Peripheral Vascular Disease

A Novel Intragraft Pressure-Guided Technique versus Angiography-Guided Technique in Salvage of Thrombosed Hemodialysis Graft: A Randomized Controlled Trial

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Purpose: To evaluate the role of an intragraft pressure-guided technique (IGT) for salvaging thrombosed arteriovenous grafts (AVGs).

Methods: Ninety hemodialysis patients with acutely thrombosed AVGs were randomized into two groups: 1) the intragraft pressure-guided technique (IGT) group, and 2) the angiography-guided technique (AGT) group. In IGT, treatment sites were identified by a balloon pullback method, and then selected according to intragraft pressure (IGP) obtained after effective thrombectomy. Whenever possible, IGP was stabilized at 50-100 mmHg by performing outflow and inflow treatments, in case IGP was greater than 100 mmHg and IGP smaller than 50 mmHg, respectively. All AGT treatments were guided by angiography, and technical success was determined by angiography as well. To further ensure the integrity of this study, operating physicians were blinded to technical endpoints.

Results: Comparisons of IGT and AGT showed that IGT required significantly fewer angiograms (4.7 ± 1.9 versus 13.1 ± 3.6; $p < 0.0001$), fewer total angiographic frames (378.0 ± 168.5 versus 1504.6 ± 407.1; $p < 0.0001$), and shorter procedure time (60.1 ± 20.5 versus 106.3 ± 30.1 minutes; $p < 0.0001$) with a low complication rate (4.4%) and a high success rate (93.3%). Final IGP is useful in predicting 3-month patency (AUC = 0.77). Patients with final IGP below 80 mmHg compared to those with IGP above 80 mmHg had a significantly higher cumulative incidence of patency at 3 months (72.7% versus 39.1%; $p = 0.007$ by log-rank test).

Conclusion: The IGT is a safe and effective technique that may reduce the need for angiography and shorten the procedure time necessary to salvage AVGs. Final IGP may predict the post-salvage 3-month patency.

Key Words: Angiography • Arteriovenous graft • Intragraft pressure • Patency • Thrombectomy

INTRODUCTION

Prosthetic arteriovenous graft (AVG) plays an important role in the administration of hemodialysis. It is prone to acute thrombosis, which is the major cause of graft failure.[1-3] Percutaneous salvage is the preferred therapy in most centers,[3,4] and is conventionally guided by angiography. We observed that the salvage of thrombosed AVGs based on angiography-guided technique (AGT) may require additional angiograms and procedure times as compared to angioplasty of stenotic AVGs. A physician typically is not aware of the interval change

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whether stenotic or thrombotic lesions are effectively resolved, and intragraft blood flow is restored by endovascular treatment unless more angiograms are taken when using the AGT. Physicians fail to realize the intragraft changes at an interval between two consecutive angiographic examinations in the AGT. Additionally, the AGT does not provide hemodynamic assessments.[5] This study therefore applied intragraft pressure (IGP) as a hemodynamic marker in a novel IGP-guided technique (IGT) that was expected to provide continuous information for monitoring intragraft condition and to minimize angiograms and procedure times. Studies have revealed that IGP or the ratio of IGP to systemic pressure is associated with the lesion location, and increases with outflow stenosis, decreases with inflow stenosis, and normalizes after a successful angioplasty.[6-12] Accordingly, in this proposed IGT, outflow and inflow treatments were respectively performed when pre-treatment IGP was greater than 100 mmHg and smaller than 50 mmHg, since 90% of successful angioplasties had a final IGP of 50-100 mmHg in our earlier study.[12] Whenever possible, stepwise focal treatments were performed as needed to achieve an IGP of 50-100 mmHg. The precise treatment sites were confirmed using a balloon pullback method. The IGT is detailed in the text.

To the best of our knowledge, this study is the first reported use of IGP for guiding AVG salvage procedures. The objectives of this randomized controlled study were: (1) to compare the proposed IGT with the conventional AGT in terms of safety and effectiveness; (2) to compare the techniques in terms of need for angiography and procedural time; and (3) to test whether final IGP can predict patency outcome.

