Research Article

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Longitudinal Micro-Incisions Prior to Balloon Angioplasty for Treatment of Arteriovenous Access Dysfunction in a Real-World Patient Population: 12-Month Cohort Analysis

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Abstract

Objective

Patients relying on hemodialysis often experience stenotic lesions in their vascular access and require percutaneous transluminal balloon angioplasty (PTA) to restore patency. Recently, an innovative device has become available that creates longitudinal, controlled-depth micro-incisions to prepare the blocked vessel before PTA. This study assessed the 12-month patency rates following this novel vessel preparation and PTA in patients with vascular access dysfunction from a real-world registry.

Methods

This multicenter, prospective, observational registry (FLEX AV) enrolled hemodialysis patients scheduled to undergo PTA of their arteriovenous fistula or graft due to clinical or hemodynamic abnormalities. A primary endpoint was anatomic success, defined as angiographic confirmation of <30% residual stenosis post-procedure without an adverse event. Additional assessments included device technical success, clinical success, target lesion primary patency, freedom from target lesion revascularization, and circuit primary patency at 12 months. Patients receiving PTA with a drug-coated balloon were excluded from clinical outcome analysis.

Results

One-hundred fourteen patients across 8 clinical sites were treated with the FLEX Vessel Prep™ System (FLEX VP) prior to PTA. Two patients did not complete the 12-month follow-up evaluation. No serious adverse events were reported. Among the 82 patients who underwent FLEX VP with plain balloon PTA, target lesion primary patency was 44.8% with an average freedom from target lesion revascularization of 256.6 days. Target lesion primary patency and freedom from target lesion revascularization for AVF cases(n=57) were 49% and 267.3 days, respectively. In cases treating AVF cephalic arch stenosis (n=23), 12-month Target lesion primary patency was 59.7% with an average freedom from target lesion revascularization of 267.7 days.

Conclusion

The FLEX AV Registry demonstrates continued safety and vascular access patency at 12-month s in end-stage renal disease patients with hemodialysis vascular access dysfunction treated with FLEX VP prior to PTA, suggesting the potential benefit of vessel preparation via the creation of longitudinal, controlled-depth micro-incisions.

Keywords: Patency • Vascular access dysfunction • Micro-incisions • Vessel preparation

Introduction

In the United States there are approximately 468,000 patients with end stage renal disease who require routine hemodialysis as their renal replacement therapy. These patients rely on an access site to maintain continuous access for the administration of life saving hemodialysis. Thus, anything to preserve its functionality and integrity is important for the patient's ongoing quality of life. Among prevalent patients as of December 2018, more than four out of every five patients receiving hemodialysis were using an AV fistula or graft (82.4%; 65.7% fistula and 16.7% graft) [1].

A real and unfortunate outcome of a hemodialysis access is the persistent development of neointimal hyperplastic stenoses requiring an access intervention. Multiple factors influence the development of lesions in the access circuit, including patient characteristics and co-morbidities; types/location of dialysis circuits established; dialysis administration preferences/differences. These stenoses cause a reduction in blood flow through the access and thereby decrease the ability to deliver effective hemodialysis treatment. If left untreated, these aggressive lesions will eventually cause the access to stenose and fail [2]. AV access flow dysfunction in arteriovenous fistulae and grafts in end-stage renal disease patients has the potential to cause significant negative impact on the quality of life for these patients, and the potential for significant morbidity and mortality if left untreated [3].

According to the KDOQI Guidelines for Vascular Access [4], percutaneous transluminal balloon angioplasty (PTA) is the primary technique for treatment of clinically and angiographically-significant stenotic lesions associated with prosthetic hemodialysis grafts and native fistulas. PTA has been recommended as the first-line therapy since KDOQI guidelines were issued [5]. Additionally, the guidelines indicate a goal of < 3 interventions per year to maintain AV access use. KDOQI reports that the median primary patency for all AV accesses is 0.36 years (131.4 days), 0.21 years (76.6 days) for grafts and 0.43 for years (156.9 days) for fistulas.

