures were performed. Repeat PTA procedures were more common for AVG than for AVF [43% (15 of 35 cases) *versus* 24% (six of 25 cases)] (Table 2). The mean time interval to repeat PTA was shorter for AVG than for AVF (109 ± 12 *versus* 169 ± 32 d, $P = 0.04$). In cases involving two PTA procedures, the time interval between the first and second PTA procedures was 113 ± 18 d ($n = 15$). In cases involving three PTA procedures, the time intervals between the first and second and the second and third PTA procedures were 122 ± 26 and 101 ± 21 d, respectively ($n = 10$, P = NS).

Decreases in Qa values after PTA were 3.7 ± 0.8 ml/min per d for AVG ($n = 38$) and 1.8 ± 0.9 ml/min per d for AVF ($n = 24$, $P = 0.06$). Coumarin use and diabetes mellitus did not affect the decrease in Qa after PTA. However, there was a correlation between Qa_{pre} levels and the subsequent decrease in Qa after PTA ($r = -0.43$, $P < 0.005$). Also, ΔQa was correlated with the decrease in Qa after PTA ($r = -0.48$, $P = 0.0009$).

The median primary patency time after PTA for AVG was 97 d. The post-PTA primary patency rates for AVG at 1, 3, and 6 mo were 100, 56, and 25%, respectively. The median patency time for AVF was 161 d. Post-PTA primary patency rates for

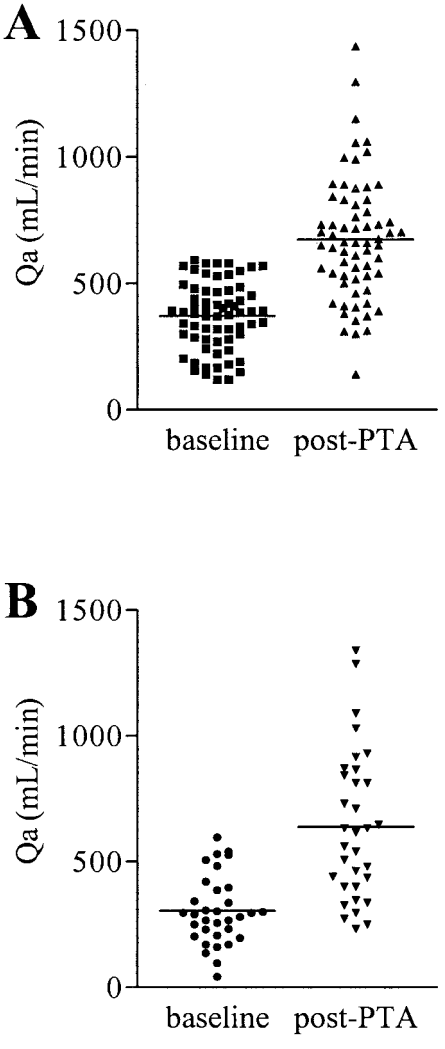

Figure 1. Access flow (Qa) results within 1 wk after percutaneous transluminal angioplasty (PTA) for arteriovenous grafts (A) and arteriovenous fistulae (B) (both $P < 0.0001$).

Table 2. Number of patients who underwent single and multiple PTA procedures[a]

	AVG	AVF	Total
Single PTA procedure	20 (20)	19 (19)	39 (39)
Multiple PTA procedures	15 (45)	6 (14)	21 (59)
two	5 (10)	4 (8)	9 (18)
three	6 (18)	2 (6)	8 (24)
four	3 (12)	0	3 (12)
five	1 (5)	0	1 (5)
Total	35 (65)	25 (33)	60 (98)

[a] PTA, percutaneous transluminal angioplasty. Values in parentheses represent the number of PTA procedures.

AVF at 1, 3, and 6 mo were 100, 92, and 50%, respectively. Log-rank comparison analysis of intervention-free survival curves demonstrated a significant difference in favor of the AVF ($P = 0.031$).

