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CLINICAL INVESTIGATION VENOUS INTERVENTIONS

The Efficacy of Paclitaxel Drug-Eluting Balloon Angioplasty Versus Standard Balloon Angioplasty in Stenosis of Native Hemodialysis Arteriovenous Fistulas: An Analysis of Clinical Success, Primary Patency and Risk Factors for Recurrent Dysfunction

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Abstract

Purpose To investigate the efficacy of paclitaxel drug-eluting balloons (PEB) versus standard balloon angioplasty (BA) in stenosis of native hemodialysis arteriovenous fistulas (AVFs).

Materials and Methods A total of 96 patients with ESRD (mean ± SD age 57.0 ± 9.1 years, 63.5% were males) who underwent endovascular treatment with PEB angioplasty ($n = 32$) and BA ($n = 64$) for a dysfunctional native AVF were included. Clinical success, complications, primary patency and postoperative recurrence parameters were recorded in each group.

Results Primary patency rate at 6 months was significantly higher in PEB than in BA group (96.9 vs. 20.3%, $p < 0.001$), while the two groups had similar primary patency rates at 9 months (66.8 vs. 50.0%) and 12 months (6.3% for each). No significant difference was noted between PEB and BA groups in terms of the rate (21.9% and. 31.3%), time (median 220 vs. 152.5 days) and reasons (reocclusion in 18.8 vs. 28.1%) for dysfunction recurrence as well as the number of recurrent treatments. AVF dysfunction recurrence was more likely in younger age AVF (median 4 vs. 23 months, $p < 0.001$ in PEB, and 8.5 vs. 20.5 months $p = 0.001$ in SBA) and in AVF $\leq$ 6 months in both SBA and PEB groups (71.4 vs. 12.0%, $p = 0.005$ in PEB, 40.0 vs. 2.3%, $p < 0.001$).

Conclusion In conclusion, our findings emphasize favorable safety and efficacy of PEB and BA in the management of dysfunctional hemodialysis AVFs with similar rates of post-PTA recurrence of AVF dysfunction. Nonetheless, there was a nonsignificant tendency for lower rate and a delay for recurrent dysfunction in patients treated with PEB and a significant association younger AVF age with an increased risk of post-PTA recurrence of AVF dysfunction.

Level of Evidence 3, Retrospective cohort study.

Keywords Paclitaxel drug-eluting balloon angioplasty · Standard balloon angioplasty · Hemodialysis · Arteriovenous fistula · Clinical success · Primary patency · Recurrent dysfunction

Introduction

Maintenance of long-term patency of hemodialysis vascular access is essential in patients with end-stage renal disease (ESRD) [1–4]. Although arteriovenous fistula (AVF) remains the best conduit for adequate hemodialysis [5–8], AVF dysfunction is commonly observed in clinical practice with a growing need for techniques to maintain patency of AVF in the dialysis population [2, 5, 6, 9, 10].

Percutaneous transluminal angioplasty (PTA) has been the mainstay of treatment in dysfunctional AVFs, whereas 1-year patency rates range from 60 to 65% [4, 5].

Paclitaxel, an antineoplastic agent with a durable inhibitory effect on neointimal proliferation [11, 12], has been associated with prevention of restenosis in other vascular

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beds [13–15]. This has led to a growing scientific interest in recent years in the potential role of paclitaxel-eluting balloon (PEB) angioplasty in improving patency rates and decreasing the risk of restenosis in patients with dysfunctional AVFs [16–21]. However, published evidence from the current literature is considered to be limited and clinically heterogeneous [22–24].

The purpose of this retrospective study was to investigate the efficacy of PEB angioplasty versus standard balloon angioplasty (BA) in stenosis of native hemodialysis AVFs in terms of clinical success, primary patency and risk factors for recurrent dysfunction.

Materials and Methods

Study Population

A total of 96 consecutive patients with ESRD (mean ± SD age 57.0 ± 9.1 years, 63.5% were males) who underwent endovascular treatment with either PEB (n = 32; treated in the 2015–2017 period) or BA (n = 64; treated in the 2010–2014 period) for a dysfunctional native AVF were included in this retrospective study conducted at two radiology clinics between September 2010 and February 2017. Follow-up visits were performed based on 3-month intervals in accordance with the routine follow-up protocol. The patients included in the study were those who were referred for fistulography with clinical signs of stenosis, while patients who had PTA combined with stenting, previous PTA for the same lesion or previous access thrombectomy were excluded from the study.

