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Research Article

Clinical Efficacy and Safety of Ultrasound-Guided Balloon Angioplasty for Immature Arteriovenous Fistula: A Retrospective Cohort Study

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Abstract

Objective: To investigate the efficacy and safety of ultrasound-guided Percutaneous Transluminal Balloon Angioplasty (PTA) in the treatment of immature autologous Arteriovenous Fistula (AVF) for hemodialysis.

Methods: A retrospective cohort study was conducted to analyze the clinical data of patients with immature AVF for hemodialysis and treated with ultrasound-guided PTA in the first affiliated hospital of Jinan University from January 2016 to December 2017. The Kaplan-Meier analysis was performed to estimate the primary patency rate of immature AVFs after PTA.

Results: Twenty-five patients with immature AVFs for hemodialysis were included in this study. Among 25 immature AVFs, 8 (32%) had multiple stenosis, and 17 (68%) had a single stenosis with a total of 33 stenosis. All the 25 patients underwent ultrasound-guided PTA, the postoperative color Doppler ultrasound showed residual stenosis less than 30% and the technical success rates were 100%. AVF fremitus was obvious after surgery, and was used for hemodialysis with a pump blood flow of more than 230 ml/min, the clinical success rates were 100%. Three patients (12%) had the minor complication of hematoma, and there were no severe complications such as rupture of blood vessel, balloon rupture, and embolism. All the patients were followed up for 12 to 29 months, the primary patency rates were 96% at 3 months, 84% at 6 months, 54.2% at 12 months, respectively.

Conclusion: Ultrasound-guided PTA is an effective method for the treatment of immature AVF. It also has a high technical success rate and clinical success rate with few complications.

Keywords: Autologous arteriovenous fistula; Color Doppler ultrasound; Immature; Percutaneous transluminal balloon angioplasty

Introduction

Hemodialysis is one of the important renal replacement therapies for patients with End-Stage Renal Disease (ESRD). Vascular access is the Achilles' heel of hemo-dialysis, effective vascular access guarantees adequate hemodialysis. At present, The National Kidney Foundation Kidney Disease Outcome Quality Initiative (NKF-KDOQI) guideline and Chinese expert consensus suggest that autologous Arteriovenous Fistula (AVF) is the first-choice vascular access in maintenance hemodialysis because of its longer patency, lower mortality and fewer complications, such as infections [1]. However, the disadvantages of autologous AVF are that they required at least 6-8 weeks for maturation and a high prevalence of immaturity.

According to statistic report, 28-53% of autologous AVF are failing to mature, resulting in an inability to meet the blood flow of hemodialysis needs [2]. Salvaging the immature AVF may increase the AVF prevalence, as well as survival rate and quality of life of hemodialysis patients [3]. According to literature, the application of endovascular treatment in mature AVF with stenosis or occlusion has achieved a comparative patency rate to the surgical revision [4,5]. Color Doppler ultrasonography is a noninvasive modality, moreover, ultrasound equipment is available and easy control for nephrologists. Clinically, ultrasound is widely used in the vascular access for hemodialysis, including the diagnosis of stenosis

in AVFs, surveillance of AVFs and guidance of endovascular treatment [6]. As the predominant cause of immature AVFs is also the presence of vascular stenosis, the color Doppler ultrasound-guided Percutaneous Transluminal Balloon Angioplasty (PTA) was used to salvage the immature AVF [7-9]. This clinical study was conducted to observe the clinical efficacy and safety of ultrasound-guided PTA for immature AVFs.

Objects and Methods

Patients and Selection Criteria

End-stage renal disease patients on hemodialysis who were diagnosed with immature autologous AVFs and received ultrasound-guided PTA from January 2016 to December 2017 at the First Affiliated Hospital of Jinan University. In this study, the criteria used to determine immature autologous AVFs were: hemodialysis pump blood flow less than 200 mL/min 3 months after autologous AVF creation; or AVFs only exist pulse, but no fremitus and color Doppler ultrasonography revealed the existence of stenosis in the AVF and the stenosis is greater than 50% of the adjacent lumen diameter. Exclusion criteria are

a. Arteriovenous fistula infection.

b. Central venous stenosis or occlusion.

Collection of Research Data

Demographic, clinical and ultra-sonographic data of included patients were recorded. Data were obtained from hospital electronic information system, hemodialysis record, and related information provided by local hemodialysis center, and telephone follow-up. The criteria of technical success: residual stenosis of arteriovenous fistula after PTA was less than 30%; The criteria of clinical success: postoperatively the AVF was used for hemodialysis with a pump blood flow of more than 230 mL/min for more than one time. Primary patency was defined as the interval following immature AVFs treated with PTA until the AVFs lost function and needs intervention again.