Although an angioplasty procedure can provide an excellent immediate result by opening the access to allow dialysis to continue, the long-term patency rates are less than satisfactory. It has been reported that patients require an average of 1.9 interventions per year [6]. Clinical studies describing the use of angioplasty to treat hemodialysis fistula-related stenoses have reported 12-month post intervention patency rates ranging from 12– 50% [7, 8]. Angioplasty failures may be due to acute elastic recoil, vascular rupture during balloon inflation or rapid re-growth of the neointimal hyperplasia due to the barotrauma caused during the procedure. Subsequent dysfunction of the dialysis circuit is a significant cause of morbidity and mortality in patients undergoing hemodialysis which results in repeated interventions and can eventually lead to loss of vascular access.

To help improve AV access maintenance outcomes, several devices have been utilized such as cutting balloons, bare metal stents, and stent grafts. However, the outcomes have been inconsistent for cutting balloon and bare metal stents and a clear benefit over conventional PTA could not be shown [9-12]. Stent graft placement has been shown to result in better patency at the graft-vein anastomosis of synthetic AV grafts [13]. While some benefit has been shown with the use of stent grafts in in-stent restenotic lesions, their use comes with concerns for follow-on AV access repair in the stent graft segment as well as concerns related to future access sites and cannulation zones [14, 15]. Thus, PTA remains the standard of care to treat obstructive AV fistulae and grafts.

Due to the progression of the disease and patient characteristics, there is widespread variability in utilization of PTA balloons (type, inflation pressures, inflation times etc.) when treating obstructions and lesions to maintain dialysis access. In addition, procedure-related complications can occur, such as perforation and vessel rupture due to high inflation pressure, and may result in a loss of the AV access [16]. New ways of treating stenosis are needed but innovation has been slow in the hemodialysis arena. In recognition of this difficult to treat population, the Kidney Health Initiative was created to improve patient safety and foster innovation that become a catalyst for "development and delivery of devices for the right patient at the right time" [17].

This manuscript details the 12-month results of the FLEX AV Registry. This Registry was a

prospective, real- world, all-comers registry that was designed to collect observational data regarding the clinical use and outcomes of the FLEX Vessel PrepTM (VP) system in AV fistulae or grafts presenting with clinical or hemodynamic abnormalities in real-world subjects per the institution's standard practice. Overall, this study provides an understanding of the impact of utilizing the FLEX Vessel Prep (FLEX VP) catheter system as a pre-treatment prior to PTA in AV access maintenance lesions. This study offers important insights related to acute safety, minimizing clinically driven reinterventions, and extending circuit patency.

Methods

This multicenter, prospective, observational registry included 114 hemodialysis patients from 8 clinical sites that were scheduled to undergo PTA of their arteriovenous fistula or graft due to clinical or hemodynamic abnormalities. This study was approved by an Institutional Review Board responsible for each site. All patients were at least 18 years of age and provided informed consent. Enrollment criteria was intentionally broad to represent real-world patients. The primary objective of the FLEX-AV Registry is to document the endovascular intervention approaches and outcomes when the FLEX VPTM system is utilized in a clinical setting per the institution's standard practice and following treatment. Once enrolled, the patient demographics, medical history, chronological access history and the following treatment details were collected: access location, target vessel reference diameter, number of lesions, pre-dilation % stenosis, number of device passes, maximum balloon inflation pressure, lesion location and lesion length. Procedural complications were also recorded.

For comparison, the manuscript presents historical performance data (both acute safety and 12-mo circuit patency) for the FLEX VP+ PTA results compared to PTA alone. Additionally, 32 patients in this registry were treated with FLEX VP++PTA+Drug Coated Balloon (DCB). The focus of this manuscript is on the 82 patients that were treated with the FLEX VP+PTA (Standard, High Pressure or Ultra High-Pressure Balloons) and followed for 12 months.

Study device and PTA

This registry was performed with marketed devices within the defined indications for use. There were no additional treatments or examinations that were required. The only differences to routine care were collection and analysis of patient data, informed consent, and the option of performing follow-up visits via telephone. This registry took place during the COVID-19 pandemic.