The study was conducted in full accordance with local GCP guideline and current legislations, and permission was obtained from the Institutional Ethics Committee for the use of patient data for publication purposes.

Study Parameters

Data on patient demographics (age, gender), etiology of ESRD, characteristics of AVF, PTA parameters (clinical success, complications), primary patency and postoperative recurrence parameters were recorded. The study parameters were evaluated in PEB versus BA groups and with respect to patients with versus without post-PTA recurrent AVF dysfunction during median 9.8 months (range 6.6–13.3 months) of follow-up.

Radiological Interventions

All radiological interventions in both study centers were performed by the same experienced interventional radiologist. Before fistulography, the patients were examined using color Doppler ultrasound (Logiq S8, GE, Milwaukee, WI, USA). The angiographic technique for diagnosis involved fistulography via brachial artery puncture with a 21G needle and injection of 10 mL of contrast under local anesthesia. Digital angiographic images were obtained of the feeding artery, arteriovenous anastomosis, juxta-anastomotic segment of the efferent vein and draining veins up to the central veins.

The stenosis was evaluated by comparing the stenotic and normal segments of the veins together with implementation of PTA for the stenotic segments with a diameter of < 50% of the normal segment. PTA was performed through the transvenous approach. Proximal access was achieved through the outflow vein with 7F vascular sheath insertion. Heparin was administered at a dose of 2500 IU, and an additional dose of 1250 IU was administered once every hour, if needed. The maximum dose was 5000 IU. Balloon size was determined according to the measured diameter of the reference vessel. According to the size of the veins, PEBs and standard balloons with a diameter of 1 mm greater than the normal size of the venous segment (range 4–7 mm) were used. In the BA group, standard balloons (Medtronic, Minneapolis, MN, USA) or high-pressure or non-compliant balloons (Conquest, Bard, Oakville, CA) in case of failure of procedure were used. In the PEB group, a Freeway 0.35 (Eurocor, Germany) over-the-wire balloon was used. The balloon was maintained insufflated for 2 min, and the procedure was repeated if necessary. Hemostasis was achieved with manual compression. If stenosis was < 30% after PTA, the procedure was considered technically successful. Clinical success was defined as adequate dialysis after the procedure.

Complications and Patency Rates After PTA

All patients were followed up for at least 6 months in their dialysis centers after PTA. Categorization of minor and major complications was based on the Society of Cardiovascular and Interventional Radiology criteria [25]. If there was a suspicion of restenosis based on clinical examination or dialysis parameters, angiography was performed. Primary patency was defined as the interval between the initial salvage procedure and the next thrombosis or repeat intervention, as previously described by Gray et al. [26]. During this period, the patients received percutaneous treatment for recurrent or new access stenosis/occlusion.

Statistical Analysis

Statistical analysis was made using IBM SPSS Statistics for Windows, Version 24.0 software (IBM Corp., Armonk, NY). Fisher's exact test, Pearson Chi-square test and Fisher–Freeman–Halton test (Monte Carlo) were used to analyze categorical variables, while numerical data were analyzed using the independent samples t test and the Mann–Whitney U test. Multivariate logistic regression analysis was performed to determine risk factors for recurrent AVF dysfunction using the forward stepwise (likelihood ratio) method. Data were expressed as mean ± standard deviation (SD), minimum–maximum values, number (n) and percentage (%) where appropriate. A value of $p < 0.05$ was considered statistically significant.

Results

Overall Characteristics

Males composed 63.5% of the total study population, and the average age was 57.0 years (range 37–78 years) (Table 1).

All of AVFs were already in use for dialysis, while insufficient fistula maturation was evident only in one patient with AVF age of 1.5 months. The median age of AVF was 18 (range 1.5–72) months ($\geq$ 6 months in 82.3% of patients). AVF was left-sided in 58.3% of patients and radiocephalic in 56.3% (Table 1).

Clinical success was achieved in 97.9% of patients with minor complications in two (3.2%) patients. The median duration of follow-up was 292.5 days (range 198–400 days). Median duration of primary patency was 270 (range 60–400) days overall, with primary patency rates of 45.8% at 6 months, 56.3% at 9 months and 6.3% at 12 months. Dysfunction recurrence was noted in 28.1% of patients (due to reocclusion in 25.1%) after median 180 (range 60–330) days (Table 1).

Demographic and Clinical Characteristics in PEB Versus BA Groups

PEB versus BA was associated with higher rate of right-sided AVF (65.6% vs. 29.7%, $p < 0.001$) and brachiocephalic AVF (53.1% vs. 1.6%, $p < 0.001$), and a lower rate of radiocephalic AVF (34.4% vs. 67.2%, $p < 0.001$) (Table 1).