METHODS

Patient selection

Hemodialysis patients with acutely failed AVGs who were referred to our center for percutaneous salvage were eligible in this prospective, randomized, and controlled study. Patients with AVGs lacking palpable thrill and auscultative bruit, and who received a successful wiring were enrolled. They were then randomized in a consecutive 1:1 ratio to either the IGT or AGT treatment group. Patients were excluded if they did not receive angioplasty arising from the following reasons: occlusion exceeding 7 days, infected AVG, or failed wiring. The study was approved by the Institutional Research Board of our hospital, and all patients signed written informed consent before undergoing study-related procedures.

Thrombectomy and angioplasty procedures

All interventions in this study were attempted via transgraft approach with two 7-French sheaths (Introducer II, Radifocus; Terumo, Tokyo, Japan) inserted toward the middle part of an AVG (Figure 1A), although the transradial approach has been reported to be an effective option.[13] Outflow and inflow routes were confirmed according to images contained in patient medical records or blood pressure measurements at anastomosed sites using a balloon catheter (Fox plus PTA catheter; Abbott Laboratories, Abbott Park, Illinois, USA). Thereafter, 0.025- or 0.035-inch hydrophilic wires (GUIDE WIRE M, Radifocus; Terumo, Tokyo, Japan) for tracking the interventional devices were inserted into the inflow and outflow routes, respectively. In both the IGT and AGT groups, mechanical thrombectomy was undergone using thromboaspiration and double balloon occlusion technique (DBOT).[14] The DBOT was conducted using 6- and 7-mm normal-pressure balloon catheters (Fox plus PTA catheter; Abbott Laboratories, Abbott Park, Illinois, USA) in the inflow segment and outflow segment, respectively. Subsequently, enclosed clots between these two inflated balloons were washed out of the sheath sideline using approximate 30-50 cc of saline injected into the other sheath sideline (Figure 1B). The precise lesion sites were also confirmed by a balloon pullback method using an inflated balloon in the DBOT. Thromboaspiration was conducted with a 6-French guiding catheter (Judkin's Right; Cook, Bloomington, Indiana, USA) connected to a vacuum syringe. Both normal- and high-pressure balloon catheters (Conquest PTA balloon dilatation catheter; Bard, Tempe, Arizona, USA) were used. High-pressure balloon catheters were generally reserved for treating stenoses that were resistant to normal-pressure balloon angioplasty. For angioplasty, balloon size was selected according to the diameter of the graft and/or that of the adjacent normal vessel. Antithrombotic agents were administered at the discretion of the physician. A successful salvage was defined