The FLEX Vessel Prep™ System provides vessel preparation prior to PTA, to optimize PTA results. The FLEX VP is an endovascular, over-the-wire, sheathed catheter with a 3-strut treatment element at the distal tip. The struts are radially opposed, and the proximal portion of each strut includes a 0.010" depth micro-surgical blade. When deployed, the device's struts independently engage with neointimal hyperplastic stenoses occluding an arteriovenous fistula or graft used for hemodialysis. As the device is pulled back though the lesion, the blades create three continuous, parallel micro-incisions approximately 320 microns in depth along the lesion's entire length. This is a non-balloon-based device. The device's struts exert a consistent force of approximately one atmosphere on the vessel wall. Additional micro-incisions may be created by using several passes of the device, rotating it within the vessel 30 to 90 degrees each time. The micro-incisions improve acute luminal gain and vessel compliance by releasing circumferential tension in the lesion.

The study population included subjects who had a designated target lesion and a maximum of four secondary lesions. The target lesion was defined by the treating physician as the most severely stenosed lesion in the setting of multiple lesions. The lesions were treated by creating longitudinal micro-incisions with the FLEX Vessel Prep™ system and then followed with standard PTA during the baseline procedure. The endovascular treatment decisions, including the type of PTA used, were at the discretion of the physician. Balloon diameters were chosen by the treating physician. The balloon was inflated until the walls were parallel.

Outcomes

Follow-up was conducted by telephone at 6, 9, and 12 months post-operatively to both the subject and/or patient's dialysis clinic to determine target lesion primary patency and freedom from target lesion revascularization While radiographic imagery is the standard

in most studies, this study was conducted during COVID infection waves, so patients were limited in access to facility follow-up. This indirect diagnostic criteria was required to complete the study in accordance with the IRB approved protocol and phone scripts. The goal of the FLEX AV Registry follow-up was to track the longitudinal course of the patient's access circuit as the subject undergoes hemodialysis. As such, there are no protocol requirements for additional follow-up imaging such as angiography at pre-specified intervals or the collection of hemodialysis-specific clinical parameters. Site physicians and dialysis centers followed their institutional procedures for hemodialysis access surveillance. Each site reported on all reinterventions required during the follow-up period, specifically identifying when the target lesion required reintervention. Access circuit primary patency was also calculated as a measure of continued availability of the overall circuit regardless of any lesion implication.

Study design and statistical analysis

Baseline characteristics and clinical endpoints, target lesion primary patency, freedom from target lesion revascularization and access circuit primary patency were analyzed. Data were categorized by vascular access type (AVF or AVG) and by PTA type (plain balloon PTA or drug-coated balloon (DCB)). A separate cohort of cephalic arch lesions, included in the overall analysis, was analyzed, and reported.

Data are presented as mean, standard deviation, and range for continuous variables and as percentages for categorical variables, respectively. Statistical analyses were performed with SAS version 9.4. Time-to-event analyses were performed with subjects censored at their latest completed follow-up visit. Target lesion primary patency rates were estimated via Kaplan-Meier analysis at the close of the 12-month visit (372 days). Freedom from target lesion revascularization was estimated using restricted mean survival time analysis restricted to 372 days of follow-up. Analyses were completed by a biostatistician (NAMSA; Minneapolis, MN).

Results

Subjects and lesion characteristics

The FLEX-AV registry enrolled a total of 114 patients with 148 lesions at 8 clinical sites from October 2019 to June 2021 with mean subject age of 63.3±12.7 years (range 31–88 years).

Table 1. Patient demographics and medical history.