Primary patency rate at 6 months was significantly higher in PEB than in BA group (96.9 vs. 20.3%, $p < 0.001$), while the two groups had similar primary patency rates at 9 months (66.8 vs. 50.0%) and 12 months (6.3% for each). No significant difference was noted between PEB and BA groups in terms of the rate (21.9% and. 31.3%), time (median 220 vs. 152.5 days) and reasons (reocclusion in 18.8 vs. 28.1%) for dysfunction recurrence as well as the in terms of the number of recurrent treatments (Table 1).

Recurrence-Related Parameters in the PEB Versus BA Groups

AVF dysfunction recurrence was more likely in males than in females treated with BA (90.0% vs. 10.0%, $p = 0.010$), and in patients with younger age AVF ($\leq$ 6 months) in both BA (71.4 vs. 12.0%, $p = 0.005$) and PEB (40.0 vs. 2.3%, $p < 0.001$) groups (Table 2, Fig. 1).

Patient age, comorbid diabetes or hypertension rates, and side and type of AVF as well as the type of fistula segment had no impact on recurrence rates. The likelihood of recurrence in patients with young AVF age ($\leq$ 6 months) was also similar with respect to AVF lesion morphology (anastomotic—mechanical or vein obstruction) in both treatment groups (Table 2).

Discussion

Our findings revealed a significantly higher primary patency rate at 6 months (96.9 vs. 20.3%) in the PEB than in the BA group, alongside a tendency for higher primary patency rate at 9 months (66.8 vs. 50.0%) and a lower likelihood (21.9 vs. 31.9%) and a delay (median 220 vs. 152.5 days) of recurrent AVF dysfunction in the PEB group. Recurrent AVF dysfunction was more likely in patients with younger age AVF in both BA and PEB groups.

Past studies with up to 12-month follow-up period revealed heterogeneous findings on patency outcome of PEB versus BA in the treatment of failing AVFs. In a retrospective analysis of 52 patients with significant AVF stenosis, PEB versus BA was reported to be associated with a significantly higher primary patency rate at 12 months (65.4 vs. 34.6%), with similar outcome at 6 months (76.9 vs. 65.4%) [4]. In a prospective, randomized study of 64 patients with autologous dialysis fistulae, primary patency rates after PEB at 3 months (88 vs. 80%), 6 months (67 vs. 65%) and 12 months (42 vs. 39%) were reported to be slightly better than those after plain BA [27]. Similarly, data from other prospective randomized studies revealed significantly higher primary patency rates for drug-coated balloons (DCB) compared to plain BA at 6 months (70% vs. 25%) [17] and 12 months (35.0 vs. 5.0%) [18].

However, in a longer-term study on comparison of failing AVFs treated with DCB versus plain BA, target lesion primary patency was reported to be significantly higher in the DCB balloon group at 6 months (90.3 vs. 61.3%), 12 months (77.4 vs. 29%) and 24 months (45.2 vs. 16.1%), alongside a lower rate of repeated interventions (38.7 vs. 80.6%) [28].

Notably, in a systematic review of 6 studies on DCB versus other methods for arteriovenous hemodialysis

Table 1 Demographic and clinical characteristics overall and in the balloon angioplasty groups