Endovascular Interventional Technique

The operations were performed by the nephrologists from the department of Nephrology, the First Affiliated Hospital of Jinan University. Preoperative color Doppler ultrasound (Toshiba xario, 7.5 MHz probe) was used to evaluate the location of the vascular stenosis and the degree of stenosis. During the operation, all AVFs were cannulated under ultrasound guidance with modified Seldinger technique; the puncture site was selected in the proximal fistula vein or the radial artery distal to the fistula anastomosis according to the location of the stenotic lesion. After successful cannulation, a 0.025″guidewire was inserted, (Terumo, Japan), withdrawal needle, local anesthesia with 1% lidocaine, and then the 6F introducer sheath was inserted (Terumo, Japan), injection of 20mg heparin through the sheath. The 0.035" hydrophilic wire (Terumo, Japan) passed through the stenotic lesion; balloon angioplasty was performed with 5-6 mm Conquest balloon (Bard, USA) according to the inner diameter of the blood vessel adjacent to the stenotic lesion. Balloons were inflated with 8-30 Atmospheres (ATM) for 30-60 seconds, repeat inflation if necessary, until the stenotic lesion resolved. After balloon angioplasty the Doppler ultrasound confirmed that the residual stenosis was less than 30%, and then removed the introducer sheath, the puncture point was sutured and compressed for 5 minutes. After dressing, the presence of fremitus was confirmed.

Statistical Analysis

Technical success rate and clinical success rate were expressed as percentages. Primary patency was estimated by Kaplan-Meier analysis. Patients in this study were censored if the patient died from an unrelated cause, quitted hemodialysis, AVFs maintained patency on January 1, 2019, or lost to follow-up. Data analyses were performed with IBM SPSS Statistics, Version 22.0 (Armonk, NY, US). All of the data were expressed as mean±Standard Deviation ($\bar{x}$±SD) (Table 1).

Patients' Characteristics	Result
Age (years, mean (SD))	56.5±13.3
Gender (Percentage)	
Male	18 (72.0%)
Female	7 (28.0%)
Comorbidity (Percentage)	
Hypertension	16 (64.0%)
Diabetes	13 (52.0%)
Coronary heart disease	2 (8.0%)
Peripheral vascular disease	0 (0%)

Table 1: General information of patients.

Results

General Information of Patients

A total of 25 patients with immature autologous AVFs underwent PTA treatment were enrolled in this study. There were 18 male patients and 7 female patients with a mean age of 56.5±13.3 years. Sixteen patients had hypertension (64.0%), thirteen patients had diabetes (52.0%), and two patients had coronary heart disease (8.0%). The mean duration between AVF creation and the PTA treatment was 123±42 days. Among the 25 patients, 8 (32.0%)

had multiple stenotic lesions, 17 (68.0%) had a single stenotic lesion, a total of 33 stenotic lesions. The most common stenotic site was located in the proximal anastomosis (juxta-anastomosis) 54.5%, followed by venous outflow tract accounting for 33.3%, and arteriovenous anastomosis accounting for 12.1% (Table 2).

AVF characteristics	Result
Age of AVF (day)[a]	123±42
Anastomosis	
End to side (Percentage)	25 (100%)
Vessels selection	
Radial artery- cephalic vein (Percentage)	25 (100%)
Stenotic lesion site (proportion)	
Artery	0/33
Arteriovenous anastomosis	4/33
Proximal anastomosis (juxta-anastomosis)[b]	18/33
Venous outflow tract[c]	11/33
Number of stenotic lesions (Percentage)	
1	17 (68.0%)
2	8 (32.0%)
≧3	0 (0%)
[a] The mean duration between AVF creation and the PTA treatment; [b] The vein proximal to anastomosis, within 2 cm of the anastomosis; [c] The venous outflow tract 2 cm away from the anastomosis.	

Table 2: Characteristics of autologous AVF.