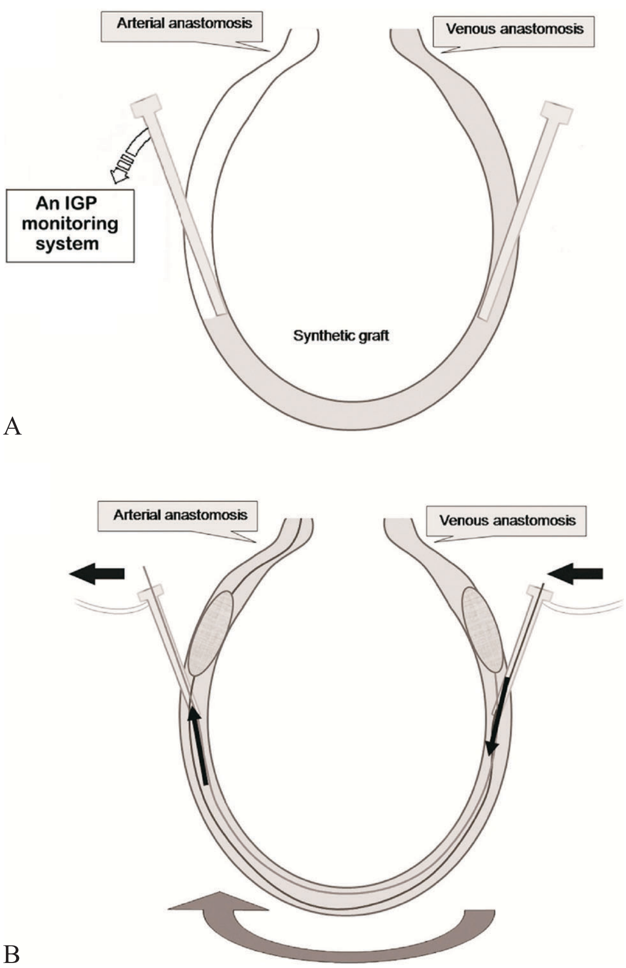

Figure 1. *(A) Definition of inflow and outflow lesions. Inflow lesions and outflow lesions were defined as lesions upstream of the sheath tip (highlighted in white) and downstream of the sheath tip (highlighted in gray), respectively. (B) Trapped clots between two inflated balloons were washed out of a sheath sideline (arrow out) using normal saline irrigation into the other sheath sideline (arrow in) in the DBOT.*

as restoration of a palpable thrill and a favorable flow by angiography. Procedure time was measured from the time of initial puncture to completion of a final angiogram. Board-certified physicians with 2-6 years experience performed the study-related procedures.

IGP-guided technique (IGT)

The IGP was obtained through thrombectomy, and then continuously displayed on a pressure transducer (Mac-Lab hemodynamic recording system; GE Healthcare, UK) linked to a sheath at the AVG artery-arm. Outflow and inflow treatments, composed of thromboaspiration and/or balloon angioplasty, were performed in patients with systolic IGP greater than 100 mmHg and smaller than 50 mmHg, respectively. This procedural setting was based on two major concepts. First, IGP is strongly associated with lesion location, which for example increases with outflow stenosis, decreases with inflow stenosis, and normalizes after a successful angioplasty.[6-12] Second, our earlier study showed that 90% of successful angioplasties had a final IGP of 50-100 mmHg.[12] If an IGP within or closer to 50-100 mmHg could be achieved by repeatedly treating either outflow or inflow lesions, one or more angiograms were required to confirm angiographic result or guide subsequent treatments. Otherwise, the unfavorable IGP far outside the 50-100 mmHg range possibly caused by vascular narrowing or/and thromboembolism was considered as a new pre-treatment IGP for determining the next treatment. This customarily would be outflow treatment in case IGP was greater than 100 mmHg, or inflow treatment if IGP was less than 50 mmHg. In this study, outflow treatments and inflow treatments were defined as treatments of segments downstream and upstream of a pressure-measured sheath-tip, respectively (Figure 1A).

Angiography-guided technique (AGT)

All lesions and treatments in the AGT group were evaluated by angiography. Initially, thrombectomy using the DBOT and thromboaspiration were repeated as needed to achieve a desired AVG flow. Outflow lesions were visualized by venograms obtained after manually injecting 5-10 cc of non-ionic contrast into a sheath. Visualizing the inflow lesion by manually compressing the outflow segment raised concerns that a sudden injection of contrast agent could cause an arterial embolism. Acknowledging this concern, a 5-French catheter (Judkin's Right; Cook, Bloomington, Indiana, USA) was gently advanced over a guide wire to the site of arterial anastomosis. Contrast medium (5-10 cc) was then slowly injected into the catheter to visualize the inflow lesion and to evaluate the post-treatment effect. A lesion with stenosis, thrombosis, or both was classified as a significant lesion if angiography indicated a 50% or more reduction in lumen diameter. As in IGT, each outflow or inflow treatment contained thromboaspiration and balloon angioplasty. The angiography-guided outflow and inflow treatments were repeated until the physicians determined a procedural end as a technical success or failure by physical examination and angiography. Total angiograms or total angiographic frames (in a setting of 15 frames/second) were summed in each index procedure. Procedure time was defined as the time between the beginning of graft puncture and completion of a final angiogram. These variables were compared between groups.