During the available follow-up period, no unpredicted thrombotic events (*i.e.*, accesses thrombosed with a Qa of >600 ml/min) occurred. For six AVG with Qa that remained below 600 ml/min after PTA, thrombosis occurred within weeks after PTA. Those cases are considered predicted thromboses. Furthermore, some thromboses occurred among patients with low Qa during the wait for PTA. Those accesses were not included in this analysis, because no PTA procedure was performed.

Angiographic Results

For AVG, 48 PTA procedures (74%) were performed on single lesions [38 venous stenoses (58%), nine midgraft stenoses (14%), and one arterial stenosis (2%)]. Seventeen PTA procedures (26%) were performed on two stenotic lesions [12 cases (18%) of venous and midgraft stenoses and five cases (8%) of arterial and venous stenoses]. Log-rank survival analysis demonstrated no difference in patency rates between AVG with a single lesion and those with multiple lesions ($P = 0.74$). Seven PTA procedures (21%) for AVF were for true anastomotic lesions, 20 (61%) were for venous lesions (in most cases located within a few centimeters from the anastomosis), and six (18%) for combined (venous and anastomotic) lesions. For 92% of all PTA procedures, angiographic improvement of the stenosis was achieved using a 6-mm balloon. Larger balloons were occasionally needed for proper dilation of stenoses in proximal AVF veins. In all cases, PTA was reported to be successful, *i.e.*, residual luminal reduction of ≤25%.

For AVG, baseline stenosis was 65 ± 3% and post-PTA stenosis was 17 ± 2% ($n = 33$, $P < 0.0001$). No correlation was observed between baseline stenosis and post-PTA stenosis ($r = -0.14$, $P = 0.47$) or Qa_{post} ($r = -0.05$, $P = 0.76$). Baseline stenosis was correlated with Qa_{pre} ($r = -0.48$, $P = 0.008$). No correlation was observed between angiographic (stenosis reduction) and functional (ΔQa) improvement ($r^2 = 0.066$) or between baseline stenosis and the subsequent decrease in Qa ($r = -0.02$, $P = 0.93$). Additionally, neither stenosis reduction ($P = 0.29$) nor post-PTA stenosis ($P = 0.07$) was correlated with the decrease in Qa after PTA. Log-rank survival analysis of the lower and upper 50th percentile baseline stenosis values revealed no difference in survival rates ($P = 0.90$).

When the AVG group was divided into a group with Qa_{post} values of <600 ml/min ($n = 24$) and a group with Qa_{post} values of >600 ml/min ($n = 41$), we observed that there was no difference in angiographic results between the two groups. The group with Qa_{post} values of <600 ml/min demonstrated stenosis of 66 ± 4% before and 19 ± 4% after PTA, whereas the group with Qa_{post} values of >600 ml/min demonstrated stenosis of 63 ± 4% before and 14 ± 3% after PTA (P = NS). The group with Qa_{post} values of <600 ml/min exhibited a Qa_{pre} value of 336 ± 24 ml/min and a Qa_{post} value of 441 ± 22 ml/min (ΔQa = 105 ± 24 ml/min). The group with Qa_{post} values of >600 ml/min exhibited a Qa_{pre} value of 392 ± 22 ml/min and a Qa_{post} value of 811 ± 29 ml/min (ΔQa = 419 ± 40 ml/min). Of the 24 patients with Qa_{post} values of <600 ml/min, six experienced thrombosis within 4 wk after PTA, eight underwent surgical correction without repeat angiography, and repeat angiography demonstrated 61% stenosis for 10. Two of those patients were subsequently referred for surgical revision, and eight underwent another PTA procedure. For AVF, baseline stenosis was 72 ± 5% and post-PTA stenosis was 23 ± 7% ($n = 8$, $P = 0.0039$).

