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Treatment of juxta-anastomotic stenoses for failing distal radiocephalic arteriovenous fistulas: Drug-coated balloons versus angioplasty

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Abstract

The aim of our study is to report the results of two types (type A, type B) paclitaxel drug-coated balloon compared with standard percutaneous transluminal angioplasty in the treatment of juxta-anastomotic stenoses of mature but failing distal radiocephalic hemodialysis arteriovenous fistulas. Two groups of 26 and 44 patients treated with two different drug-coated balloon are compared with a control group of 86 treated with standard percutaneous transluminal angioplasty. A color Doppler ultrasound was performed to evaluate stenosis and for treatment planning. We assess primary patency, defined as the absence of dysfunction of the arteriovenous fistulas, patent lesion or residual stenosis < 30% and no need for further reintervention of target lesion. Primary patency and secondary patency are evaluated after 12 months with color Doppler ultrasound for the whole arteriovenous fistulas, defined as absolute (absolute primary patency, absolute secondary patency) and target lesion. Postprocedural technical and clinical success was 100%. After 12 months, absolute primary patency is 81.8% for type A, 84.1% type B, and 54.7% for standard percutaneous transluminal angioplasty; target lesion primary patency is 92% type A, 86.4% type B, and 62.8% standard percutaneous transluminal angioplasty; absolute secondary patency is 95.4% type A, 95.5% type B, and 80.7% standard percutaneous transluminal angioplasty; target lesion secondary patency is 100% type A, 97.7% type B, and 80.7% standard percutaneous transluminal angioplasty. All the patients treated with drug-coated balloon (type A + type B) have an absolute primary patency of 83.3%, a target lesion primary patency of 87.9%, an absolute secondary patency of 95.5%, and a target lesion secondary patency of 98.4%. Our study confirms that the use of drug-coated balloon, indiscriminately among different brands, improves primary patency with statistically significant difference in comparison with standard percutaneous transluminal angioplasty and decreases reintervention of target lesion in juxta-anastomotic stenoses of failing distal arteriovenous fistulas maintaining the radiocephalic fistula as long as possible.

Keywords

Paclitaxel eluting ballons, standard angioplasty, stenosis, juxta-anastomotic region, distal radiocephalic fistulas

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Introduction

Nowadays, end-stage renal disease (ESRD) is a very widespread and disabling condition in the world, affecting 65,000 new patients in Europe every year while in the United states this number reached 115.000 in 20111,2 increasing the number of hospitalizations with significant economic disadvantages. The Kidney Disease Outcome Quality Initiative and the recent clinical practice guidelines of the American Society for Vascular Surgery recommend the creation of autogeneous fistulas as the first choice to

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start a dialytic therapy in view of their superior patency rates and lower rates of complications once matured, compared to prosthetic graft or to a central venous catheter.[3]

Stenosis, the most common problem among the arteriovenous fistulas (AVF), can lead to an inadequate dialysis or can precipitate in vessels occlusion and access loss; an almost 50% failure rate of the fistulas is reported after a median lifespan of 3–7 years caused by stenosis and totals of 41%–64% of these stenosis are located in the juxta-anastomotic portion of the fistula within 3 cm proximal to distal of the arteriovenous anastomosis.[4–7]

According to the updated American Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines, it is now well established that the endovascular approach with percutaneous transluminal angioplasty (PTA) is the first-choice treatment instead of surgery in clinical practice for the treatment of perianastomotic stenosis; despite the high recurrence rate of restenosis after PTA, multiple therapeutic sessions may be needed to maintain long-term pate ncy.[4,6,8–12]

Events like surgical trauma of the vascular area, hemodynamic shear stress, vessel injury by multiple dialytic puncture, and repeated angioplasty are responsible for the endothelial injury that could lead to an exaggerated vessel reparative process response and to neointimal hyperplasia.[13–16]

