Clinics of Surgery

Research Article ISSN: 2638-1451 | Volume 8

Intraoperative Plain Balloon Angioplasty to Augment Creation of Radiocephalic Arteriovenous Fistula in Those with Small Cephalic Veins

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Received: 10 Aug 2022
Accepted: 18 Aug 2022
Published: 25 Aug 2022
J Short Name: COS

Citation:

Yen HT. Intraoperative Plain Balloon Angioplasty to Augment Creation of Radiocephalic Arteriovenous Fistula in Those with Small Cephalic Veins. Clin Surg. 2022; 8(1): 1-6

Keywords:

Arteriovenous fistula; Plain balloon angioplasty; Cephalic vein; Patency rate; End stage renal disease

Abbreviations:

AVF: arteriovenous fistula; CAD: coronary artery disease; CKD: chronic kidney disease; DM: diabetes mellitus; ESRD: end stage renal disease, HD: hydrostatic dilatation; HTN: hypertension; PAOD: peripheral artery occlusive disease; PBA: plain balloon angioplasty; PTA: percutaneous transluminal angioplasty

1. Abstract

1.1. Introduction: The native small cephalic vein may be overlooked during radiocephalic Arteriovenous Fistula (AVF) creation due to concerns over failure rates particularly if the diameter is small. However, native access has benefits in patency and infection risk in selected patients over alternatives such as arteriovenous graft or tunneled hemodialysis catheter. The aim of this study was to review the outcomes of intraoperative Plain Balloon Angioplasty (PBA) in patients with small cephalic veins during AVF creation. We evaluated the maturation, primary and secondary patency rate of salvaged arteriovenous fistulae and identified risk factors related to patency rate.

1.2. Methods: This study is a single center, single surgeon, retrospective study of 94 patients with PBA during radiocephalic arteriovenous fistula creation for small cephalic vein (> 1.0mm caliber ≤ 2.0mm). 10 patients were excluded either from failure of angioplasty (n=5) or loss of follow up (n=5). Primary patency was defined as freedom from intervention while secondary patency was defined as the time from creation to abandonment.

1.3. Findings: Intraoperative success rate of plain balloon angioplasty was 94.7% and among 84 patients, maturation rate of arteriovenous fistula was 95.2%. The one year, three year and five year primary patency rates were 55.2%, 51.3% and 32.3% while secondary patency rate were 98.8%, 95.2% and 95.2% respectively. During the follow up period, 47.6% of the patients received percutaneous transluminal angioplasty and only 4% of the AVFs was abandoned. Univariate and multivariate analysis of risk factors suggested advanced age (> 60 years) was significantly related to the patency rate.

1.4. Discussion: In this series, intraoperative plain balloon angioplasty was successful in facilitating the creation of a functional radiocephalic arteriovenous fistula in patients that may have otherwise not have been successful. The primary and secondary patency rate is satisfactory without any major complications. This would be important if confirmed in other series as a useful tool to improve the utility of more distal AV access.

2. Introduction

In patients with End Stage Renal Disease (ESRD), vascular accesses are essential for them to receive hemodialysis. According to various studies, native Arteriovenous Fistula (AVF) accesses

exhibit the best patency rates with lower frequency of infection, thrombotic and non-thrombotic complications, compared to arteriovenous graft or tunneled central venous catheter [1, 2, 3]. Although there is no minimum diameter threshold to AVF creation, cephalic veins less than 2mm in diameter should be considered meticulously, as their primary patency was only 16% compared to 76% in those with diameter greater than 2.0mm [4, 5]. In order to facilitate the use of smaller cephalic veins, there are several studies suggesting different plausible methods such as intraoperative Plain Balloon Angioplasty (PBA), Balloon Assisted Maturation (BAM), accessory vein ligation, based on patient's condition and operator's clinical evaluation [3, 6-11]. These studies facilitating intraoperative Plain Balloon Angioplasty (PBA) showed satisfying AVF maturation and patency. -10 However, the effectiveness of PBA with non-compliant balloon in retrieving cephalic veins < 2.0mm for long term functional use is still not well established in ESRD patients. Furthermore, the risk factors related to decreased functional primary patency rate have not been clearly identified. Therefore, this study aimed to evaluate the efficacy of intraoperative PBA with non-compliant balloon on maturation rate, primary patency and secondary patency rate in radiocephalic AVF surgeries while attempting to identify the risk factors that affected primary patency rate.

