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The femoral artery: An alternative safe and effective cannulation localization in the angiographic treatment of dysfunctional arteriovenous fistulas. Single-center experience; long term outcomes

La arteria femoral: una alternativa de localización de canulación segura y eficaz en el tratamiento angiográfico de las fístulas arteriovenosas disfuncionales. Experiencia en un solo centro; resultados a largo plazo

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RESUMEN

Antecedentes: no hay consenso sobre la localización óptima de la punción en la angioplastia transluminal percutánea (ATP), la modalidad de tratamiento principal para tratar las fístulas arteriovenosas (FAV) disfuncionales. En este estudio retrospectivo de un solo centro, presentamos los resultados tempranos y tardíos de nuestras intervenciones de ATP realizadas con punción de la arteria femoral para tratar la FAV disfuncional. **Material y Métodos**: Este estudio incluyó a 29 pacientes en hemodiálisis diagnosticados de disfunción de la FAV entre enero de 2016 y junio de 2021 y por tanto sometidos a ATP con punción de la arteria femoral. Los datos demográficos, clínicos y de resultados de los pacientes se obtuvieron de la base de datos del hospital y de los registros electrónicos del centro de hemodiálisis de los pacientes. **Resultados**: 29 pacientes en hemodiálisis (72,4% hombres) que se sometieron a ATP por disfunción de la FAV fueron seguidos durante 53,0 (47,0-58,0) meses. La mediana de edad fue de 61 años (RIC 55,0-68,0). Se realizó angioplastia con balón liberador de paclitaxel en 27 pacientes. La tasa de éxito clínico del procedimiento fue del 93,1%. Se desarrolló hematoma local en el sitio de punción de la arteria femoral en dos pacientes. No se observaron otras complicaciones. Las FAV seguían siendo funcionales en 25 (82,8 %) pacientes al final del seguimiento. Los análisis de regresión multivariable de Cox determinaron que el no cumplimiento con la toma de fármacos anticoagulantes/antiagregantes predecía de forma independiente la recurrencia. **Conclusión**: La ATP realizada a través de la punción de la arteria femoral es una modalidad de tratamiento eficaz y segura para las disfunciones de la FAV. El riesgo de recurrencia es excepcionalmente alto en pacientes que no cumplen con el tratamiento antiagregante/anticoagulante.

Palabras clave: Disfunción de la fístula arteriovenosa, Angioplastia transluminal percutánea, Arteria femoral.

ABSTRACT

Background: There is no consensus on optimal puncture localization in percutaneous transluminal angioplasty (PTA), the primary treatment modality for treating dysfunctional arteriovenous fistulas (AVF). In this

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retrospective single-center study, we present the early and late results of our PTA interventions performed with femoral artery puncture to treat dysfunctional AVF. **Material and Methods**: This study included 29 hemodialysis patients diagnosed with AVF dysfunction between January 2016 and June 2021 and therefore underwent PTA with femoral artery puncture. The patient's demographic, clinical, and outcome data were obtained from the hospital database and electronic records of the patient's hemodialysis center. **Results**: 29 hemodialysis patients (72.4% male) who underwent PTA for AVF dysfunction were followed for 53.0 (47.0-58.0) months. The patients median age was 61 (IQR 55.0-68.0). Paclitaxel-eluting balloon angioplasty was performed in 27 patients. The clinical success rate of the procedure was 93.1%. Local hematoma developed at the femoral artery puncture site in two patients. No other complications were observed. AVFs were still functional in 25 (82.8%) patients at the end of follow-up. The multivariate Cox regression analyses determined that anticoagulant/antiaggregant drug noncompliance independently predicted recurrence. **Conclusion**: The PTA performed via the femoral artery puncture is an effective and safe treatment modality for AVF dysfunctions. The risk of recurrence is exceptionally high in non-compliant patients with antiaggregant/anticoagulant treatment.

Keywords: Arteriovenous fistula dysfunction, Percutaneous transluminal angioplasty, Femoral artery.