Several systemic or perivascular therapies and many methods have been proposed to prevent neointimal hyperplasia and restenoses[16–18] without any good clinical validation in dialytic vascular access.[14,19–22] Many studies have shown good results in vivo models of the use of the antiproliferatives drugs like paclitaxel or sirolimus to reduce neointimal hyperplasia in the coronary arteries or in the venous side of the hemodialysis access.[10–12,23]

So the rationale of our retrospective study is that the use of drugs that inhibit fibromuscular intimal hyperplasia combined with PTA could reduce the high restenosis rate and improve the long-term patency. In particular, the juxta-anastomotic region is considered by many authors a critical area both for its rate of stenosis and for the reported lower results of the standard PTA; therefore, low patency rates encourage many nefrologists to abandon the malfunctioning AVF.[13,24,25] The aim of our study was to evaluate the efficacy of the use of paclitaxel drug-coated balloon (DCB) in the treatment of mature but failing distal radiocephalic AVF stenosis and assess their performance on primary patency (PP), secondary patency (SP), and target lesion revascularization (TLR) after 12 months also comparing it with our experience with standard PTA.

Materials and methods

A monocentric retrospective study was performed evaluating 70 consecutive patients with juxta-anastomotic stenosis of distal radiocephalic hemodialytic AVF treated with DCB: 26 treated with In.Pact, Amphirion, Invatec Technology Center GmbH, Switzerland (type A) and 44 with BARD LUTONIX 0.014″, BARD Peripheral Vascular, Inc. Tempe, USA (type B) within our standard practice.

Among our historical case series, we included in the analysis only the patients who have reached 1 year of clinical and instrumental follow-up. For retrospective studies, a formal consent for inclusion is not required but an informed consent before the procedure was obtained from all individual participants included in the study. These data were compared with a control group of 86 patients with distal radiocephalic AVF, treated with standard PTA for a stenosis in the juxta-anastomotic region, between September 2002 and July 2009 when DCBs were not available in our department. This control group has similar demographic characteristics as the DCB cohort.

All the procedures performed in the standard percutaneous transluminal angioplasty (sPTA) group and in the DCB group were performed by the same experienced interventional radiologists.

The main objective of our retrospective study was to evaluate PP and SP after 12 months:

- PP was defined as the proportion of patients with freedom from any restenosis at specific time points; it was divided in absolute (absolute primary patency (aPP) (the outflow of all the treated districts was compromised), and as target lesion (TL) (the compromised area was the juxta-anastomotic one/above treated with DCB);
- SP was defined as the proportion of patients with freedom from any restenosis at specific time points.

A hemodialysis session not satisfactory or the absence of “thrill” at clinical evaluation led to a preliminary color Doppler ultrasound (CDUS). CDUS evaluation permits to evaluate the site and the cause of dysfunction (stenosis, thrombotic occlusion), the degree of stenosis, venous outflow conditions, and its diameters and also to plan treatment; it is also mandatory to perform ultrasound-guided percutaneous access to perform the procedure.

If a hemodynamically significant stenosis was found at the CDUS, patients were referred to the endovascular treatment before their next dialysis session. The treatment, according to the site of stenosis, was performed with retrograde access from venous outflow side; an anterograde access from the arterial side in the brachial artery was performed with a 4F vascular introducer sheath only when the anastomosis lesions were uncrossable from the venous side. A 6 Fr. Vascular sheath was placed in the outflow