Discussion

To our knowledge, this is the first study reporting both angiographic and functional results of PTA for the treatment of AVG and AVF. This study contains novel information. We demonstrate that angiographic results are not correlated with functional results. Importantly, we demonstrate that functional variables are predictive of long-term outcomes, whereas angiographic results are not. The study confirms recent data indicating that PTA results in a direct increase in Qa of approximately 250 ml/min (18). We also confirm that a substantial percentage of PTA procedures are not successful. Finally, the time to repeat PTA in this study was substantially shorter than that in other studies (9,18,19), which suggests a more rapid recurrence of stenosis in this study. The combined data from these studies suggest that there is an optimal time for PTA.

On the basis of the vast experience reported in the literature, the National Kidney Foundation/Kidney Disease Outcomes Quality Initiative Task Force has suggested PTA as a preferred treatment for vascular access stenosis (3). In most studies, post-PTA stenosis is used to express the efficiency of PTA procedures. However, post-PTA stenosis poorly predicts patency rates after PTA (9,11–14). Recently, the SCVIR Technology Assessment Committee recommended reporting both angiographic and functional data as efficacy parameters for PTA (15).

Our patients all exhibited Qa values of <600 ml/min, which is a strong predictor for imminent thrombosis, especially in grafts (3,20–23). They all exhibited baseline stenosis of ≥50%, which was treated by PTA. We confirm earlier data indicating that, on average, Qa increases by approximately 250 to 300 ml/min (18,24). Among the patients with adequate angiograms, post-PTA stenosis in AVG was ≤25% in almost all cases. This is considered to be an adequate angiographic result (3). However, the decrease in resistance was not correlated with stenosis reduction, indicating that angiographic improvement does not necessarily represent functional improvement. Preliminary data for a small group of patients also indicated that stenosis reduction was not correlated with the increase in Qa (14). Results for diabetic patients did not differ from those for nondiabetic patients. The percentage of PTA procedures that resulted in Qa_{post} values above the threshold value of 600 ml/min was 66% for AVG and 50% for AVF. Schwab *et al.* (18) defined failure of PTA as an increase in Qa of <20%, which occurred for 21% of grafts. This lack of effect may be caused by rapid recoil of the stenotic lesion, occurring

in the period between PTA and the first Qa measurement. Intravascular ultrasonography after PTA demonstrated that immediate elastic recoil occurred in 50% of the stenotic lesions (25). These findings may also indicate that other stenotic lesions, which importantly contribute to overall resistance, were not identified and not treated. Qa measurements during or immediately after PTA, in the intervention room, could be helpful for optimization of procedure results (24).

For patients who required multiple procedures, similar increases in Qa were obtained with subsequent PTA procedures. This finding supports earlier data indicating that patency rates do not decrease after repeat PTA (9). Lumsden *et al.* (12) randomized patients with >50% stenosis to either undergo PTA or not, and they observed that outcomes did not differ. Later, the same authors reanalyzed their data and reported that patency rates did improve but only for grafts without prior angioplasty or thrombosis (13). In this study, the PTA procedure included was the first intervention for only a minority of AVG. We were unable to confirm the earlier results indicating that the outcomes of first interventions are better than those of second or later interventions.

