Cardiovasc Intervent Radiol (2019) 42:835–840
https://doi.org/10.1007/s00270-019-02213-w

Drug-Eluting Balloon Angioplasty for Juxta-Anastomotic Stenoses in Distal Radiocephalic Hemodialysis Fistulas: Long-Term Patency Results

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Received: 21 November 2018 / Accepted: 26 March 2019 / Published online: 29 March 2019

Abstract

Purpose To evaluate long-term primary and secondary patency results of drug-eluting balloon angioplasty for the treatment of juxta-anastomotic stenoses in distal radiocephalic arteriovenous fistulas.

Materials and Methods Thirty-eight patients with juxta-anastomotic stenotic distal radiocephalic arteriovenous fistulas who underwent endovascular treatment with drug-eluting balloons between January 2014 and August 2016 in our interventional radiology department were included in this retrospective study. Color Doppler examination for follow-up was performed 15 days, 6 months, 12 months, 18 months, 24 months, 36 months, and 48 months after the procedure. Kaplan–Meier analysis was used to estimate primary and secondary patency rates.

Results Totally, 42 angioplasty with drug-eluting balloons was performed in 38 patients (20 men and 18 women; mean age 66.42 ± 12.01). Technical and clinical success rate was 100% (42/42). The mean follow-up period was 27.71 months ± 12.98 (range, 1–54 months). The estimated primary patency rates at 6 months were 94.7% (95% CI, 80.9%–99.0%), at 12 months were 81.2% (95% CI, 64.6%–91.4%), at 24 months were 60.7% (95% CI, 43.6%–75.7%), and at 48 months were 53.1% (95% CI, 36.5%–69.1%). The estimated secondary patency rates at 6 months were 97.3% (95% CI, 84.5%–99.8%), at 12 months were 86.5% (95% CI, 70.7%–94.8%), at 24 months were 69.0% (95% CI, 51.8%–82.4%), and at 48 months were 61.7% (95% CI, 44.6%–76.5%).

Conclusion Drug-eluting balloon angioplasty is a useful, effective technique in dysfunctional radiocephalic fistulas due to juxta-anastomotic stenoses. We demonstrated remarkably high primary patency rates at 6, 12, 24, and 48 months.

Keywords Drug-eluting balloon · Percutaneous transluminal angioplasty · Juxta-anastomotic stenosis

Introduction

End-stage renal disease (ESRD) is the final stage of chronic kidney disease. It is predicted that the prevalence of ESRD and the need for hemodialysis will grow in the future as the average lifespan increases [1]. The Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines advise autologous arteriovenous fistula (AVF) for vascular access [2]. Distal radiocephalic AVFs are the first option due to its technical simplicity, lower complication, and higher patency rates [3]. However, in spite of being superior to other accesses, fistulas also have a limited time for appropriate usage. Stenosis, which usually occurs in 3 cm before and after the anastomosis, is the main reason for

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dysfunctional AVFs [4–6]. These types of stenoses are regarded as juxta-anastomotic stenoses (JASs) [7].

Endovascular treatment in AVFs is recommended in K/DOQI guidelines. Several reports have revealed the efficacy of endovascular treatment in AVFs [6, 8–10], but most of the studies have included all types of fistulas such as radiocephalic, radioulnar, or brachial-basilic. Moreover, long-term patency results after percutaneous transluminal angioplasty (PTA) in the most preferred fistula type, radiocephalic fistulas [3], are lacking. Over the past few years, drug-eluting balloons (DEBs) have evolved and taken part in stenotic AVF treatment by inhibiting neointimal hyperplasia [11]. However, it is still needed to be demonstrated how effective is the DEB angioplasty, which has been proven as the primary treatment method [12], in distal radiocephalic fistulas.

The aim of our study was to assess long-term patency results of DEB angioplasty for the treatment of JASs in distal radiocephalic AVFs.