3. Patients and Methods

This study was approved by the institutional review board of our institution (IRB: 202001393B0). This was a single center retrospective study including all patients who received intraoperative PBA intervention during AVF creation from June 2013 to December 2017 and observations of the outcome were continued to 1st of May 2018. Inclusion criteria were all patients with cephalic vein diameters greater than 1.0 mm, less or equal to 2.0 mm (found intraoperatively) and with consequent plain balloon angioplasty performed during the same operation. Patients with brachiocephalic AVF creation, failed intraoperative PBA, loss of follow up or death within one month were excluded. A total of 84 patients were included and Figure 1 is a flow chart showing patient selection. Demographic data on age, gender, and co-morbidities such as diabetes, hypertension, cigarette smoking, stroke, coronary artery disease and peripheral artery disease were collected.

All surgeries were performed by the same cardiovascular surgeon, Dr. Yen. After local anesthesia with lidocaine 1%, a 3.0 cm longitudinal incision was made on the lateral side of the wrist. The radial artery and cephalic vein were dissected and isolated. After clamping both vessels, venotomy and arteriotomy were performed respectively. Proximal runoff in the cephalic vein was examined gradually using a series of coronary dilator, starting from 1.0 mm. In cases where coronary dilator could not be passed easily (1.0 - 2.0mm) with resistance or where backflow was inadequate, ultrasound was used to examine possible stenosis or sclerotic site. After stenosis site was identified, balloon angioplasty was carried out. A non-compliant balloon catheter, 4.0 mmx150 mm (Pacific Extreme, Medtronic, USA) was inserted from the venotomy site to the forearm level. The balloon was over the wire and was inflated to a pressure of 6-8 atmospheres slowly for one minute. Whilst performing long segment balloon dilation, another hand was placed over the balloon to palpate the balloon inflation to avoid over expansion. After balloon angioplasty, the cephalic vein was irrigated with heparin solution (50 IU/ml) to verify if there had been any free rupture of the venous wall. The vein was then examined again using a coronary dilator up to elbow level. End to side or side to side anastomosis of the artery and vein was done using Prolene 7-0 running sutures. Immediate intraoperative success was defined as the presence of thrill during palpation after declamping of arteries and veins. If thrills could not be confirmed, the AVF was considered to have failed and further vascular access creation would be carried out according to the patient's condition.

The functional maturation of AVF was defined as successful cannulation of fistula for smooth flow hemodialysis one month after surgery. The outcomes of the study are the duration of primary patency and secondary patency in days. Primary patency was defined as the interval from the time of AVF creation to thrombosis or stenosis of AVF requiring Percutaneous Transluminal Angioplasty (PTA) to re-establish patency or to remove a thrombus. While the secondary patency was defined as the interval from the time of AVF creation to either AVF abandonment or endpoint of study which was the 1st of May 2018 [2]. Patients were further followed up at cardiovascular surgeon outpatient department one week after surgery to examine if arteriovenous fistula is still intact. One month postoperatively, patients would undergo hemodialysis as scheduled and further follow up every three months at cardiovascular surgeon outpatient department or whenever thrombosis or stenosis of arteriovenous fistula was suspected.

The demographic data of patients, categorized according to whether they had received PTA or not, was examined with the chi-square or Fisher's exact test. Patency rate curves and univariate analysis of risk factors related to functional primary patency were estimated using the Kaplan-Meier method while the multivariate association of risk factors was analyzed with Cox regression. A value of $P < 0.05$ was used to determine statistical significance and analysis was carried out using IBM SPSS Version 22.