Variable	All (n=114)	FLEX VP + PTA (n=82)	FLEX VP + PTA + DCB (n=32)
Age(years)	63.3 ± 12.7(114)	63.1+12.7(82)	63.7+12.9(32)
	31.0-88.0	31.0-88.0	38.0-87.0
Race			
American Indian or Alaska Native	2/114(1.8%)	2/82 (2.4%)	0/32 (0%)
Asian	1/114(0.9%)	1/82 (1.2%)	0/32 (0%)
Black or African American	75/114(65.8%)	51/82 (62.2%)	24/32 (75.0%)
White	36/114(31.6%)	28/82 (34.1%)	8/32 (25.0%)
Gender			
Female	61/114(53.5%)	46/82 (56.1%)	15/32 (46.9%)
Male	53/114(46.5%)	36/82 (43.9%)	17/32 (53.1%)
Diabetes	71/114(62.3%)	52/82 (63.4%)	19/32 (59.4%)
Hypertension	105/114(92.1%)	77/82 (93.9%)	28/32 (87.5%)
Congestive Heart Failure	44/114(38.6%)	30/82 (36.6%)	14/32 (43.8%)
Prior AV access Interventions(count)	4.9 ± 5.8(104)	5.1 ± 5.9 (74)	4.3 ± 5.4 (30)
	0.0-29.0	0.0-29.0	0.0-24.0
Years since AV access Creation(years)	3.1 ± 2.6(114)	3.2 ± 2.7 (82)	2.9 ± 2.2 (32)
	0.1-13.9	0.1-13.9	0.5-10.0
Years since Started Hemodialysis(years)	4.7 ± 4.0(114)	4.7 ± 4.0 (82)	4.8 ± 4.0 (32)
	0.1-19.3	0.1-19.3	0.9-15.2
Days since last dialysis(days)	2.3 ± 11.1(113)	2.8 ± 13.1 (81)	1.2 ± 0.7 (32)
	0.0-119.0	0.0-119.0	0.0-4.0
Tobacco Abuse			
Current	17/114(14.9%	13/82 (15.9%)	4/32 (12.5%)
Never	60/114(52.6%)	43/82 (52.4%)	17/32 (53.1%)
Past	37/114(32.5%)	26/82 (31.7%)	11/32 (34.4%)

The demographics and medical history of these subjects are shown in Table 1. Hypertension (92.1%) and diabetes (62.3%) were the most encountered medical conditions. Patient and lesion characteristics for all 114 patients (FLEX VP+PTA+DCB) are included for completeness. One hundred fourteen target lesions (of 148 lesions total) were all treated with FLEX VP before PTA (71.9%) or before PTA+DCB (28.1%). The mean age of all AV access was 3.1+2.6 years (range 0.1-13.9). 104 subjects (91.2%) had experienced prior interventions. The mean number of prior interventions was (4.9+5.8; range 0-29). The lesion location and characteristics are shown in Table 2 and Table 3, respectively. Secondary lesions were found in 32/114 (28.1%) of subjects. For target lesions, mean lesion length was 21+25mm (1-200 mm) with a mean pre-procedure stenosis of 75.2%+14.7% stenosis. For all lesions, mean lesion length was 20+25mm (1- 200 mm) with a mean pre-procedure stenosis of 72.4%+15.7%.

Performance of the vessel preparation

Vessel preparation was performed with a mean 5.1+1.0 passes (range 2.0-8.0). FLEX Vessel preparation was followed by PTA in 82/114(71.9%) of subjects and PTA+DCB in 32/114(28.1%) of the subjects. Maximum PTA pressure was 15.2+5.9 atm (range 4.0-32.0).

Complications

Five procedural complications were recorded: One dissection related to the FLEX VPTM system device, three dissections related to PTA and one balloon burst causing an embolectomy also related to PTA. No serious adverse events were reported.

Clinical outcomes

We were unable to obtain follow-up data on two subjects (1.7%). The remaining 112 subjects were evaluated out to 12 months with no serious adverse events reported during follow-up. The patient cohorts treated included patients with native fistulas with

Table 2. Access location and type for target lesion.

Variable	All (n=114)	FLEX VP+PTA(n=82)	FLEX VP + PTA + DCB (n=32)
Location			
Forearm	12/114 (10.5%)	7/82 (8.5%)	5/32 (15.6%)
Other	4/114 (3.5%)	3/82 (3.7%)	1/32 (3.1%)
Upper Arm	98/114 (86.0%)	72/82 (87.8%)	26/32 (81.3%)
Location – Detailed			
Basilic -Cephalic trans fistula	1/114 (0.9%)	1/82 (1.2%)	0/32 (0%)
Brac-Basil Fistula	27/114 (23.7%)	20/82 (24.4%)	7/32 (21.9%)
Brach-Axill Graft	36/114 (31.6%)	24/82 (29.3%)	12/32 (37.5%)
Brach-Ceph Fistula	37/114 (32.5%)	30/82 (36.6%)	7/32 (21.9%)
Brachial Artery -Antecubital	3/114 (2.6%)	0/82 (0%)	3/32 (9.4%)
Graft			
Left thigh graft	1/114 (0.9%)	2/82 (2.4%)	1/32 (3.1%)
Radial Artery-Cephalic Vein Fistula	8/114 (7.0%)	6/82 (7.4%)	2/32 (6.3%)
Right Thigh	1/114 (0.9%)	1/82 (1.2%)	0/32 (0%)

Table 3. Target lesion characteristics.