Balloon Angioplasty and Intraoperative Complications

Twenty-five immature AVFs with 33 stenotic lesions were treated with balloon angioplasty under color Doppler ultrasound guidance, each patient used only one balloon catheter. Preoperative evaluation of the 25 immature AVFs by color Doppler ultrasound revealed that the mean lumen diameter of the stenotic lesions was 1.7±0.5 mm, and the mean diameter was 3.9±0.4 mm after balloon angioplasty (Table 3). After balloon angioplasty, color Doppler ultrasound showed residual stenosis less than 30% in all 33 stenotic lesions, and the technical success rate was 100%. The fremitus of the 25 immature AVFs was obvious after balloon angioplasty, and was used for hemodialysis with a pump blood flow of more than 230 ml/min for more than one time, the clinical success rates were 100%.

Variable	Results
The mean lumen diameter of the stenotic lesions	1.7±0.5 mm
The mean lumen diameter of the stenotic lesions after angioplasty	3.9±0.4 mm
Technical success rate	100%
Clinical success rate	100%
3-month primary patency rate	96.0%
6-month primary patency rate	84.0%
1-year primary patency rate	54.2%

Table 3: Balloon angioplasty and postoperative follow-up.

Regarding the intraoperative complications, one patient with juxta-anastomosis stenosis had local swelling after balloon inflation, and local hematoma was revealed by ultrasound, considering the venous rupture, it was managed by prolonged balloon inflation and external compression for about 2 minutes. After management, color Doppler ultrasound showed no extravascular blood flow signal, and the local hematoma gradually subsided the next day after the operation. One patient with arteriovenous anastomosis stenosis had small hematoma with ecchymosis on the second day after operation, color Doppler ultrasound revealed that no extravascular blood flow signal and the hematoma gradually subsided. One patient developed local hematoma in the puncture point after removal of the introducer sheath; it was managed by external compression for about 15 minutes. The next day after the operation, color Doppler ultrasound revealed no extravascular blood flow signal, and the local hematoma subsided gradually. Twenty-five patients had no severe complications such as arterial rupture, balloon rupture, or embolism.

Postoperative Follow-Up

Twenty-five patients were followed up for 12-29 months. As of January 1, 2019, the mean follow-up time was 543±166 days. The Kaplan-Meier analysis was performed to estimate the primary patency rate of immature AVFs after balloon angioplasty. The primary patency rate was 96%, 84%, 54.2% in 3 months, 6 months, and 12 months respectively (Figure 1, Table 3). Due to insufficient blood flow, three patients required repeat PTA treatment within 6 months after PTA, and 7 patients required repeat PTA treatment 6 to 12 months after PTA treatment. One patient constructed Arteriovenous Graft (AVG) 5 months after PTA because of the AVF blood flow insufficient. One patient died of Disseminated Intravascular Coagulation (DIC) 1 year after PTA, and her AVF was maintained patency.

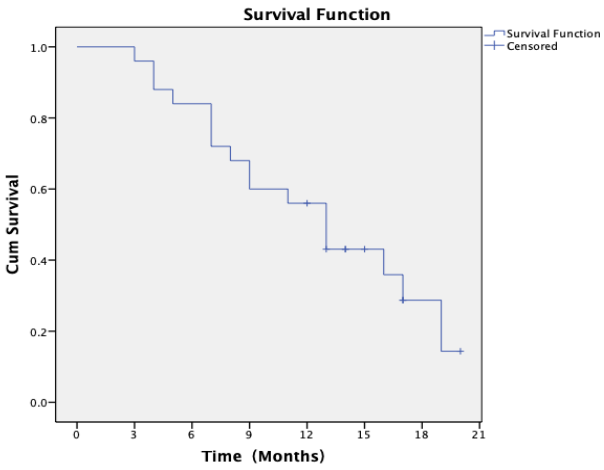

Figure 1: Primary patency of immature AVFs after ultrasound-guided PTA.

Discussion

The NKF-KDOQI guideline and Chinese expert consensus suggest that autologous Arteriovenous Fistula (AVF) as vascular access for maintenance hemodialysis accounting for at least 80% of the total vascular access [1]. However, the early failure rate of AVF is as high as 28%-53%, so salvaging immature AVFs is an vital manner to increase AVF prevalence [2]. The current study suggests that the leading cause of AVF immuration is the presence of stenotic lesions and competitive veins, but the mechanism of AVF immuration is not fully elucidated yet [5]. Roy-Chaudhury, et al. summarized the underlying pathophysiological mechanisms of AVF immuration: genetic susceptibility, low shear stress, increased transmural pressure, turbulence, differences in arterial and venous compliance, and vascular injury may lead to intimal hyperplasia and ultimately poor vascular remodeling [10]. Scholars have proposed that there must be stenotic lesions in the immature AVF. However, the competitive veins are not necessarily present [11]. In combination with our experience, stenotic lesions should be treated first for immature AVF, while collateral side branches generally do not require ligation or embolization. Ligation or embolization of the collateral side branch only after management of the stenotic lesion, and the AVF still do not have sufficient blood flow, due to the collateral side branch acting as competitive vein divert main blood flow. Therefore, subjects in this study were hemodialysis patients having immature AVFs with stenotic lesions, and no collateral side branch was ligated or embolized.