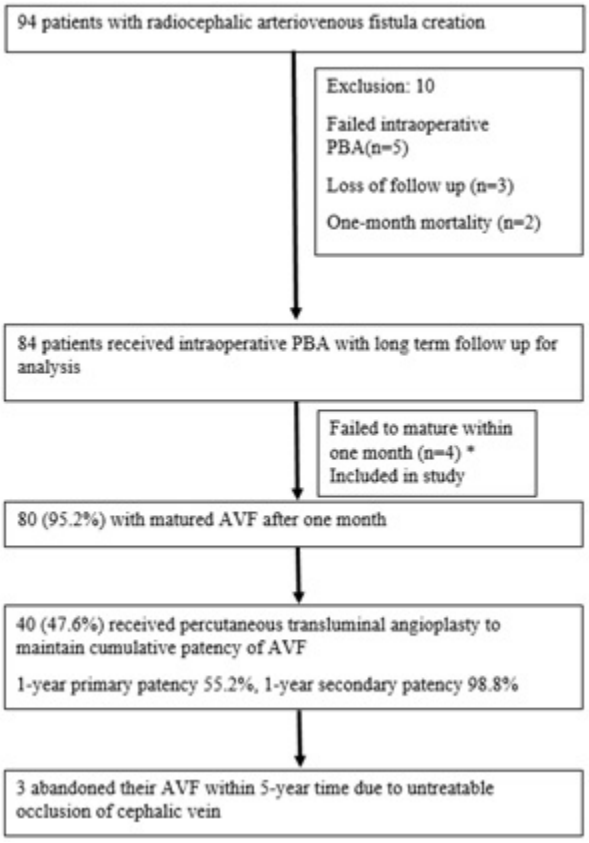


Figure 1: Flow chart of patient selections and analysis * This is an analysis by treatment, failed PBA cases were excluded.

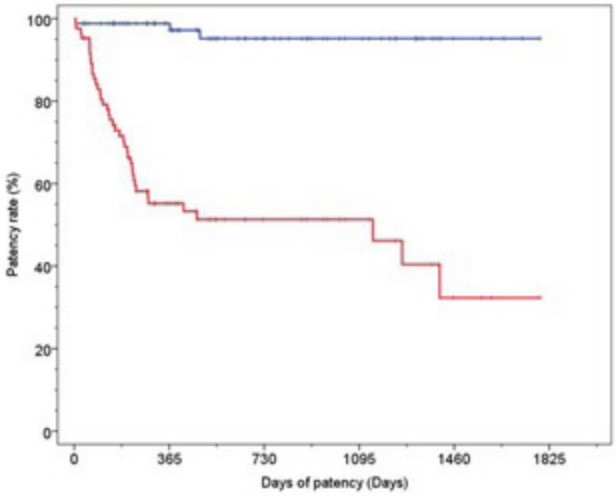
4. Results

During the study period, 94 ESRD patients received intraoperative PBA during radiocephalic AVF creation and 84 patients (89.4%) were included in this study. Ten patients were excluded from analysis of long-term outcomes for failed procedure (n=5), loss of follow up within one month (n=3) and death (n=2). The demographic data of patients are summarized in Table 1.

A total of 67 (79.8%) patients had cephalic vein of 1.5mm in diameter while 17 (20.2%) had cephalic veins of 2.0 mm. Cephalic veins less than 1.0 mm were considered unsuitable for further intervention. Vein diameter of at least 1.5mm is the safe limit to proceed with balloon angioplasty dilation. There are six cases with minimal or limited injury of veins with hematoma formation but there was no major free rupture of veins noted. PBA had high intraoperative success rate of 94.7% regardless of the small size of the veins, where thrills were detected after arteriovenous shunt formation. In five cases, plain balloon angioplasty failed to expand the native cephalic vein to greater than 2.0mm. Those patients were continued with alternative hemodialysis access choices. The functional maturation rate of post plain balloon angioplasty treated radiocephalic arteriovenous fistula was 95.2% (80 out of 84). Three patients required further PTA within the first month to achieve functional status and one needed alternative access creation.

The primary patency rate at six months, one year, three years, five years were 71.6%, 55.2%, 51.3% and 32.3% respectively. The one-year secondary patency rate was 98.8% while the three and five years functional cumulative patency rate were 95.2% respectively, as shown in Figure 2. 4% of the fistula was abandoned at the end point of the study. The cause of fistula failure in all three cases was attributed to occlusion of the cephalic vein. There were no major perioperative complications including infection or mortality. During the follow up period, a total of 40 (47.6%) patients received PTA due to thrombosis or stenosis of AVF during hemodialysis and mean sessions of PTA received within a five-year study period were 1.75. Most of the first PTA sessions were carried out within the first 8 months of operation.