INTRODUCTION

Approximately 4 million people worldwide receive renal replacement therapy. [1] While an individualized treatment plan centered on disease progression is recommended to improve treatment and outcomes for these patients on dialysis [2], autologous arteriovenous fistulas (AVF) are preferred in most patients. [3] However, one of the significant challenges to the widespread adoption of continuous hemodialysis through autologous AVF is the high dysfunction incidence caused by vascular stenosis within the fistula circuit, resulting in inadequate hemodialysis. [3]

Moreover, vascular access problems frequently cause hospitalizations in the hemodialysis patient population. Dialysis failure occurs in approximately 50% of patients within 3-7 years due to stenosis and/or thrombotic problems in the AVF circuit. [3-5] Due to the vascular manipulations made to the fistula during dialysis, the holes in the endothelium cause endothelial and smooth muscle cell damage, leading to proliferation in progenitor cells, which causes neointimal hyperplasia. [6] Additionally, the uremic environment and changes in vascular physiology and anatomy reinforce the adverse effects of endothelial dysfunction and neointimal hyperplasia. [7-9]

Although 1-year patency rates range from 60% to 65%, the primary treatment for dysfunctional AVFs is percutaneous transluminal angioplasty (PTA). [10, 11] Different puncture sites, such as a brachial artery or venous outflow of AVF, may be preferred for catheterization during PTA interventions. In our center, we performed these procedures using femoral artery puncture. This retrospective study aims to determine the early and late results of PTA interventions with femoral artery catheterization to treat dysfunctional AVF.

MATERIALS AND METHODS

Study Population

This study included twenty-nine hemodialysis patients [median age 61 (IQR 55.0-68.0, 72.4% male)] diagnosed with AVF dysfunction in the Nephrology outpatient clinic of State Hospital between January 2016-June 2021 who underwent PTA. Patients with online and monthly conventional single pool Ktv (spKtv) levels below target levels or who could not detect "thrill" in the AVF on clinical evaluation were considered possible AVF dysfunction. All patients were evaluated by color Doppler ultrasound (USG). Dysfunction (stenosis, thrombotic occlusion) etiology, venous outflow conditions, and vessel diameters were measured with Doppler USG, and those with hemodynamically significant stenosis (>70%) on Doppler USG were referred for PTA. Re-detection of 'thrill' after the procedure, successful cannulation, and achievement of target spKtv levels immediately after treatment were considered "clinical success". The same experienced interventional cardiologist performed all PTAs. We obtained demographic, clinical, laboratory, and radiological data of the patients and data on primary patency, procedural complications, and anticoagulant/antiaggregant treatments from the hospital database and electronic

records of the patient's hemodialysis center. The notation of healthcare personnel determined compliance with drug use. The study protocol was performed following the Helsinki Protocol and approved by the Local Scientific Ethics Committee of the State Hospital. (Approval date 14/02/2020-71290220/045.99.141).

Digital subtraction angiography (DSA) and Endovascular intervention

We used commercially available DSA systems using nonionic contrast for all angiograms. PTA was attempted for inflow, anastomotic, and outlet strictures that showed ≥50% diameter reduction in DSA. After applying five cc prilocaine for local anesthesia, a 6F 10 cm short sheath was placed in the main femoral artery using the Seldinger method. The process was done in two stages:

1. Diagnostic imaging: The procedure was performed using a 6F JR4 diagnostic catheter and a 0.035" 190 cm hydrophilic guidewire. The catheter was advanced through the aortic arch to the right and left subclavian arteries proximal. In the meantime, small test injections were made between the aortic arch and the subclavian artery, visualizing lumen patency and appropriate trace. By giving contrast from the proximal subclavian artery, this artery, the brachial artery, the radial, the ulnar arteries, arteriovenous anastomosis, and the venous tree from the beginning of the fistula vein to the superior vena cava were visualized. Heparin was not used at this stage.