Materials and Methods

Patients

Local ethics committee approval was obtained for this retrospective study. Patients who underwent fistulography and endovascular treatment in our department between January 2014 and August 2016 were reviewed. Since we wanted to elucidate long-term outcomes, patients with a minimum follow-up of 2 years were selected for the present study. The interventions performed before the year 2014 were not scanned for the lack of acceptable demographic and clinical data. The inclusion criteria were as follows: autologous distal radiocephalic fistulas with JASs. Arteriovenous grafts, patients without follow-up information, and fistulas that had treated formerly in different hospitals were the exclusion criteria. JASs were described as stenoses occurred in 3 cm before and after the anastomosis. After all, a total of 38 patients (20 men and 18 women; mean age 66.42 ± 12.01) with sufficient demographic, clinical, and radiologic follow-up data were incorporated in the study.

Pretreatment Evaluation

Patients in the study were directed to our department with AVF problems from dialysis units. The decrease of the blood flow greater than 20% per month, observing total access blood flow less than 300 mL/min were the conditions that displayed AVF dysfunction. One operator with 15 years of experience performed all the color Doppler examinations and operated all the endovascular treatments (A.G.). Color Doppler examination was used to localize the abnormality, estimate the degree of stenosis, evaluate the outflow vein, figure out the treatment method, and determine the access site. Along with clinical problems, narrowing greater than 50%, peak systolic velocity (PSV) ratio greater than 2:1 compared to the 2-cm proximal from the lesion, and PSV of $\geq$ 500 cm/sec were considered abnormal [13]. Further evaluation with fistulography was performed in these patients.

Endovascular Treatment

A digital subtraction angiography device (Allura Xper FD10, Philips Healthcare, the Netherlands) was used for fistulography and endovascular procedures. Retrograde outflow vein puncture was performed by ultrasound guidance to minimize hematoma in all procedures. Inflow, fistula, and outflow segments were assessed carefully before the procedure. Blood pressure cuff was used to observe arterial anastomosis better. Initially, we performed a fistulography via 18G cannula. Fistulography images were evaluated, and treatment decision was made by the same experienced interventional radiologist who had performed patients' initial color Doppler examination.

A standard technique was used for the treatment of JASs [14]. If we decided to do angioplasty after fistulography, we placed the sheath using 0.035-inch guidewire through the 18G cannula under local anesthesia. Heparin (5000 IU) was administered intravenously after vascular sheath placement in all cases. Juxta-anastomotic target lesion was passed by manipulation of a 0.035-inch hydrophilic guidewire and a 4F multipurpose vertebral catheter. After advancing the catheter to the arterial side, hand injection was performed for the final decision of balloon size. Then, 0.035- or 0.018-inch guidewire was advanced, and the catheter was removed. After predilatation with plain balloons, DEBs were advanced via guidewire to the lesion. Types of DEBs we used were Elutax SV OTW, ab medica, Dusseldorf, Germany (in 12 procedures), and IN.PACT Admiral Drug-coated balloon, Medtronic, California, USA (in 30 procedures). After the termination of the stenosis, the balloon was held on inflated for 2 min to prevent the elastic recoiling. For refractory lesions, cutting balloons were used. When successful appearance was gained, the procedure was terminated with control of central veins. After sheath removal, hemostasis was gained by manual compression.

Clinical Outcome and Follow-Up

Technical success, clinical success, primary patency, secondary patency, and minor and major complication rates were considered during clinical outcome analysis.

Technical success was described as the increase in the "thrill" and residual stenosis lower than 30% in both angiographic images and color Doppler examination. The operator performed color Doppler examination and thrill assessment before and after the procedure. During the procedure, the operator evaluated the angiographic images. However, all angiographic images were reviewed retrospectively by 6-year (O.S.) and 5-year (A.P.) experienced radiologists. The radiologists were unaware of the patients' diagnosis and operation findings. The two radiologists assessed the pre- and post-dilatation images and recorded the residual stenoses of $\geq$ 30% if any. Clinical success was defined as the access of the fistula without any problem during dialysis. Total access blood flow of $>$ 300 mL/min was a supportive criterion of the clinical success. Clinical success was evaluated by dialysis unit nephrologists. In the first dialysis session after the procedure, feedback was received via phone call.