All the patients' data in this study underwent univariate and multivariate analysis of risk factors correlating to functional primary patency rate. Univariate analysis of risk factors is shown in Table 2. Sex and underlying disease such as DM, HTN, history of smoking, CAD, PAOD and stroke had no significant correlation with functional primary patency rate in both univariate and multivariate analysis. However, patients with more than 60 years of age, showed significant correlation to functional primary patency rate in both univariate and multivariate analysis ($p=0.023$ and $p=0.026$). Patients more than 60 years of age displayed a hazard ratio of 2.255, with median functional primary patency of 649 days while patients 60 years old or younger had a median of 1179 days.



No.at risk

	183	365	548	730	913	1095	1278	1460	1643	1825
Primary	54	33	21	17	15	11	7	3	1	0
Cumulative	73	61	42	34	25	21	15	5	3	0

Figure 2: Cumulative Kaplan-Meier survival estimate showing primary and secondary patency of arteriovenous fistula receiving intraoperative plain balloon angioplasty in days. * This is an analysis by treatment, failed PBA cases were excluded.

Table 1: Baseline characteristics of 84 patients receiving intraoperative plain balloon angioplasty during radiocephalic arteriovenous fistula creation with long term follow up and grouped according to Percutaneous Transluminal Angioplasty (PTA) intervention.

Patient characteristics	Total n=84 (%)	PTA , n=40 (%)	No PTA, n=44 (%)	*p
Sex				
Male	58(69.0)	24 (60.0)	34 (77.3)	0.087
Female	26(31.0)	16 (40.0)	10 (22.7)	
Age				
<= 60	31 (36.9)	11 (27.5)	20 (45.5)	0.089
>60	53 (63.1)	29 (72.5)	24 (54.5)	
Size of cephalic vein (mm)				
1.5	67 (79.8)	33 (82.5)	34 (77.3)	0.551
2	17 (20.2)	7 (17.5)	10 (22.7)	
Diabetes mellitus	46 (54.8)	22 (47.8)	24 (52.2)	0.967
Hypertension	73 (86.9)	37 (50.7)	36 (49.3)	0.147
Smoking	27 (32.1)	10 (37.0)	17 (63.0)	0.181
Coronary artery disease	20 (23.8)	10 (50)	10 (50)	0.807
Stroke	10 (11.9)	4 (40)	6 (60)	0.741
Peripheral artery occlusive disease	9 (10.7)	4 (44.4)	5 (55.6)	1

Table 2: Univariate analysis of risk factors correlate with primary patency rate, * This is an analysis by treatment, failed PBA cases were excluded.

Characteristics		N(%)	Median days of primary patency	Primary patency rate at 6 months (%)	Primary patency rate at 1 year (%)	Primary patency rate at 2 years (%)	p
Sex	Male	34 (77.3)	1148	74.5	59.6	56.5	0.196
	Female	10(22.7)	225	65.4	46.2	41	
Age	<=60	20(45.5)	1404	86.8	69.5	69.5	**0.023
	>60	24(54.5)	283	62.4	46.6	40.8	
Cephalic vein size	1.5mm	34(77.3)	1148	69.3	53.8	51.2	0.588
	2.0mm	10(22.7)	-	80.8	60.6	51.9	
DM	No	20(45.5)	1148	77.9	59.8	56	0.774
	Yes	24 (54.5)	420	66.5	51.6	47.6	
HTN	No	8(18.2)	-	90.9	79.5	63.6	0.282
	Yes	36(81.8)	420	68.9	51.7	49.6	
Smoking	No	27(61.4)	472	67.7	54.1	49.2	0.373
	Yes	17(38.6)	-	80.2	57.2	-	
CAD	No	34(77.3)	1260	74.5	57	51.9	0.648
	Yes	10(22.7)	283	61.5	48.9	-	
Stroke	No	38(86.4)	1148	72.2	55.6	51.4	0.741
	Yes	6(13.6)	-	66.7	53.3	-	
PAOD	No	39(88.6)	1148	72.5	54.2	52	0.77
	Yes	5(11.4)	420	62.5	62.5	46.9	