2. Interventional treatment: The guiding catheter suitable for the balloon angioplasty catheter, elected for the lesion, was parked in the brachial artery. A balloon angioplasty was performed by advancing a 0.014" 300 cm guidewire through the lesion. The type of balloons and stents used were at the operator's discretion. At this stage, 2500-5000 units of heparin were administered according to the patient's weight.

Since approximately half of the lesions were very tight, the operator applied a balloon after predilatation with a coronary non-compliant balloon. We started antiaggregant/anticoagulant treatment in all patients after the interventions using acetylsalicylic acid and clopidogrel after PTA. Clopidogrel was discontinued after three months, continuing with acetylsalicylic acid for another three months. There was no change in the current treatment of patients who used anticoagulants for any indication before the procedure.

Statistical Analysis

Statistical analyzes were performed using IBM SPSS Statistics for Windows, Version 23.0 software (IBM Corp., Armonk, NY). Data were expressed as mean ± standard deviation (SD), median (IQR 25-75), number (n), and percent (%) when appropriate. Cox regression analyses were performed to identify factors predicting recurrence and dysfunctional AVF. Multivariate analyses were performed for factors with $p<0.2$ in univariate analyses. $p<0.05$ was considered statistically significant.

RESULTS

Twenty-nine hemodialysis patients (72.4% male) underwent PTA for AVF dysfunction were followed for 53.0 (47.0-58.0) months. The median age of the patients was 61 (IQR 55.0-68.0), and 72.4% were male. 41.4% of patients had diabetes, and 27.6% were active smokers. The vast majority of AVFs were radiocephalic and brachiocephalic. The median AVF age was 44.0 (24.0-92.0) months. Juxtaanastomotic (48.3%) and efferent venous stenosis (37.9%) were the leading causes of AVF dysfunction. (**Table 1**) Most lesions received a paclitaxel-released balloon (27/29). Two patients required a balloon >8 mm, so plain balloon angioplasty was performed. The clinical success rate of the procedure was 93.1%. Two patients who did not achieve clinical success with the endovascular procedure were both diabetic. Only two patients had local hematoma at the femoral artery puncture site, detecting no other major or minor complications. Additional details are shown in **Table 1.**

At 6 and 12 months, the AVF patency rate was 93.1% and 85.2%, respectively. AVF dysfunction recurrence occurred in 8 (27.6%) patients during the follow-up period. The mean recurrence time was 2.3±4.6 months. The reason for repetition was restenosis in 7 patients and thrombosis in 1. AVFs are still functional in 25 (82.8%) patients. Three patients died during the follow-up period.

Multivariate Cox regression analyses with recurrence-related variables found that noncompliance to anticoagulant/antiaggregant therapy independently predicted recurrence (HR: 12.905, 95% CI 1.55-107.127, p=0.018). (**Table 2**) AVF age and non-adherence to anticoagulant/

antiaggregant therapy showed to be significant in univariate Cox regression analyses related to dysfunctional AVF. However, none of these were statistically significant in multivariate analyzes. (**Table 3)**

Table 1: Demographic, clinical characteristics, and follow-up parameters of patient's study groups.