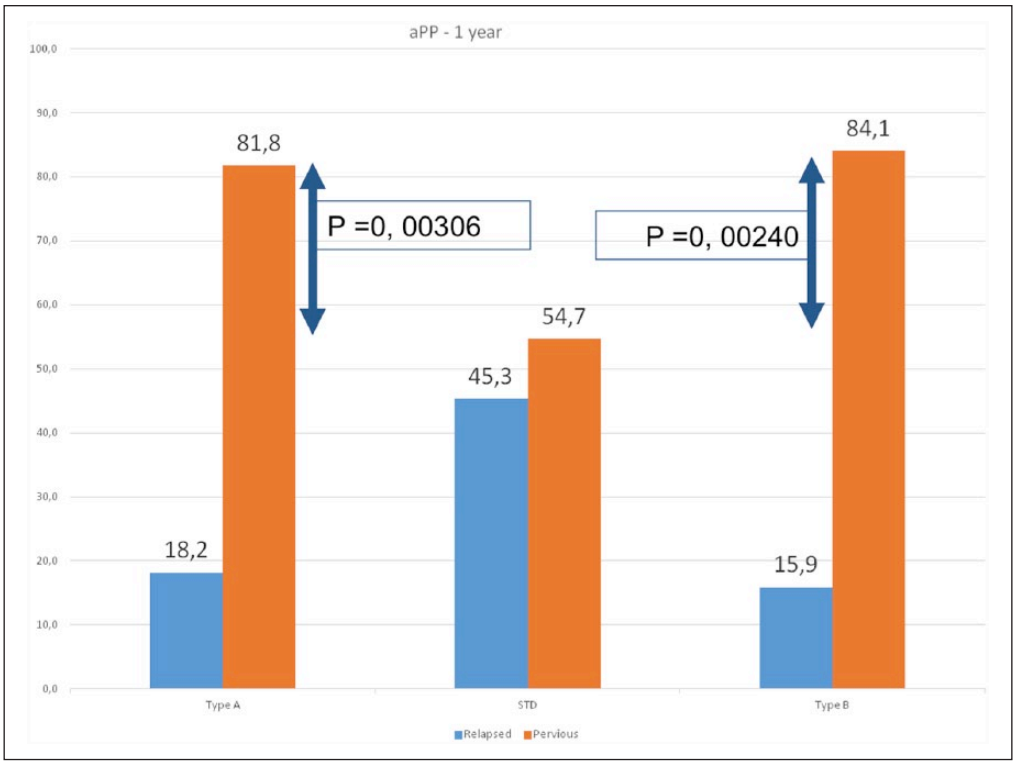

Figure 1. The histogram chart compares the rates of absolute primary patency before 1 year.

vein, than heparin (2500 IU) was administrated and diagnostic angiography was performed.

We crossed juxta-anastomotic stenosis and anastomosis with 0.014″ guide wire, which was retrogressively advanced into the proximal radial artery; considering that the vessel diameters range in the juxta-anastomotic region is among 2.5–4 mm, a low-profile PTA compliant balloon catheter about 3−3.5 mm of diameter was passed over the wire and then advanced to the most central lesion. Multiple inflations were used for resistant lesions, using growing PTA balloons, inflated for at least 2 min to avoid elastic recoil. Once a good angiographic morphological result was achieved, treatment was completed with inflation of DCB (paclitaxel-eluting balloon) over the wire with the same diameter of the last balloon dilatation or 5 mm more of length if available; DCB's diameters in the anastomosis were 3−4 mm with 8−12 cm of length, always inflated at the nominal pressure for at least 2 min up to 3 min. In case of resistant outflow side lesions in the venous side PTA with high-pressure balloons was performed.

The aim was to use PTA with conventional balloons to reach a good dilatation of stenosis and after to apply DCB to deliver paclitaxel on all the surfaces of the vessels. Technical success was established as the absence of stenosis or a stenosis <30% at the angiographic venous retrograde phlebography.

Clinical success was the report of "thrill" from the anastomosis at the end of the procedure and the ability to perform a regular dialysis immediately after treatment. Follow-up was performed with CDUS at 3–6–9–12 months.

Results

The patients' baseline demographics and characteristics of the DCB group showed a wide range group with an average of 70 years of age, high predominance of males with 41 patients (58.5%), 37 patients with hypertension (42.5%), 20 patients with hyperlipidemia (28%), and 45 patients with diabetes (64.2%). All patients had a mature AVF (fistulas mean age 31 ± 36 months). Table 1 summarizes epidemiological and demographical characteristics of the three groups of patients.