Variable	All (n=114)	FLEX VP + PTA (n=82)	FLEX VP + PTA + DCB (n=32)
Target Vessel Reference Diameter (mm)	7.8 ± 2.2 (114)	8.0 ± 2.5 (82)	7.8 ± 1.6 (32)
Target Lesion Location			
Anastomosis	6/114 (5.3%)	3/82 (3.7%)	3/32 (9.4%)
Cannulation Zone (Up to 1st large collateral vein)	3/114 (2.6%)	3/82 (3.7%)	0/32 (0%)
Cephalic Arch	25/114 (21.9%)	23/82 (28.0%)	2/32 (6.3%)
Inflow (2 cm from Anastomosis)	2/114 (1.8%)	1/82 (1.2%)	1/32 (3.1%)
Outflow (Above Cannulation Zone)	57/114 (50.0%)	34/82 (41.5%)	23/32 (71.9%)
Peri-Anastomosis	3/114 (2.6%)	2/82 (2.4%)	1/32 (3.1%)
Swing Segment	18/114 (15.8%)	16/82 (19.5%)	2/32 (6.3%)
Target Lesion Length (mm)	21 ± 25 (113)	22.2 ± 27.5	17.0 ± 15.4
Target Lesion Pre-Procedure Stenosis (%)	75.2 ± 14.7 (114)	74.1 ± 15.1(82)	78.1 ± 13.6 (32)

a subset of lesions in the cephalic arch, and patients with synthetic grafts. As PTA is presently the gold-standard for AV access interventions, these 12-month results are focused on the 82 patients treated with FLEX VP+PTA. The target lesion primary patency and freedom from target lesion revascularization are reported for each cohort in (Figure 1). This observational study required patient follow-up for up to 12 months. As shown in Table 4, the 12-month Target lesion primary patency for all included FLEX VP+PTA patients was 44.8% with an average freedom from target lesion revascularization of 256.6 days. When separating AVFs from AVGs, as generally reported in the literature, the target lesion primary patency for AVFs was 49% and freedom from target lesion revascularization for AVFs was 267.3 days. Kaplan-Meier estimates are presented in (Figures 2 and 3). In AVG cases treated with PTA, 12-month target lesion primary patency was unable to be determined since no patients were under observation at day 372, but the freedom from target lesion revascularization was determined to be 228.5 days. It should be noted that the 9-month target lesion primary patency for AVGs was 41.2%. A sub-analysis of subjects with AV access dysfunction due to cephalic arch stenosis through 12-month evaluation (23/82;28.0%), demonstrated target lesion primary patency of 59.7% with a mean freedom from target lesion revascularization of 267.7 days following PTA (Table 5). All the cephalic arch lesions were in AVF patients. Access circuit primary patency, defined as the time interval from initial study treatment to the next access thrombosis or intervention performed within the vascular access circuit, is an important measure of overall continued availability of the existing AV circuit including implications from any lesion not just target lesion. The 12-month ACPP for all patients treated with FLEX VP+PTA was 39% with 42.9% for all AVF patients (n=57) and 55.3% for AVF-cephalic arch patients (n=25). AVG access circuit primary patency was unable to be determined as no patients were under observation on day 372, the time-point restriction used for statistical analysis. Based