Primary patency and secondary patency rates were evaluated based on the instructions of Society of Interventional Radiology Technology Assessment Committee [15]. Primary patency was defined as the time between the first intervention until access thrombosis and repeated endovascular treatment. The interval after the first intervention until the fistula is surgically revised or abandoned was regarded as secondary patency.

Color Doppler examination for follow-up was performed 15 days, 6 months, 12 months, 18 months, 24 months, 36 months, and 48 months after the procedure by an 8-year experienced radiologist (O.A). If a problem was detected by nephrologist, or dialysis unit nurse, patients were directly referred without waiting for the follow-up date. Color Doppler examinations, repeated angiography images, and records of dialysis units were inspected for follow-up data. Follow-up ended in August 2018. Complications were graded according to the CIRSE classification [16].

Statistical Analysis

Statistical analysis was performed by using the Statistical Package for the Social Sciences (SPSS) version 22.0 (SPSS Inc., Chicago, IL, USA). Kaplan–Meier survival analysis was used to estimate primary and secondary patency rates after intervention. Stated patency rate intervals in this study were 95% confidence intervals (CIs). Renal transplantation, exitus because of an independent cause from renal disease with functional AVF, and loss to follow-up were regarded as censored data.

Results

Characteristics of AVFs and patients' demographic data are demonstrated in Table 1. Forty-two PTA with DEBs was performed in 38 patients. The mean size of the balloons was 5.55 mm $\pm$ 0.67. Cutting balloon was used in one procedure due to refractory stenosis after DEB.

Our technical and clinical success rate was 100% (42/42). Grade 1 complications were experienced in 4 cases. Hematomas at the puncture site that did not affect blood flow were reported after two interventions (2/42, %4.76). Contrast extravasation was observed in two procedures and was managed with balloon inflation (2/42, %4.76).

The mean follow-up period in this study was 27.71 months $\pm$ 12.98 (range, 1–54 months). Eight patients died of an unrelated cause from renal disease with functional fistula during the follow-up period.

At the sixth month, one patient underwent surgical creation of a new fistula; one patient needed reintervention due to stenosis of the same location; one patient died with functional fistula. Thirty-five patients had successfully working AVF at the end of 6 months.

Between the 6th and 12th months, 4 fistulas were thrombosed and abandoned. Repeated endovascular treatment to the same region was performed in one patient.

After 18 months, 4 patients died with functional fistula. 3 fistulas were surgically revised. One patient had recurrent JAS and reintervention was done.

At 24-month follow-up, 3 patients could not continue dialysis with their fistulas and underwent surgical revision.

Table 1 Demographic features of the patients and characteristics of the AVFs

Number of patients	38
Age (years)	66.42 $\pm$ 12.01
Female to male ratio	18/20
Hypertension	21/38 (55.3%)
Hyperlipidemia	17/38 (44.7%)
Diabetes mellitus	
Type 1	1/38 (2.6%)
Type 2	20/38 (52.6%)
Type of AVF	
Radiocephalic	38/38 (100%)
Side of AVF	
Right	13/38 (34.2%)
Left	25/38 (65.8%)
Age of AVF at the first intervention (months)	15.2 $\pm$ 18.3
Stenosis location	
Juxta-anastomotic	38/38 (100%)

AVF arteriovenous fistula

One patient died with functional fistula. At the end of 2 years, there were 18 patients remaining with no necessity for additional intervention.

Between the 24th and 36th months, 2 patients died of heart problems with functional fistula. No endovascular intervention or surgery was performed during this period.

At 48th month, two fistulas were occluded, and surgery was performed to revise. By the end of 48 months, 14 patients did not need any intervention and underwent dialysis successfully. At the end of the follow-up interval, 17 patients (%44.7) had functional AVFs.

At the follow-up, three patients were needed reintervention. At 5 months, one patient had stenosis and the patient was treated by angioplasty with DEB. Two months later, restenosis was detected and the same procedure was performed; 11 months later, restenosis was detected again at the same region and treated with DEB again. No further intervention was needed, and fistula is still patent. The second patient had stenosis at the same site after the intervention, and the patient was treated by angioplasty with DEB. No further stenosis was detected during the follow-up period. The other patient also had recurrent stenosis at 14 months of follow-up; he was treated by angioplasty with DEB. No more stenosis occurred during the follow-up period.