5. Discussion

Native arteriovenous fistula is most preferred for patients with end stage renal disease. According to various studies, size and quality of the vessels are important predictors for functional maturation of the fistula.3,12,13,14,15 Nonetheless, there are several methods proposed to improve long term patency of arteriovenous fistula with small cephalic vein and our study aimed to investigate the effect of intraoperative PBA on cephalic veins of 1.5 -2.0mm. Balloon angioplasty has a higher immediate success rate compared to Hydrostatic Dilation (HD), which was shown by Veroux et al.6 with success rate of PBA 100% vs HD 67% and another study of Khan et al. with success rate of PBA 100% vs HD 73%16. Chawla et al supported the use of PBA with BAM and proposed that with staged sequential dilatation of AVFs to larger vascular access, vascular injury such as rupture could be minimized [8]. However there are concerns with BAM, such as more contrast and radiologic exposure, patient's discomfort, higher cost and possible repeated intimal injury causing restenosis and thrombosis [6].

In our study, we used a relative subjective and straightforward method to evaluate the diameter of the cephalic vein intraoperatively by using a dilator. Whenever small veins or stenotic sites were detected, balloon angioplasty was carried out. The advantage of our technique is that it is an easily reproducible intervention that does not require the use of contrast and is done by hand assisted balloon expansion. It is rather important to avoid contrast use in patients with ESRD as it may worsen patient's renal function and accelerate patient's need for hemodialysis. Despite the small size and fragile nature of these veins, in most of the cases the vein could be successfully expanded and matured to functional fistula with functional maturation rate of 95.2%. This result was comparable to other studies such as those by De Marco Garcia et al [7]. with an intraoperative success rate of 85.4% and maturation rate of 96.3%, and by Veroux 6 with an immediate success rate of 100%. Intraoperative plain balloon angioplasty over long segment of small cephalic vein not only helps with dilation of the sclerotic segments but also examine the distensibility of vein and finally achieve a low resistance venous outflow [6, 12]. Although some patients experienced regional hematoma, they resolved spontaneously and the AVFs were adequately functional.

In our series, the six-month and one-year primary patency rate was 71.6% and 55.2% while one- year secondary patency was up to 98.8% respectively. We tried to further explore factors that might affect the primary patency rate. Univariate and multivariate analyses showed that significant correlation to decreased functional primary patency was only shown in patients older than 60. This may be associated with relatively poor artery inflow caused by thrombosis or calcified arterial walls [17]. These older patients might also be weaker and were unable to perform the hand grasp exercise, which is essential to enhance maturation of AVF by transformation of veins into wide fibrotic, venous conduits [18]. Without this stimulation, expansion of the venous size will be inadequate, and cannulation can easily fail. Though primary patency was not favorable in our study, anyhow with timely PTA intervention, the AVFs were long term functional with satisfactory secondary patency.

There are a few limitations of our study. First, measurement of cephalic vein caliber was determined subjectively by the vascular surgeon using a dilator. Currently, there is still no definite answer for the best way of evaluating vascular compliance, as it may varies according to patient's hydration status, anesthesia used, evaluation technique and vessel spasm [20]. However, for better quantification, in further study measurement of vessels size will be performed using preoperative ultrasound. Second, this is a retrospective study with no control group and limited patient numbers. It is due to the nature of this study that we could not set up another control group without any intervention. Nevertheless, we can continue further study regarding intraoperative plain balloon angioplasty by constructing prospective study with a bigger patient group and collect long term result. Another limitation of this study was the high loss to follow up rate at 2 years, hence limiting the interpretation of the result. The main reasons of loss to follow up are either mortality or transferal of patient to another medical institution for further treatment.

Our results revealed that intraoperative non-compliant balloon angioplasty helped in the remodeling of small vein and reduced outflow resistance, resulting in good maturation and long- term patency with assistance of PTA. No major complications were noted during these operations, with no cases of wound infection or operation related mortality. Studies have shown that forearm loop AVG has a one-year primary patency rate of 32.4% with a secondary patency rate of 83.4% which is less than we found in this study [19]. As compared to other alternatives such as AVG and tunneled hemodialysis catheter, this method is worth a try in patients with small cephalic vein.

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