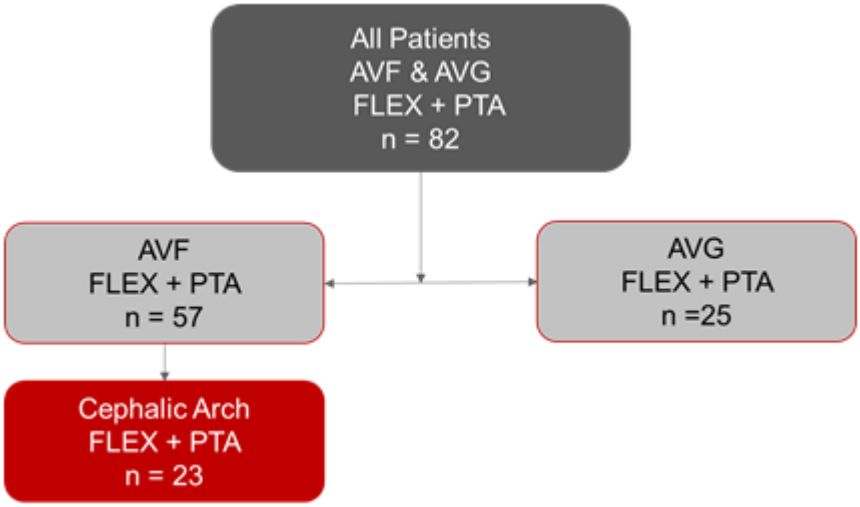

Figure 1. Patient cohorts treated with FLEX VP + PTA

Table 4. 12-Month target lesion primary patency (TLPP) and freedom from target lesion revascularization (FFTLR) for all patients.

Cohort	FU	FLEX VP+PTA	
		TLPP	FFTLR (days)
ALL		N=82	
	12 m	44.80%	256.6
AVF		N=57	
	12 m	49.00%	267.3
AVG		N=25	
	12 m	---%*	228.5
*TLPP 9-month FLEX VP+PTA in AVG = 41.2%			