Long-term results of PTA are usually quantified as primary patency rates. For AVG, these rates vary from 38 to 64% at 6 mo and from 10 to 40% at 12 mo (8). We observed an intervention-free primary patency rate at 6 mo of 25% for AVG. The median time to the next PTA procedure was 97 d, compared with 5.8 mo in the study by Schwab *et al.* (18). Their results seem substantially better than the results presented here, whereas the short-term functional effects in the two studies are comparable. Some of the differences between these studies may be important in this respect. In our study, AVG were almost exclusively localized in the lower arm, whereas the study by Schwab *et al.* (18) included mainly upper-arm AVG. We selected patients when the threshold of 600 ml/min was reached, whereas in the other study most patients were referred when Qa values demonstrated a decrease of ≥20%. As a result, Qa values before and after PTA differed considerably, *i.e.*, 371 ± 17 and 674 ± 30 ml/min in this study and approximately 750 and 950 ml/min in the previous study, respectively (18). The decrease in Qa after PTA was correlated with Qa_{pre}, suggesting that the severity of stenosis before PTA is predictive of the rate of stenosis recurrence. The decrease in Qa was 4.1 ± 1.0 ml/min per d for patients with Qa_{pre} values between 100 and 350 ml/min, compared with 2.7 ± 1.2 ml/min per d for patients with Qa_{pre} values between 350 and 600 ml/min. Additional support for this notion is derived from data for patients who underwent PTA because of high venous pressure, who were not included in this study. For patients ($n = 12$) who exhibited Qa_{pre} levels of 600 to 800 ml/min, the decrease in Qa was 1.6 ± 1.8 ml/min per d, which perfectly corresponds to the 5.8 mo between consecutive interventions reported by Schwab *et al.* (18). Whereas baseline stenosis was correlated with Qa_{pre}, post-PTA results (both post-PTA stenosis and stenosis reduction) were not correlated with the subsequent decrease in Qa. These data suggest that Qa, and therefore resistance, is more predictive of the longevity of the effects of PTA than are angiographic variables.

Also, the correlation between ΔQa and the decrease in Qa deserves comment. It is likely that a greater ΔQa is an indication of greater dilation of the stenosis, probably corresponding to more tissue injury. This may favor more rapid stenosis recurrence. Indeed, there is some indication that less traumatic dilation, for instance with a cutting balloon, results in less activation of growth factors (reviewed in Reference 23).

The combined results of this study and the study by Schwab *et al.* (18) warrant the initiation of a new discussion on the optimal timing of PTA. It is tempting to hypothesize that post-PTA patency in AVG is related to Qa_{pre} and/or the functional result of the PTA. If this is the case, then PTA should be performed as soon as a decrease in Qa is observed, as advocated by some (18,26), rather than when a low Qa value is reached, as proposed by others (7,27). In such cases, a "mild" PTA procedure may result in a better long-term outcome than a more vigorous one. The quality of patient care and the cost-effectiveness of PTA may benefit importantly from properly designed studies addressing this hypothesis.

Possibly the best way to quantify the long-term effects of PTA is to calculate secondary patency rates. However, this study was not designed to address that issue. Many patients were included in the surveillance and intervention program of this study long after access implantation. Some of them had undergone interventions before their inclusion in the study, making it impossible to express the true secondary patency rates for AVG followed by the surveillance and intervention program, as in this study. However, survival estimations of our secondary patency rates for AVG revealed a 6-mo patency rate of 85% and a 1-yr patency rate of 79%. For AVF, survival analysis demonstrated a 6-mo patency rate of 89% and a 1-yr patency rate of 82%. With the aforementioned limitation in mind, we can conclude that our secondary patency rate is comparable to the literature data on secondary patency rates (3,8).

The association between Qa and the risk of thrombosis is less well documented for AVF than for AVG. AVF with Qa levels of <300 to 500 ml/min can remain patent (3). Kidney Disease Outcomes Quality Initiative recommends that AVF should be monitored as AVG. The efficacy of PTA for AVF was comparable to that for AVG. The long-term effects for AVF seem substantially better than those for AVG. Primary (post-PTA) patency rates for AVF ranged from 47 to 67% at 6 mo and from 16 to 62% after 12 mo (8). We observed a 6-mo, intervention-free, primary patency rate of 50% and a median survival time of 161 d for AVF. None of the investigated variables was predictive of long-term results for AVF.

In conclusion, Qa increases after PTA but, in a substantial percentage of cases, not to a level of >600 ml/min. Qa before PTA and the increase in Qa were correlated with long-term outcomes, whereas angiographic results were not. These data, combined with the literature findings, suggest that there is optimal timing for PTA.

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