	Total (n = 96)	Paclitaxel-eluting BA (n = 32)	Standard BA (n = 64)	p value
Patient demographics				
Gender, n(%)				
Female	35 (36.5)	14 (43.8)	21 (32.8)	0.369[1]
Male	61 (63.5)	18 (56.3)	43 (67.2)	
Age (y), mean ± SD	57.0 ± 9.1	55.0 ± 10.9	58.0 ± 8.0	0.155[2]
Follow-up time (day)				
Mean ± SD	292.2 ± 48.1	296.9 ± 41.1	289.9 ± 51.4	0.933[2]
Median (min–max)	292.5 (198–400)	300 (210–400)	290 (198–400)	
Diabetes mellitus				
Absent	10 (21.7)	4 (17.4)	6 (26.1)	0.722[3]
Present	36 (78.3)	19 (82.6)	17 (73.9)	
AVF characteristics				
Age of AVF (month)				
Median (min–max)	18 (1.5–72)	20 (3–59)	17.5 (1.5–72)	0.595[4]
≤ 6 months, n(%)	17 (17.7)	8 (25.0)	9 (14.1)	0.256[3]
> 6 months, n(%)	79 (82.3)	24 (75.0)	55 (85.9)	
Type, n(%)				
Brachiocephalic	18 (18.8)	17 (53.1)*	1 (1.6)	< 0.001[5]
Radiocephalic	54 (56.3)	11 (34.4)*	43 (67.2)	
Brachiobasilic	24 (25.0)	4 (12.5)	20 (31.3)	
Fistula segment				
Central	7 (7.0)	3 (9.0)	4 (6.0)	0.824[5]
Anastomosis	27 (28.0)	8 (25.0)	19 (30.0)	
Juxta-anastomotic	36 (38.0)	11 (34.0)	25 (39.0)	
Efferent	26 (27.0)	10 (31.0)	16 (25.0)	
PTA success, n(%)				
No	2 (2.1)	0 (0.0)	2 (3.1)	0.551[3]
Yes	94 (97.9)	32 (100.0)	62 (96.9)	
Primary patency rate, n(%)				
6 months	44 (45.8)	31 (96.9)	13 (20.3)	< 0.001[1]
9 months	54 (56.3)	22 (66.8)	32 (50.0)	0.126[1]
12 months	6 (6.3)	2 (6.3)	4 (6.3)	0.999[1]
Duration of patency				
Days, median (min–max)	270 (60–400)	290 (150–400)	267.5 (60–400)	0.076[2]
Months, median (min–max)	9.0 (2.0–13.3)	9.7 (5.0–13.3)	8.9 (2.0–13.3)	
Recurrence, n(%)				
Absent	69 (71.9)	25 (78.1)	44 (68.8)	0.471[1]
Present	27 (28.1)	7 (21.9)	20 (31.3)	
Reasons for recurrence, n(%)				
Reocclusion	24 (25.0)	6 (18.8)	18 (28.1)	0.999[3]
Thrombosis	3 (3.1)	1 (3.1)	2 (3.1)	
Time to recurrence (day)				
Mean ± SD	185.6 ± 86.3	224.3 ± 57.1	172.0 ± 91.7	0.089[2]
Median (min–max)	180 (60–330)	220 (150–300)	152.5 (60–330)	
Number of recurrent treatments, n(%)				
0	64 (66.7)	39 (60.9)	25 (78.1)	0.153[5]
1	5 (5.2)	5 (7.8)	0 (0.0)	
2	27 (28.1)	20 (31.3)	7 (21.9)	

AVF arteriovenous fistula, *BA* balloon angioplasty, *SD* standard deviation, *PTA* percutaneous transluminal angioplasty

[1]Pearson Chi-square test (Exact), [2]Independent samples *T* test(Bootstrap), [3]Fisher exact test (Exact) [4]Mann–Whitney *U* test (Monte Carlo), [5]Fisher–Freeman–Halton test (Monte Carlo)

*$p < 0.001$ compared to SBA

Table 2 Demographic and clinical characteristics according to recurrence overall and in the balloon angioplasty groups