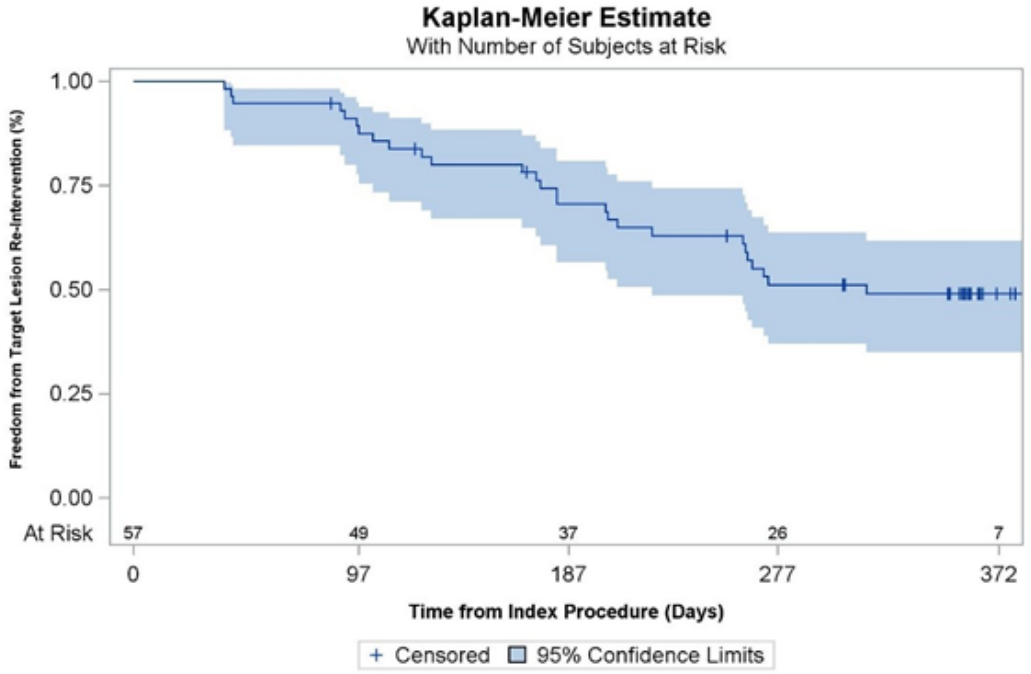

Figure 2. 12-Month Kaplan Meier estimate for FLEX VP + PTA in AVFs

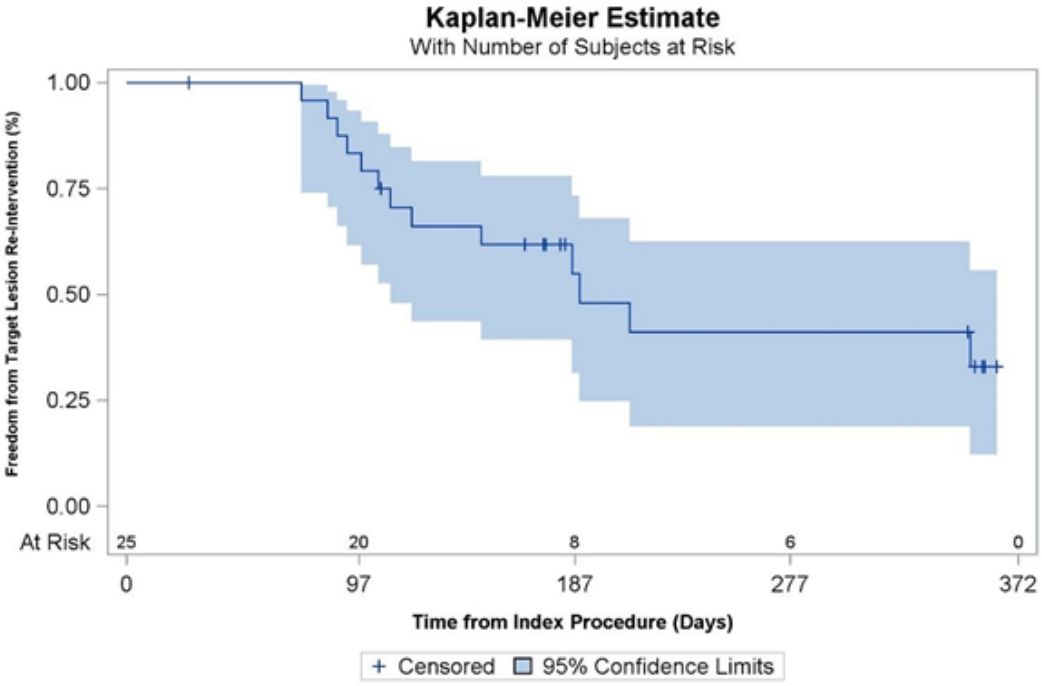

Figure 3. 12-month Kaplan Meier estimate for FLEX VP+PTA in AVGs.

on the calculated contribution of AVG patients (n=25) to the total (N=82) and the overall access circuit primary patency result of 39%, an approximation of access circuit primary patency for AVG patients is likely about 30%.

Discussion

The aim of the FLEX AV Registry was to collect observational data regarding safety and efficacy of FLEX VP+PTA for vascular access dysfunction per the institution's standard practice. No serious adverse events were reported. As a comparison, the JVIR Quality Improvement Guideline thresholds cite 2-7% major complications from AV access interventions.

As noted earlier, there is widespread variability in the utilization of PTA balloons when treating obstructions and lesions to maintain dialysis access. While angioplasty is the gold standard treatment, comparable data shows those results are less than optimal. A recent meta-analysis reported average freedom from target lesion revascularization [18]. A comparison of this study's outcomes with the reported literature on PTA effectiveness is summarized in (Table 6) [5, 18]. While this is not an exact comparison to a real-world registry, the PTA arms provide an approximation for controlled populations. The average freedom from target lesion revascularization time from this article reported for AVF and AVGs ranged from 124-237 days. The KDOQI guidelines for AV access Dysfunction report median time of patency of 157.9 days for AVF + PTA and 76.6 days for AVG+PTA [4]. The FLEX VP with PTA in AVF had an average time of 267.3 days and for AVG was 228.5 days.

Treatment of AVF with FLEX prior to PTA yielded a target lesion primary patency of 49% which also compares favorably to the literature for treating fistulas using PTA alone. As noted in (Table 7) [18-21], there is a large variation of target lesion primary patency results for fistulas from 0 to 47.2%.

Patients with AV access dysfunction due to stenosis in AVGs also show improvement when treated with FLEX VP prior to PTA. These lesion types are associated with low patency outcomes after PTA treatment [22]. The literature reports the primary patency at 12 months in graft patients ranges from 0% to 24.8% (Table 8) [18- 23]. When FLEX VP is used prior to PTA in grafts, the 12-month target lesion primary patency was unable to be determined since there were not any patients remaining under observation at 372 days, but the freedom from target lesion revascularization was found to be 228.5 days, which is substantially higher than the published literature shown in Table 6 as discussed above. Cephalic arch lesions are challenging lesions to maintain access patency.

Cephalic arch lesions have documented 12-month primary patency that ranges from 0% - 33.9%. These lesions may be more vulnerable to balloon inflation pressures with one report observing 15% of cephalic arch lesion interventions resulting in vessel rupture [24]. Beathard et al. [25] reported that the incidence of reinterventions in cephalic arch lesions is up to 3.5 times per year [26]. The 12-month FLEX VP+PTA data demonstrated target lesion primary patency

Table 5. 12-Month target lesion primary patency (TLPP) and freedom from target lesionrevascularization (FFTLR) for all FLEX VP+PTA patients.