The estimated primary patency rates at 6 months were 94.7% (95% CI, 80.9%–99.0%), at 12 months were 81.2% (95% CI, 64.6%–91.4%), at 18 months were 70.3%, (95% CI, 53.1%–83.4%), at 24 months were 60.7% (95% CI, 43.6%–75.7%), at 36 months were 60.7% (95% CI, 43.6%–75.7%), and at 48 months were 53.1% (95% CI, 36.5%–69.1%).

The estimated secondary patency rates at 6 months were 97.3% (95% CI, 84.5%–99.8%), at 12 months were 86.5% (95% CI, 70.7%–94.8%), at 18 months were 78.4%, (95% CI, 61.6%–89.4%), at 24 months were 69.0% (95% CI, 51.8%–82.4%), at 36 months were 69.0% (95% CI, 51.8%–82.4%), and at 48 months were 61.7% (95% CI, 44.6%–76.5%). Figure 1 summarizes the patency results.

Discussion

Our study demonstrated that endovascular treatment of JASs in radiocephalic hemodialysis fistulas with DEBs is an effective method. We recorded pretty high primary patency rates even at 48 months with DEBs in this study. Secondary patency rates were greater than primary patency rates as expected.

PTA is an established procedure and is the first option for the management of JASs with its minimally invasive nature [7, 17, 18]. Although surgical creation of a new fistula has lower rates of recurrence [19], secondary patency rates are comparable with surgery and PTA [20]. Despite high recurrence rates, endovascular treatment allows immediate usage of AVF after the procedure and prevents waiting for maturation after the new surgery.

Many studies compared the DEBs and plain balloons in the treatment of stenotic AVFs [12, 21, 22]. All these studies demonstrated that DEBs provide significantly higher primary patency rates and lower recurrence rates. Animal trials displayed the efficacy of paclitaxel on preventing neointimal hyperplasia and reported that local therapy is more useful [23, 24].

Although miscellaneous reports assessed the efficacy of DEBs in AVFs, the sample in these studies included radiocephalic and brachiocephalic fistulas or grafts, juxta-anastomotic, or outflow venous stenoses [6, 8, 9, 25, 26]. As far as we know, minimal number of studies assessed the long-term patency rates after DEB angioplasty in a uniform sample such as autologous radiocephalic AVFs with JASs [7].

We demonstrated better primary patency rates at 6 (94.7%) and 12 (81.2%) months compared to other studies [6, 9, 27, 28]. These results illustrate the efficacy of DEB angioplasty in JAS. Patanè D et al. [7] achieved similar results. The treatment of JASs with DEBs reduces the rate of restenosis and therefore makes the primary patency rates higher. With less repeated interventions, patient comfort and cost-effectiveness get better [22]. After the intervention, two restenoses occurred, and reintervention was performed within 1 year in our study. This number was much better than most of the other studies, except one study had the same number [7].

Patanè D et al. [7] showed a significant decrease in the primary patency rates from the 12th month to the 24th month. Similarly, there was a decline in our study from the 18th (70.3%) month to the 24th (60.7%) month. This decrease may be the consequence of repetitious punctures and vascular damage. However, the results remained the same at the 36th (60.7%) month. These rates are significantly higher than all studies that assessed the management of JASs in radiocephalic fistulas [7, 17, 27, 28].

Manninen et al. [17] assessed the effectiveness of the brachial arterial approach to the failing radiocephalic fistulas. Their primary patency rate was 32.0% at 36 months. This significant lower result compared to our study may be due to the heterogeneous target lesion (JASs or other segments) selection. Moreover, not only DEB angioplasty but also other treatment options such as thromboaspiration or stent deployment were performed in their study. Mortamais et al. [28] evaluated long-term results after endovascular treatment in JASs. They included only radiocephalic AVFs with JASs in their research and reported primary patency rates of 25.5% at 36 and 48 months. We demonstrated significantly greater rates at