Characteristics		**Study group (n= 29)**
Age, years, median, (IQR 25-75)		61 (55.0-68.0)
Follow up time, months, median, (IQR 25-75)		53.0 (47.0-58.0)
Gender, n, (%)	Male	21 (72.4)
	Female	8 (27.6)
Diabetes mellitus, n, (%)		12 (41.4)
Smoking, Yes, n, (%)		8 (27.6)
AVF localization, n, (%)	Radiocephalic	14 (48.3)
	Brachiocephalic	14 (48.3)
	Brachiobasilic	1 (3.4)
AVF age, months, median, (IQR 25-75)		44 (24.0-52.0)
Anticoagulant drug, n, (%)	ASA	16 (55.2)
	ASA+clopidogrel	11 (37.9)
	ASA+warfarin	2 (6.9)
Antiagregan/coagulant therapy non-compliance, n, (%)		3 (10.3)
Intervention, n, (%)	Balloon	27 (93.1)
	Balloon+stent	2 (6.9)
Early procedural success, n, (%)		27 (93.1)
AVF dysfunction etiology, n, (%)	Thrombosis	2 (6.9)
	Anastomotic stenosis	2 (6.9)
	Juxtaanastomotic stenosis	14 (48.3)
	Efferent venous stenosis	11 (37.9)
Procedure complication, n, (%)	No	27 (93.1)
	Local hematoma	2 (6.9)
Primary patency 6th month, n,(%)		27 (93.1)
Primary patency 9th month, n, (%)		23 (85.2)
Primary patency 12th month, (%)		23 (85.2)
Recurrence, n, %		8 (27.6)
Recurrence time, months, mean±SD		2.3±4.6
Recurrence type, n, %	Restenosis	7 (87.5)
	Thrombosis	1 (12.5)
Current status, n, %	Non-functional	5 (17.2)
	Functional	24 (82.8)

***Abbreviations**: **PTA**: percutaneous transluminal angioplasty, **ESRD**: end-stage renal disease, **ADPKD**: Autosomal Dominant Polycystic Kidney Disease, **AVF**: arteriovenous fistula, **ASA**: Acetylsalicylic acid*

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Table 2. Univariate and multivariate Cox-regression analysis with associated variables with recurrence

	Univariate Analysis		Multivariate Analysis	
	HR (95% CI)	**p**	**HR (95% CI)**	**p**
AVF age	0.970 (0.930-1.012)	0.156	0.994 (0.947-1.044)	0.804
Patient age	0.996 (0.949-1.046)	0.881		
Diabetes mellitus	0.205 (0.025-1.719)	0.231		
Smoking	0.897 (0.103-7.825)	0.735		
Non-compliance with anticoagulant/ antiaggregant therapy	14.916 (2.458-90.535)	0.003	12.905 (1.55-107.127)	0.018

***Abbreviations**: **AVF**: arteriovenous fistula*

Table 3. Univariate and multivariate Cox-regression analysis with parameters associated with non-functional AVF

	Univariate Analysis		Multivariate Analysis	
	HR (95% CI)	**p**	**HR (95% CI)**	**p**
AVF age	0.933 (0.873- 0.995)	0.013	0.946 (0.883- 1.014)	0.117
Patient age	1.032 (0.960- 1.109)	0.362		
Diabetes mellitus	0.327 (0.036-2.940)	0.319		
Smoking	0.033 (0.001- 269.7)	0.457		
Non-compliance with antiaggregant/ anticoagulant therapy	10.896 (1.522- 78.022)	0.017	3.889 (0.450- 33.586)	0.217

***Abbreviations**: **AVF:** arteriovenous fistula*

DISCUSSION

This study shows that endovascular treatment procedures performed with femoral artery cannulation for dysfunctional AVF are safe and have high clinical success. No significant complications were observed in any patients. The AVF dysfunction recurrences develop relatively early after the procedure. The risk of recurrence was exceptionally high in patients' noncompliance with antiaggregant/anticoagulant treatment.

Following AVF formation, neointimal hyperplasia may develop in the anastomotic region. This hyperplasia may lead to flow-mediated vasodilation, enlargement, and outlet stenosis that prevents maturation in AVFs. Venous juxtaanastomotic stenosis may cause poor graft flow and early thrombosis if there is an AV graft. [12-14] Vasodilation occurs in response to intimal hyperplasia, but failure in vasodilation can also lead to tight AVF stenosis. However, in some cases, despite significant neointimal hyperplasia, this is compensated by outward positive vascular remodeling or vein dilatation, and stenosis may not develop. [13] Furthermore, frequently in uremic patients, endothelial dysfunction may exaggerate the venous neointimal hyperplasia, medial hypertrophy, and vessel wall intima-media thickening that may be present even before the AVF creation. [15-17]