	FLEX VP+PTA N=23	
Cephalic Arch	TLPP	FFTLR (days)
	59.70%	267.7

Table 6. FLEX VP+PTA 12-Month freedom from target lesion revascularization (FFTLR) compared with the literature.

Lesion Type	FLEX AV Registry FFTLR (Avg days)	FFTLR Liao 2020 [18] (Avg Days)	FFTLR KDOQI [5] Median days
AVF + PTA	267.3	161- 193*	157.9
AVG + PTA	228.5	68	76.6

*A study for AVFs where 48% of the patients were in-stent restenosis was excluded for comparison.

Table 7. 12-Month target lesion primary patency (TLPP) For All AVF patients treated with FLEX VP+PTA compared with the literature.

Published Results	FLEX Registry FLEX VP+PTA	Liao 2020 [18]	Rajan 2004 [19]	Ng 2021 [20]	Hu 2021 [21]
12-month TLPP AVF	49.00% (n=34)	31.50% (n=273)*	26% (n=53)	0-21.2%* (n=143)	47.20% (n=341)*

* Restricted to studies in AVFs

Table 8. 12-Month target lesion primary patency for AVG patients treated with FLEX VP+PTA compared with the literature.

Type of Access	FLEX AV Registry FLEX VP+PTA	Yang 2018 [23]	Liao 2020 [18]	Ng 2021 [20]
AVG	----* (n=25)	7.80% (n=49)	9% (n=22)	0-24.8%* (n=339) * meta-analysis of RCTs of covered stents - AVGs

* Kaplan Meier estimates are only provided when there are patients remaining under observation at 372 days. The 9-month TLPP = 41.2%.

Table 9. 12-Month target lesion primary patency (TLPP) for cephalic arch patients treated with FLEX VP+PTA compared with the literature.

Published Results	FLEX AV Registry FLEX VP+PTA	D'Cruz 2019 [26]	Tng 2021 [27]	Vasanthamohanm 2015 [28]	Miller 2018 [29]
12-month TLPP Cephalic Arch	59.70% (n=14)	9.5%* (n=146) *pooled multi-studies (0%-39.6%)	0-23%* 33.90% (n=59) (n=13-24) * multi-studies small sample sizes		11% (n=50)* *Historical Controls

Table 10. 12-Month access circuit primary patency (ACPP) For AVF and Avg patients treated with FLEX VP+PTA compared with the literature.

Published Results	FLEX AV Registry FLEX VP+PTA	Dolmatch 2023 [30]	Holden 2022 [31]	Fong 2021 [32]	Haskal 2016 [33]
12-month ACPP AVF	43% (n=57)	17.70% (n=138)	32.40% (n=160)	29.80% (n=424)	
12-month ACPP AVG	--*	n/a	n/a		11% (n=132)

* Kaplan meier estimates are only provided when there are patients remaining under observation at 372 days.

of 59.7% with the freedom from target lesion revascularization of 267.7 days [27]. When compared with the literature, the results here demonstrate a substantial increase in target lesion primary patency for these difficult to treat lesions. A summary of this comparison is shown in (Table 9).

Maintaining hemodialysis access is the goal for patients to reduce the number of interventions and improve the quality of life [28]. Access circuit primary patency is a measure of maintaining patency of the arteriovenous access regardless of target or secondary lesion stenoses. Access circuit primary patency 12-month literature for AVF's ranges from 17.7% to 32.4% (Table 10). When FLEX VP+PTA was used, access circuit primary patency AVF's was 43% [29]. This observation is a notable improvement to the ability to maintain access circuit patency for continuing hemodialysis [30].

This manuscript describes the 12-month outcomes of the FLEX AV Registry for the use of the FLEX Vessel Prep System in AV access interventions [31]. As compared to common standards and existing published literature, the use of the FLEX VP System prior to PTA demonstrates fewer complications and longer patency than PTA alone, even including more challenging AVG and cephalic arch lesions [32]. These intriguing and meaningful results merit additional consideration for further clinical studies [33].

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