	Paclitaxel-eluting BA (*n* = 32)		*p* value	Standard BA (*n* = 64)		*p* value	Total (*n* = 96)		*p* value
	Recurrence			Recurrence			Recurrence		
	No (*n* = 25)	Yes (*n* = 7)		No (*n* = 44)	Yes (*n* = 20)		No (*n* = 69)	Yes (*n* = 27)	
Patient demographics									
Gender, *n* (%)									
Female	12 (48.0)	2 (28.6)	0.426[1]	19 (43.2)	2 (10.0)	**0.010[1]**	31 (44.9)	4 (14.8)	**0.009[1]**
Male	13 (52.0)	5 (71.4)		25 (56.8)	18 (90.0)		38 (55.1)	23 (85.2)	
Age (year), mean ± SD	54.6 ± 12.0	56.3 ± 6.2	0.727[2]	56.7 ± 6.9	60.9 ± 9.4	0.079[2]	55.9 ± 9.1	59.7 ± 8.8	0.081[2]
Diabetes mellitus									
Absent	4 (23.5)	0 (0.0)	0.539[1]	2 (66.7)	4 (20.0)	0.155[1]	6 (30.0)	4 (15.4)	0.292[1]
Present	13 (76.5)	6 (100.0)		1 (33.3)	16 (80.0)		14 (70.0)	22 (84.6)	
AVF characteristics									
Age of AVF (month)									
Median (min–max)	23 (4–59)	4 (3–21)	**< 0.001[3]**	20.5 (4–72)	8.5 (1.5–42)	**0.001[3]**	21 (4–72)	7 (1.5–42)	**< 0.001[3]**
≤ 6 months, *n*(%)	3 (12.0)	5 (71.4)	**0.005[1]**	1 (2.3)	8 (40.0)	**< 0.001[1]**	4 (5.8)	13 (48.1)	**< 0.001[1]**
> 6 months, *n*(%)	22 (88.0)	2 (28.6)		43 (97.7)	12 (60.0)		65 (94.2)	14 (51.9)	
Type, *n*(%)									
Brachiocephalic	14 (56.0)	3 (42.9)	0.836[5]	0 (0.0)	1 (5.0)	0.160[1]	14 (20.3)	4 (14.8)	0.460[5]
Radiocephalic	8 (32.0)	3 (42.9)		28 (63.6)	15 (75.0)		36 (52.2)	18 (66.7)	
Brachiobasilic	3 (12.0)	1 (14.3)		16 (36.4)	4 (20.0)		19 (27.5)	5 (18.5)	
Fistula segment, n(%)									
Total									
Central	1 (4.2)	2 (28.6)	0.221[5]	1 (2.8)	3 (10.7)	0.449[5]	2 (3.3)	5 (14.3)	0.100[5]
Anastomotic	7 (29.2)	1 (14.3)		11 (30.6)	8 (28.6)		18 (30.0)	9 (25.7)	
Juxta-anastomotic	7 (29.2)	3 (42.9)		13 (36.1)	12 (42.9)		20 (33.3)	15 (42.9)	
Efferent	9 (37.5)	1 (14.3)		11 (30.6)	5 (17.9)		20 (33.3)	6 (17.1)	
Young AVF age (≤ 6 months)									
Anastomotic (mechanical)	2 (66.7)	4 (80.0)	0.999[1]	1 (100.0)	6 (75.0)	0.999[1]	3 (75.0)	10 (76.9)	0.999[1]
Vein obstruction	1 (33.3)	1 (20.0)		0 (0.0)	2 (25.0)		1 (25.0)	3 (23.1)	

AVF arteriovenous fistula, *BA* balloon angioplasty, *SD* standard deviation

[1]Fisher exact test, [2]Independent samples *T* test (Bootstrap), [3]Mann–Whitney *U* test (Monte Carlo), [4]Pearson Chi-square test (Exact), [5]Fisher–Freeman–Halton test (Monte Carlo)

access stenosis in 162 participants with a median 13 months (range 6–24 months) of follow-up, significantly higher primary patency rates were reported at 6 months with DCB (range 70–97%) than with other methods (range 0–26%) [24]. However, the authors emphasized the need for large multicenter randomized controlled trials (RCTs) to clarify the role of DCB in the percutaneous treatment of AV HD access stenosis, given the limited and clinically heterogeneous evidence from the current literature [24].

The high prevalence of radiocephalic type of AVF and comorbid diabetes in our cohort seems in line with the consideration of radiocephalic fistula as the most commonly preferred type of AVF [5, 29] and its association with a higher likelihood of AVF failure especially in diabetic patients [5, 8, 29–31]. Our findings revealed no significant impact of AVF type on recurrence rates, regardless of the balloon angioplasty method. Nonetheless, the similar rates for PTA success in the PEB and BA groups together with the tendency for lesser and later recurrence in PEB in the current study cohort should be interpreted in the light of the lower prevalence of radiocephalic type of AVF in the patients treated with PEB than in those treated with BA.

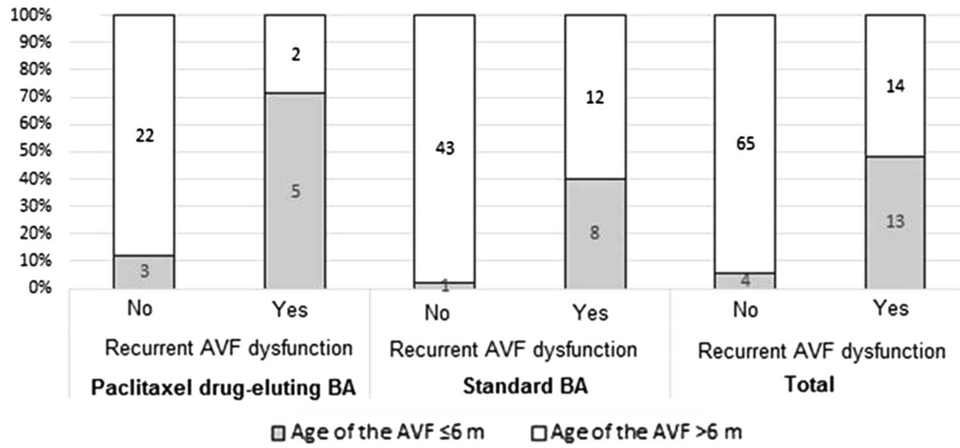

Fig. 1 Recurrent AVF dysfunction rates in paclitaxel drug-eluting balloon angioplasty and standard balloon angioplasty groups according to age of AVF