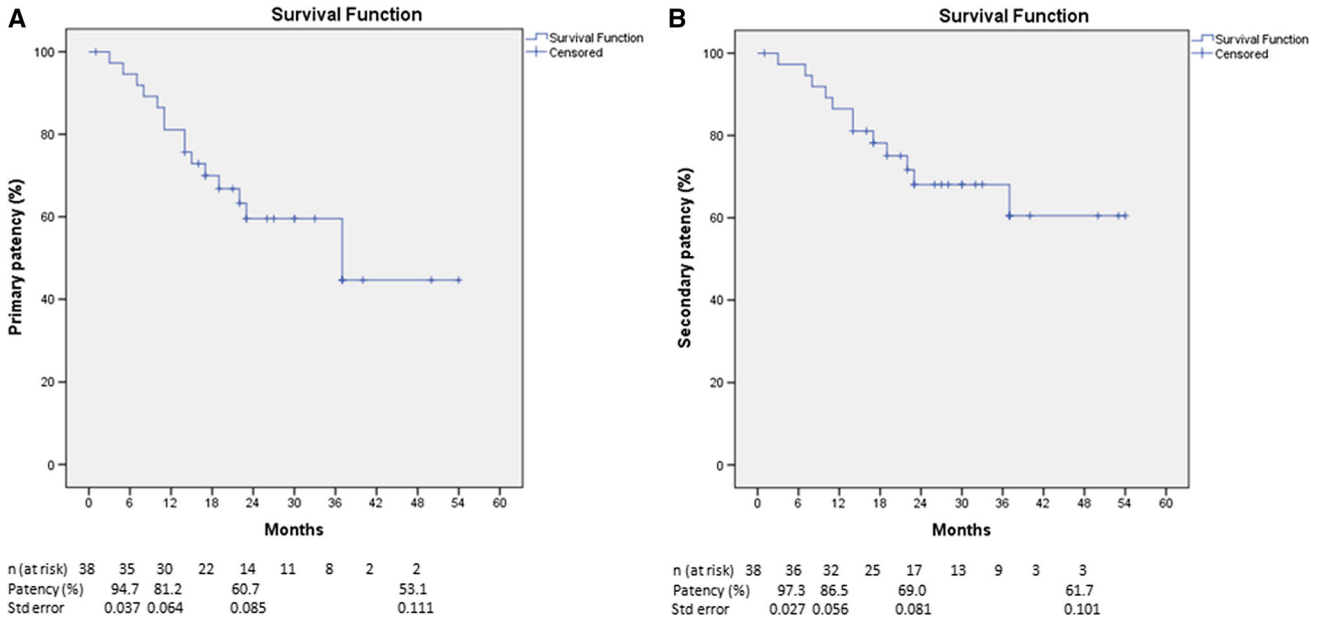

Fig. 1 Kaplan–Meier survival curves of estimated primary (**A**) and secondary (**B**) patency

48 months (53.1%). These encouraging rates at 6, 12, 18, 24, 36, and 48 months may be the result of DEB selection for the particular lesions in radiocephalic AVFs.

During our follow-up period, recurrent stenosis in the juxta-anastomotic region occurred in only three patients. This promising result may be due to the relatively small sample group. Mortamais et al. [28] reported that residual stenosis after the intervention, stenosis length, and time before the first restenosis significantly increase repeated interventions. On the other hand, Rajan et al. [8] demonstrated that no clinical or anatomic variable affects patency outcome.

The study had some limitations. The retrospective study design was the major limitation of the present study. Second significant limitation was the lack of a control group who were treated by plain balloons. Another limitation was the relatively small sample size of the patient group.

In conclusion, DEB angioplasty is a safe, effective treatment method with high primary patency rates even at long terms. The results we gained in this study demonstrate that JASs in distal radiocephalic AVFs can be effectively treated with DEBs and AVFs can be used safely for years after DEB angioplasty.

Acknowledgements This study was carried out in Dokuz Eylul University Faculty of Medicine, Izmir, Turkey.

Compliance with Ethical Standards

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

Ethical Approval For this type of study, formal consent is not required. Ethics committee approval was received for this study from the local ethics committee.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Consent for Publication Consent for publication was obtained for every individual person's data included in the study.

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