Study endpoints and follow-up

All operating physicians in the same team were blinded to the study endpoints. The number of angiographic frames was calculated by summing all angiogram frames. The angiographic findings were independently interpreted by two experienced physicians. All participants were followed up for at least 3 months after the index procedures. In the hemodialysis units, the AVG function was assessed using the clinical or hemodynamic indicators recommended by the Kidney Disease Outcomes Quality Initiative guidelines.[3] The follow-up protocol required referral to our center whenever target AVGs showed signs of malfunction. Referral for angiography and possible angioplasty were based on five criteria: (1) abnormal findings with prospective trend analysis consistent with stenosis; (2) static pressure ratio at the venous segment > 0.5; (3) static pressure ratio at the arterial segment > 0.75; (4) flow rate < 400-500 ml/min; and (5) acute occlusion. Physicians who were unaware of the study-group assignments rechecked all referred patients' AVGs using physical examination and angiography. If a percutaneous intervention or surgical intervention was required, follow-up was terminated. The duration of primary patency was defined as the time of the current salvage until any subsequent intervention or AVG abandonment. The duration of secondary patency was defined as the time of the current salvage until any subsequent surgical intervention or AVG abandonment.

Statistical analysis

All variables were analyzed using SPSS software for Windows (SPSS Inc., Chicago, Illinois, USA). Categorical data and all rates were displayed as percentages and numbers and analyzed by chi-square test or Fisher's exact test. Continuous data were expressed as means ± standard deviation and analyzed by Student's *t*-test. The IGT and AGT data were compared by independent *t*-test, and pre- and post-treatment data were compared by paired *t*-tests. The receiver operating characteristic (ROC) curve was used to detect the predictive performance of the final IGP on patency outcome and its cut-off value. Cut-off values were selected after using Kaplan-Meier analysis with log-rank test to evaluate group differences in patency. A p value < 0.05 with two-sided 95% confidence interval (CI) was considered statistically significant for all tests.

RESULTS

Baseline characteristics

From June, 2008 to July, 2010, 90 patients (40 males and 50 females) were enrolled in this study. Forty-five were randomly assigned to the IGT group and 45 were to the AGT group. The two groups had identical baseline characteristics (Table 1).

IGT versus AGT

Compared to the AGT group, the IGT group required significantly fewer total angiograms (4.7 ± 1.9 versus 13.1 ± 3.6; p < 0.0001), fewer total angiographic frames (378.0 ± 168.5 versus 1504.6 ± 407.1; p < 0.0001), and shorter procedure time (60.1 ± 20.5 versus 106.3 ± 30.1 minutes; p < 0.0001). However, the AGT and IGT groups had identical technical success rates (93.3%) and identical complication rates (4.4%). The IGT and AGT groups did not significantly differ in primary patency (57.8%, 26/45 versus 51.1%, 23/45; p = 0.627) or in secondary patency at 3 months (93.3%, 42/45 versus 93.3%, 42/45; p = 1.000) (Table 2).

Data in IGT

In the IGT group, seventy-eight focal treatments distributed among three stepwise procedures were collected and analyzed. Initially, the IGPs guided forty outflow treatments and five inflow treatments. The twenty-seven remaining IGPs far out of the range of 50-100 mmHg were unfavorable. They were considered as new pretreatment IGPs to guide seventeen outflow treatments in case the IGPs were greater than 100 mmHg, and ten inflow treatments in case the IGPs were less than 50 mmHg. Finally, the six unsatisfactory IGPs were used to guide four outflow and two inflow treatments. We further demonstrated the dynamic IGP changes in a real IGT case matched with angiographic findings (Figure 2).

Table 1. Baseline characteristics between IGT and AGT groups

Characteristic	IGT (n = 45)	AGT (n = 45)	p value*
Gender (F/M)	55.6% (25/20)	55.6% (25/20)	1.000
Age (year-old)	64.6 ± 13.4	62.5 ± 11.7	0.427
Diabetes	40.0% (18/45)	35.6% (16/45)	0.828
Hypertension	40.0% (18/45)	42.2% (19/45)	1.000
HD duration (years)	4.2 ± 4.3	4.0 ± 3.3	0.885
Graft age (years)	2.3 ± 2.0	2.3 ± 1.7	0.955
Occlusion duration (days)†	2.4 ± 1.7	2.7 ± 1.4	0.311
Recurrent lesion	68.9% (31/45)	62.2% (28/45)	0.658
Use of HP balloon catheter	13.3% (6/45)	11.1% (5/45)	1.000
Use of heparin	71.1% (32/45)	75.6% (34/45)	0.812
Use of urokinase	86.7% (39/45)	84.4% (38/45)	1.000

* Comparison between IGT and AGT groups by chi-square test for categorical variables and by independent *t*-test for continuous variables.