In type A group, stenosis was "de novo" in 19 patients (72%) and "recurrent" in 7 patients (28%); in type B group, stenosis was "de novo" in 30 patients (68.2%) and "recurrent" in 14 patients (31.8%). After 12 months, we found that in the type A DCB group, aPP of 81.8%, target lesion primary patency (TLPP) was 92%, absolute SP was 95.4%, and target lesion secondary patency (TLSP) was 100%. These data are very similar to the DCB type B that after 12 months had an aPP of 84.1%, a TLPP of 86.4%, an absolute SP of 95.5%, and a TLSP of 97.7%.

In all the 70 patients treated with paclitaxel DCB, cumulative aPP was of 83.3%, with a TLPP of 87.9%; absolute SP was 95.5%, with a TLSP of 98.4%. Mean time

Table 1. Comparison of demographics characteristics of the three groups analyzed.

	Type A group	Type B group	sPTA group
Number of patients	26	44	86
Mean age	71 ± 13 years	70 ± 8 years	68 ± 14 years
Male gender	21/26 (80.0%)	20/44 (45.0%)	65/86 (76%)
Hypertension	13/26 (52.0%)	24/44 (54.5%)	52/86 (61%)
Hyperlipidemia	11/26 (44.0%)	9/44 (20.4%)	38/86 (44%)
Diabetes mellitus	15/26 (56.0%)	30/44 (68.2%)	52/86 (61%)
Arteriovenous fistulas mean age	31 ± 36 months	31 ± 36 months	28 ± 37 months
De novo stenosis	19/26 (73.0%)	30/44 (68.2%)	64/86 (75%)
Recurrent stenosis	7/26 (28.0%)	14/44 (31.8%)	21/86 (25%)

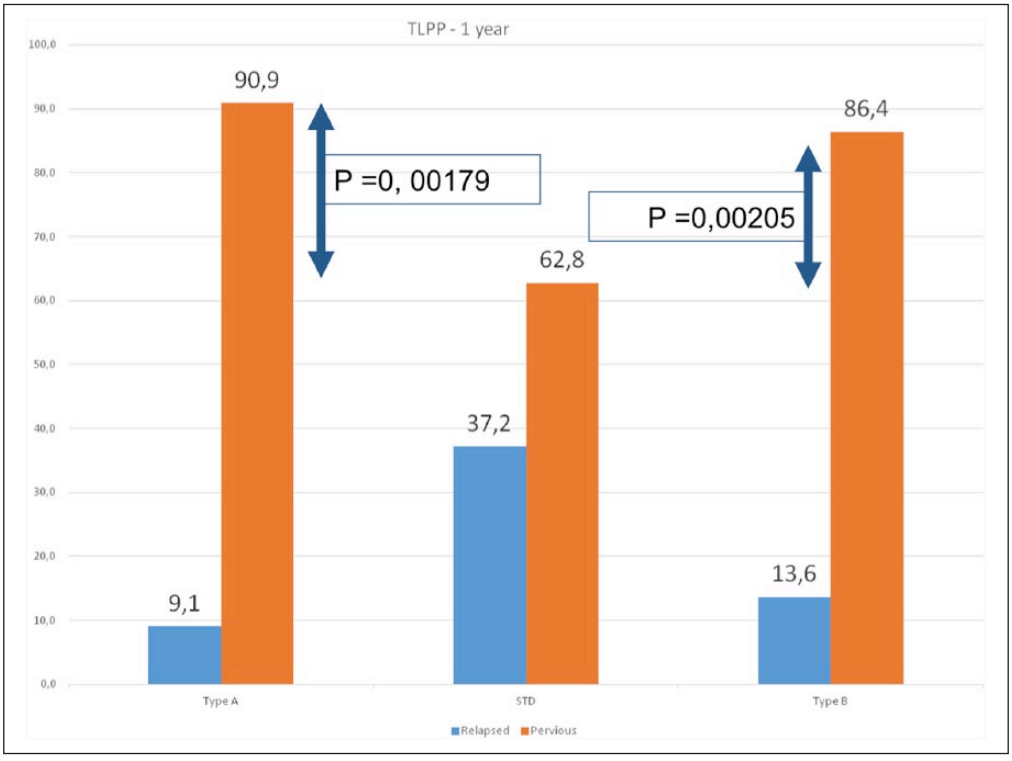

Figure 2. The histogram chart compares the rates of target lesion primary patency before 1 year.

of first occurrence was 9.0 ± 2.8 months in type A group, and 5.4 ± 2.5 months in type B group.