Interventional endovascular treatment of mature AVF is a mature technique, but more widely believed that the immaturity of AVF is a contraindication for endovascular treatment [11]. In recent years, clinical experience and research have found that interventional endovascular treatment can be applied to immature AVF, and many studies have reported that endovascular treatment can salvage immature AVF, with a success rate of 74-98% [2,11,12]. Compared with surgical revision, interventional endovascular treatment can maximize the protection of vascular resources, and the patency rate is competitive [4]. One or multiple stenotic lesions were found by color Doppler ultrasound in the immature AVFs for hemodialysis in this study. The most common stenotic site was the vein proximal to anastomosis (juxta-anastomosis) within 2 cm of the anastomosis, accounting for 54.5%, followed by the venous outflow tract 2 cm away from the anastomosis accounting for 33.3%, at last, the anastomosis accounting for 12.1%. The distribution of stenotic lesion sites of immature AVFs in this study is similar to that of mature AVFs stenosis lesions reported in the literature [2].

In this study, 25 patients with immature AVFs for hemodialysis were treated by ultrasound-guided percutaneous balloon angioplasty. There were 33 stenotic lesions were found in the immature AVFs, and the residual stenosis was less than 30% after PTA treatment, and the technical success rate was 100%. The fremitus of the 25 immature AVFs was obvious after balloon angioplasty and was used for hemodialysis with a pump blood flow of more than 230 ml/min for more than one time; the clinical success rates were 100%. The primary patency rate was 96% at 3 months postoperatively, which was significantly higher than the 72% reported in the literature [11]. Three patients (12%) developed hematoma and no severe complications such as uncontrolled vascular rupture, balloon rupture. Summarize the 25 cases of balloon angioplasty with high success rate, high primary patency rate and less complications, which may be attributed to the application of color Doppler ultrasound guidance and a high-pressure balloon catheter, as well as good interventional endovascular treatment skills. The 2015 European Interventional Ultrasound (INVUS) guidelines suggests that ultrasound intervention can be applied to the interventional endovascular treatment of hemodialysis vascular access [13]. Ultrasound applied to hemodialysis vascular access is not limited to guide endovascular treatment, but also includes preoperative assessment of vascular access and postoperative follow-up monitoring. Color Doppler ultrasound diagnosis of vascular stenosis has a sensitivity of 92% and a specificity of 84% [14]. Ultrasound-guided balloon angioplasty instead of traditional Digital Subtraction Angiography (DSA) can reduce radiation exposure, reduce the side effect of using contrast medium, and reduce medical costs. Color Doppler ultrasound-guided balloon angioplasty can not only observe the blood flow inside blood vessels but also display the blood vessel wall and extravascular structure [15]. The leading cause of AVF immaturity is the present of the stenotic lesion in the superficial vessels in the upper limbs, and the color Doppler ultrasound can display the superficial vessels and the complete procedure of balloon angioplasty clearly, including cannulation, passing through

guidewire, balloon inflation, even management of intraoperative complications. Therefore, the color Doppler ultrasound is suitable for the guidance of balloon angioplasty for the treatment of stenotic lesion or even occlusion of AVF and may be contributing to the high success rate and less complications. Scholars suggest that high-pressure balloons are the first choice for the treatment of AVF stenosis compared with ordinary balloons [16]. The stenotic lesion of autologous AVF is composed of dense fibrotic tissue which is difficult for the ordinary balloon to inflate fully. In contrast, the high-pressure balloon can fully inflate the stenotic lesion, reduce residual stenosis, and reduce the incidence of restenosis.

In Conclusion

The incidence of AVF immaturity is high. Ultrasound-guided percutaneous balloon angioplasty is one of the effective treatments for the salvage of immature AVFs. It can significantly increase AVF prevalence in maintenance hemodialysis patients and has a high success rate and few complications. However, large sample size，long-term follow-up study still needed to further verify the efficacy and safety of ultrasound-guided percutaneous balloon angioplasty for the treatment of AVF immaturity.

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