Our findings indicated a higher likelihood of postoperative AVF dysfunction recurrence in patients with younger age AVF (≤ 6 months), regardless of the angioplasty method. This supports data from previous studies that have revealed a higher likelihood of post-PTA recurrence of AVF dysfunction with younger AVF age (< 6 months) of fistula before the first failure [32–35]. The association of younger AVFs with poor post-PTA patency has been considered to indicate the predictive role of hemodynamic shear stress and anatomic factors in the occurrence of restenosis [36].

While older patient age [2, 37], presence of diabetes [33, 38, 39] and longer-segment stenosis [36] have also been reported to predict a risk of post-PTA recurrence, our findings revealed no association of patient age or comorbid diabetes, or type or side of AVF and type of fistula segment with recurrence risk in both the PEB and BA groups.

Albeit not statistically significant, there was a tendency for a lower likelihood (21.9 vs. 31.9%) and a delay (median 220 vs. 152.5 days) of recurrent AVF dysfunction in the PEB than in BA group in our cohort, while the number of recurrent treatments was similar between two treatment groups. Past studies revealed inconsistent findings on restenosis rate and interval after PEB versus BA treatments in primary or recurrent stenosis in a failing native AVF. PEB was shown to be associated with significantly prolonged restenosis intervals (median 9 vs. 4 months) compared to plain BA [40] and a significant delay in restenosis and a reintervention-free period of at least 12 months [41] in some studies. However, poorer target lesion revascularization-free survival (relative risk for DCB 7.09) and shorter time-to-target lesion revascularization (110 vs. 193 days) with PEB [42] as well as no beneficial effects over BA in the prevention of recurrent stenosis with primary patency duration of 130 versus 189 days, respectively [43] have also been reported.

No significant difference was noted in the likelihood of recurrence with respect to type of fistula segment in our cohort, while the likelihood of recurrence in patients with young AVF age (≤ 6 months) was also similar with respect to AVF lesion morphology (anastomotic—mechanical or vein obstruction) in both treatment groups. In fact, from the initial experiences with PEB of vascular access stenoses, it has been considered to be a safe and effective alternative, providing superior reintervention-free intervals compared to plain BA, by reducing restenosis without any device-related complications. However, a need for further large-scale RCTs has been emphasized to verify the clear benefit of PEB in the treatment of dysfunctional AVFs, as to date few dialysis patients treated with PEB have been reported and there is a lack of data on the type of lesions that would benefit most from this technology [22–24].

Certain limitations to this study should be considered. First, due to the retrospective design of the present study and the relatively small number of patients, it was difficult to establish temporality between cause and effect and to generalize the findings to the overall dysfunctional vascular access population. Therefore, further randomized studies are required to verify these findings. Lack of data on preoperative artery and vein size, pre- and post-intervention shunt volume is another limitation which otherwise would extend the knowledge achieved in the current study. Third, the imbalance of the location of the fistula (brachiocephalic vs. radiocephalic) seems to be another important limitation which might lead to the results of the treatment groups to be less comparable.

Conclusion

In conclusion, our findings in a retrospective cohort of ESRD patients emphasize the favorable safety and efficacy of PEB and BA in the management of dysfunctional hemodialysis AVFs with similar rates of post-PTA recurrence of AVF dysfunction. Nevertheless, PEB was superior to BA in terms of primary patency rate at 6 months, while there was a nonsignificant tendency for lower rate and a delay in recurrent dysfunction in patients treated with PEB. Younger AVF age seems to be associated with a higher risk of increased risk of post-PTA recurrence of AVF dysfunction, regardless of balloon angioplasty method. These findings emphasize the need for future larger scale RCTs to validate the potential efficacy of PEB angioplasty in improving clinical outcomes and to provide high-quality evidence to help establish specific indications for the use of this technology in dialysis access stenosis.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Consent for Publication While the present study was exempt from the requirement of ethical approval in relation to its retrospective design, the permission was obtained from our institutional ethics committee for the use of patient data for publication purposes.

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