The standard PTA series is composed of 86 patients with juxta-anastomotic stenosis with similar demographics characteristics as the DCB cohort. After 12 months, aPP rate was 56.6%, TLPP 65%, absolute secondary patency 80.7%, and TLSP 80.7%.

We have therefore performed a statistical analysis with "*t* student" test comparing paclitaxel DCB cumulative values and the control group demonstrating a statistical significance with a p value of $p = 0.0017$ for aPP and $p = 0.0016$ for TLPP in the use of DCB regarding the sPTA (Figures 1 and 2). Results are summarized in Table 2.

No major complications were observed during the procedures. All of the AVF were used successfully for dialysis at the end or within 48 h of either procedure.

Discussion

The first choice for ESRD hemodialytic patients was autologous AVF, as all the international guidelines suggest[24,26,27] and, in particular, radiocephalic arteriovenous shunt is to be preferred because it allows venipuncture of a large venous territory.[28]

On the other hand, juxta-anastomotic region could be affected by stenosis resulting in dysfunction and loss of vascular access with higher rate than other portions of venous

Table 2. Comparison of the patency rates evaluated in the three groups.

	Type A group	Type B group	Standard percutaneous transluminal angioplasty group
Absolute primary patency	18/22 (81.8%)	37/44 (84.1%)	54.7%
Target lesion primary patency	20/22 (90.9%)	38/44 (86.4%)	62.8%
Mean time of first occurrence	9.0 ± 2.8 months	5.4 ± 2.5 months	5.3 months
Absolute secondary patency	21/22 (95.4%)	42/44 (95.5%)	80.7%
Target lesion secondary patency	22/22 (100%)	43/44 (97.7%)	80.7%

outflow or than arterial stenosis.[13,15,25,29] The established method of preserving failing dialysis access was sPTA, sometimes associated with pharmacological or mechanical thrombolysis or thromboaspiration in the event of thrombotic occlusion. This minimal invasively technical procedure maintains larger venous territory and made AVF immediately available for hemodialysis.[30]

Standard PTA is also recommended for the treatment of dysfunction of AVF in KDOQI guidelines and major international reports confirm high rates of technical success and satisfying patency rate but obtained with multiple angioplasties and repeated hospitalizations.[26] The increase of new hemodialytic vascular accesses in association with an high reintervention rate could lead to the abandonment of the distal AVF and to its most proximal construction at the first warning of stenosis;[25,31,32] in fact this type of fistula, which is generally the first native autogenous access used, in our opinion is the one which should be maintained as long as possible even at the cost of repeated endovascular procedures. The most important pathophysiological mechanisms that cause stenotic dysfunction of AVF is venous neointimal hyperplasia that usually develops in the juxta-anastomotic region[14,16,28,33–36] especially in distal radiocephalic fistulas.

The underlying events are surgical trauma of the vascular area, hemodynamic shear stress, vessel injury by multiple dialytic puncture, and repeated angioplasty. All these factors are responsible for the endothelial injury that could lead to an exaggerated vessel reparative process response.