Maintaining the openness and functionality of the dialysis access pathway is a crucial need for dialysis patients. Previously, in patients with inadequate dialysis access or thrombosis, either the problematic circuit was surgically corrected or tunneled/non-tunnel catheter-based interventions were on the agenda. Today, applying interventional endovascular approaches is safe and successful for such vascular access problems. In 80% of cases and patients, they restore patency without needing temporary dialysis catheters or surgical consumption of additional venous channels. [14] However, this process is not lacking concerns: most critical stenosis develops either in the region of the AVF or along the venous outflow tract. Balloon

angioplasty may cause intima-media rupture, followed by neointimal hyperplasia (normal vascular response to injury), resulting in restenosis. For this purpose, paclitaxel is often preferred, being local applications more effective than systemic treatment. In animal studies, paclitaxel abolished early elastic recoil of the vasculature and significantly inhibited neointimal hyperplasia. [18] Drug-coated balloon technology has emerged as a potential solution to the limitations of angioplasty.

Katsanos et al. found the procedure's success rate 100% in plain and drug-coated balloon angioplasty and did not report any significant or minor complications. However, the cumulative target lesion primary patency was significantly higher in drug-coated balloon applications at the 6th-month follow-up. (70% in the PCB group versus 25% in the BA group, p<0.001; HR 0.30), p=0.006). [19] Due to these advantages in the literature, we also used paclitaxel-coated balloons in the PTA procedure. Even after more than four years of follow-up, 82.8% of patients still had functional AVFs.

Imaging to demonstrate the AVF circuit can be done via the brachial artery or the femoral artery. Another alternative is to retrograde the puncture of an outlet vessel and advance to the central arterial inlet of a catheter. Although it is often preferred because it is less invasive, retrograde approaches to an outlet vein are only sometimes successful. In addition, it may cause additional problems, such as thrombosis, as long-term pressure may be required on the AVF after the procedure.

Femoral artery approaches need longer catheters, guide wires, and shaft balloons than other puncture localizations. In addition, it requires a hospital stay for hemostasis, and complications such as lipo-aeroembolism are relatively high compared to routine brachial artery approaches. [20] Hemodialysis patients are a very challenging and high-risk group for arterial catheterization and endovascular interventions due to severe comorbidities (diabetes, dyslipidemia, hypertension) and bone mineral metabolism disorders. [21, 22] The destructive effects of these disorders on arterial structure are observed in the iliac and femoral arteries and other major arteries. It increases the risk of access-site bleeding after catheterization due to concomitant renal anemia. [23, 24] However, approaches from the femoral artery have some advantages. In this way, it is possible to see the entire vascular network from the aortic arch to the superior vena cava. It is not necessary to compress the AVF for hemostasis.

We did not observe any significant complications, such as major bleeding or atheroembolic disease, that may be associated with femoral artery puncture. Only two patients developed a local hematoma at the puncture site, which could be easily controlled with local measures.

The main limitations of this study are that its retrospective structure included data from a single center. However, this study also had some strengths. First is the long follow-up period; second, it provides data on the factors predicting AVF dysfunction recurrence.

Although there are only three patients with drug noncompliance, this number corresponds to 10.3% of the cases proportionally since the sample size is 29. Therefore, in multivariate Cox-regression analyses, noncompliance independently increases the risk of recurrence approximately 13 times (HR 12.905, CI 95% 1.55-107.127, p=0.018). The number of patients that agreed with this condition was low because of the sample size, and statistical analysis suggests that this condition could be a risk factor for recurrences. Larger scale and prospective studies will increase the confidence of that observation. In conclusion, percutaneous angioplasty via the femoral artery is an effective and safe treatment modality for AVF dysfunctions. Compliance of patients with antiaggregant/anticoagulant therapy is vital for the long-term success of the procedure.

Ethics Committee Approval: This study was approved by the Local Scientific Ethics Committee of Yalova State Hospital. (Approval date 14/02/2020-71290220/045.99.141)

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