† Occlusion duration was calculated from the last day of hemodialysis until the day of AVG confirmed AVG failure.

AGT, angiography-guided technique; HD, hemodialysis; HP, high-pressure; IGT, intragraft-guided technique.

Table 2. Procedural data and patency outcomes between IGT and AGT groups

	IGT (n = 45)	AGT (n = 45)	p value*
Angiogram (n)	4.7 ± 1.9 (1-9)	13.1 ± 3.6 (6-22)	< 0.0001
Angiographic frames (n)	378.0 ± 168.5	1504.6 ± 407.1	< 0.0001
Procedural time (minutes)	60.1 ± 20.5 (28-108)	106.3 ± 30.1 (55-189)	< 0.0001
Complications	4.4% (2/45)	4.4% (2/45)	1.000
Mild hemotoma	4.4% (2/45)	4.4 (2/45)	
Venous rupture	0% (0/45)	0% (0/45)	
Symptomatic embolic event	0% (0/45)	0% (0/45)	
Technical success	93.3% (42/45)	93.3% (42/45)	1.000
Primary patency at 3 months	57.8% (26/45)	51.1% (23/45)	0.627
Secondary patency at 3 months	93.3% (42/45)	93.3% (42/45)	1.000

* Comparison between IGT and AGT groups by chi-square test for categorical variables and by independent *t*-test for continuous variables.

Outflow treatments significantly decreased mean systolic IGP in 61 patients (from 160.4 ± 37.3 to 85.1 ± 31.7 mmHg; p < 0.0001), and inflow treatments significantly increased mean systolic IGP in 17 patients (from 43.5 ± 22.8 to 118.3 ± 40.2 mmHg; p < 0.0001) in our IGT group. After completing the procedure, the patient group had a mean systolic IGP (final IGP) of 85.5 mmHg (85.5 ± 27.9 mmHg, 37-140 mmHg) (Table 3).

The ROC curve analysis confirmed that final IGP was a good predictor for 3-month primary patency (area under the ROC curve = 0.77; 95% confidence interval; 0.63-0.92; p = 0.002). For a cut-off of 80 mmHg, sensitivity was 60.0%, and specificity was 80.0% (Figure 3A). The primary patency rates were calculated using Kaplan-Meier estimates and were compared between the patients with final IGP below 80 mmHg, and those patients with final IGP above 80 mmHg using the log-rank test. The patient group with final IGP below 80 mmHg had a significantly higher patency rate at 3 months as compared to that with final IGP above 80 mmHg (72.7%, 16/22 versus 39.1%, 9/23; p = 0.007 by the log-rank test) (Figure 3B).

DISCUSSION

This prospective, randomized, and controlled study analyzing hemodialysis patients with thrombosed AVGs