This mechanism is (also) similar to arterial mild-intimal hyperplasia.[13–16] Several systemic or perivascular therapies and many methods have been proposed to prevent intimal hyperplasia and restenosis;[16] without any good clinical validation in dialytic vascular access,[14,19–22] only animal trials on sheep and pigs showed that paclitaxel inhibits neointimal formation on Arteriovenous graft (AVG) model.[12,23]

Paclitaxel had the function of eliminating early elastic recoil with vessel scaffolding and significantly inhibit neointimal hyperplasia. It was demonstrated that local therapy is more effective than systemic therapy.[12]

There are also a great number of scientific studies and clinical trials regarding coronaries[37–45] and arterial district of superior[46] and inferior limbs[47] that described great advantages of drug-eluting stents and balloons to avoid reappearing arterial intimal hyperplasia.

Therefore, similar to arteries, antiproliferative agents could be useful for avoiding or delaying the recurrence of stenosis. This concept was well supported by scientific studies that showed greater increase of proliferation index inside venous neointima and media in vascular access submitted to PTA for recurring restenosis than in primary stenosis.[48]

Applying this well-established information about efficacy of paclitaxel upon neointimal hyperplasia, therefore, we decided to use paclitaxel DCBs in the juxta-anastomotic region and we have already evaluated and assessed, in our series, the efficacy of paclitaxel DCB to increase PP, SP, and TL with a paclitaxel DCB balloon catheter (paclitaxel-coated balloon, In.Pact, Amphirion, Invatec Technology Center GmbH, Switzerland)[8] also comparing it to standard PTA[5] in a homogeneous population. Therefore, we decided to retrospectively evaluate our series and in particular 70 patients with juxta-anastomotic stenoses of failing distal radiocephalic AVF treated with both paclitaxel DCB balloon available in our department. Our results using DCBs evaluating all the 70 patients showed 12 months of aPP (83.3%) and, even more, TLPP (92%) with a mean time of first occurrence of 9.0 ± 2.8 months.

These results are significantly better compared to the published case series of similar treatments on juxta-anastomotic region.[6,9,49–51] This is further proof of the efficacy of the drug-eluting devices also in vascular access.[8,52–55]

There are many studies that demonstrate and encourage the use of DCB for the treatment of dialytic fistulas stenosis, but all evaluate non-homogeneous population comparing graft and native fistulas, juxta-anastomotic and distal vein stenosis in the same analysis; in our knowledge, there are no published studies which perform a statistical and scientific analysis, using an homogeneous population that include and evaluate only autogenous native mature radiocephalic AVF and stenoses of the juxta-anastomotic region who reached 1 year of follow-up.

In our experience, we supported the use of DCB only in patients with juxta-anastomotic stenosis in autogenous mature fistulas; this showed the effectiveness of treatment with DCB in preventing restenosis in juxta-anastomotic region of radiocephalic fistulas, increasing PP, also limiting the number of hospitalizations with significant economic advantages. It also demonstrates that the antiproliferative

drug certainly works on neointimal hyperplasia[56] regardless of carrier and device used. In our study, there is a significant statistical difference in terms of PP between the patients treated with PTA standard and those treated with two different types of paclitaxel medicated balloons.

Paclitaxel DCB prolongs the effectiveness of the treatment of the PTA and the survival of the fistula. All these lead to enormous benefits for the patient with only minor risk of losing the fistula and available venous territory puncture and reduced hospitalization costs. We therefore believe that the extensive use in our daily practice can change the general direction in favor of the DCB, minimizing the need for surgical procedure of most proximal construction of the malfunctioning AVF.

Conclusion

In conclusion, our studies confirm that the use of paclitaxel-coated balloon is a safe and effective treatment in juxta-anastomotic lesions with remarkably higher patency than conventional PTA. This study further contributes to others in the literature which validates the use of DCB with paclitaxel molecule in the treatment of complication of stenotic hemodialytic fistulas. However, it represents one of the few studies to focus on the effectiveness of this treatment in the juxta-anastomotic lesion of distal radiocephalic fistula; in fact, this type of fistula should be maintained as long as possible, even today is all too often abandoned at the first sign of stenosis, resorting prematurely surgical solutions. However, our study is retrospective; further randomized studies are needed to confirm such promising results.

Declaration of conflicting interests

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