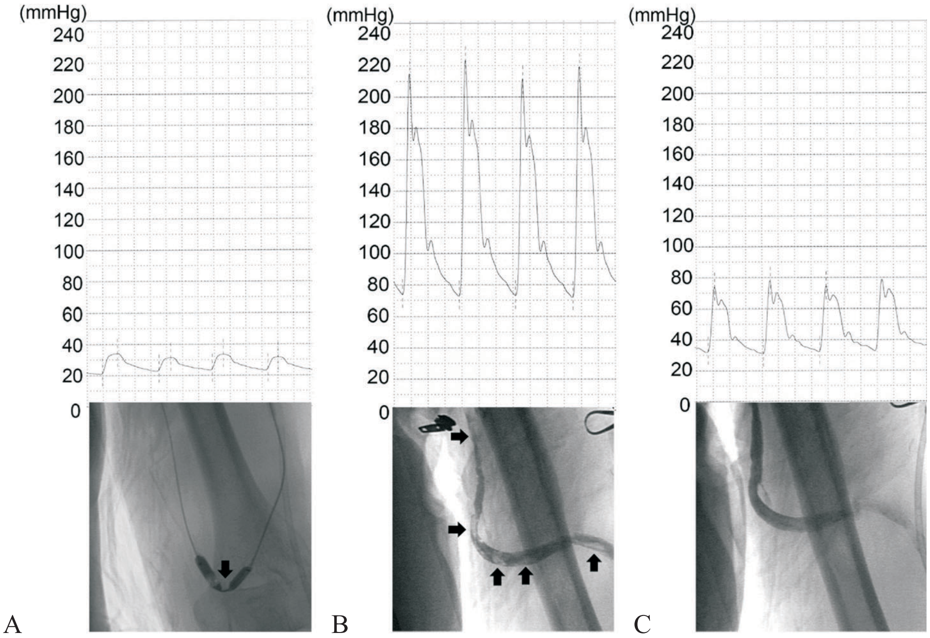

Figure 2. *A case presentation for the IGP-guided technique. (A) The left column displays the low systolic IGP of 32 mmHg directing the inflow treatment. The lesion (arrow) is demonstrated with the narrowing of an inflated balloon. (B) After the inflow treatment, the IGP became remarkably high (213 mmHg). The angiogram presents a few defects of contrast filling indicating residual thrombi (arrows). (C) The IGP exhibited an acceptable level of 75 mmHg after the outflow treatment, consistent with an optimally angiographic result.*

Table 3. Procedural data and patency outcomes in the IGT group

Mean final IGP (mmHg)	85.5 ± 27.9 (37-140)
Distribution of final IGPs	
< 50 mmHg	8.9% (4/45)
50-100 mmHg	62.2% (28/45)
> 100 mmHg	28.9% (13/45)
Outflow and inflow treatments (n = 78)	
Outflow treatments (n = 61, 78.2%)	
Pre-treatment IGP (mmHg)	160.4 ± 37.3 (99-269)
Post-treatment IGP (mmHg)	85.1 ± 31.7 (37-159)*
Inflow treatments (n = 17, 21.8%)	
Pre-treatment IGP (mmHg)	43.5 ± 22.8 (10-79)
Post-treatment IGP (mmHg)	118.3 ± 40.2 (68-223)*
Primary patency rate	
at 1 month	84.4% (38/45)
at 2 months	71.1% (32/45)
at 3 months	57.8% (26/45)

All displayed pressures are systolic pressures.
* p < 0.0001 (comparison before and after treatments by paired *t*-test).

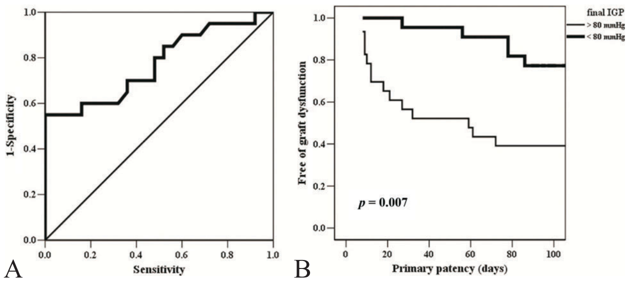

Figure 3. *(A) The predictive performance of final IGP for 3-month primary patency was confirmed by an area under the receiver operating characteristic (ROC) curve of 0.77. (B) Kaplan-Meier survival analysis illustrates superior 3-month primary patency in patients with final IGP below 80 mmHg compared to those with final IGP above 80 mmHg (p = 0.007 by log rank test).*

receiving the IGT or the AGT has disclosed three major findings: (1) that the low complication rate and high technical success rate by definition observed in this study confirm that both the IGT and the AGT are safe and effective; (2) that the IGT has been proven to significantly reduced both the need for angiography and the necessary procedure time compared to the AGT; (3) that IGP may be a valuable adjuvant guide and a good predictor for 3-month primary patency.

First, IGP alone appears to be promising in its capacity to serve as a hemodynamic indicator, like the IGP-systemic pressure ratio conventionally used for post-angioplasty assessment.[7-10] Indeed, the literature implies that, in patients who have received successful angioplasties, pressure ratios are normalized mainly by changes in IGP rather than in systemic artery pressure.[7-10,12] That is, IGP indicates normalization of pressure ratio whereas systemic artery pressure does not. Another problem is that using cuff blood pressure on the opposite arm to represent feeding artery pressure instead of directly measuring feeding artery pressure may obtain an inaccurate ratio.[7-9] A final problem is the impracticality of repeatedly recording systemic pressure and making calculations during salvage procedures if guidance is provided using IGP-systemic pressure ratios. Therefore, we propose the simplification of this technique by using IGP alone rather than pressure ratio. On the other hand, although many thrombectomy devices and techniques have been reported,[14-19] the DBOT was applied in this study as a part of the IGT or the AGT.[14] Freedom from iatrogenic arterial embolism in our series of 90 cases may be due to an inflated balloon at the AVG arterial limb during thrombectomy procedures. This design had been documented to be safe and effective (Figure 1B).[14]

Second, percutaneous salvage of thrombosed AVGs is involved with both outflow and inflow treatments.[14-19] As noted above, IGP varies according to the lesion location. IGP generally increases in the presence of an outflow lesion and decreases in the presence of an inflow lesion.[6-12] Application of IGP to select the treatment site was strengthened by our subsequently responsive IGPs and consistent angiographic findings. Our results also demonstrated that, in most patients, IGP promptly responded to the outflow treatments in a descendant manner and the inflow treatments in an ascendant manner, respectively. Consistent with the hemodynamic pressure profiles in previous studies,[6-12] our data regarding post-treatment IGPs have reinforced that, in general, IGP significantly declines after outflow treatments, significantly increases after inflow treatments, and normalizes after effective angioplasties. Furthermore, two IGP thresholds of 50 and 100 mmHg used in this proposed IGT have been proven to be valid for continuously guiding treatments particularly when the lesion is not visualized at an angiography-free interval. Achievement of 50-100 mmHg of IGP by repetitive treatments, when possible, may indicate an appropriate timing for taking angiograms, and as a result, angiograms may be minimized. These may explain our results that the IGT group was likely to require less angiography and procedure time as compared to the AGT group. We surmise that the reduced number of required angiograms and related procedures at least partially explains the shorter procedure time in the IGT group. The similar patency outcomes obtained by the IGT and AGT was possibly caused by their same balloon-based treatment strategy.

Finally, IGP is not only a valuable adjuvant guide for such salvage procedures, but also a good predictor of 3-month primary patency as shown in ROC analysis. In terms of clinical implications, our data further depicted that aggressive outflow treatment to achieve a final IGP lower than 80 mmHg might improve 3-month primary patency as compared to a final IGP remaining higher than 80 mmHg. A final IGP, to some degree, may quantify the technical result consistent with angioplastic findings, and predict subsequent short-term patency outcome. Taken together, intraprocedural IGP is useful for selecting the treatment site, quantifying the angioplastic result, and predicting the patency outcome in the salvage of thrombosed AVGs.

Our study had several limitations and cautions. First, the disadvantage of the IGT includes the need of adequate awareness of complex hemodynamics as background knowledge. The IGP data should be interpreted cautiously on the basis of comprehension of AVG hemodynamics. Analyzing trends in IGP may be more informative and reliable than analyzing a single value. Remarkably, a pseudo-normalization of IGP presented with coexisting outflow and inflow lesions may be hard to distinguish from an actual normalization achieved by a successful intervention. In such cases, both IGP monitoring and angiography are suggested. Second, in patients with pseudo-normalized IGP, an inflow treatment must be performed prior to an outflow treatment in order to regain an adequate flow and a typical IGP presentation.[11] Third, the outflow route must be distinguished from the inflow route. A feeding artery may be injured by the procedures done in the outflow vein, especially when the routes are not visualized. Fourth, the dysfunction-driven referrals may potentially produce outcome bias. Finally, this study analyzed only the transgraft approach with two-sheath setting performed in a single center.

CONCLUSION

The IGT is a safe and effective method for guiding

AVG salvage procedures, and reduces the need for angiography and shortens the procedure time compared with the AGT. In addition, our data suggest that final IGP is a good predictor of 3-month primary patency and aggressive outflow treatment to reduce final IGP below 80 mmHg may enhance the 3-month primary patency rate.

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