Drug-eluting balloon for the treatment of failing hemodialytic arteriovenous fistulas

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Aims and objectives

Thrombosis following stenosis of arteriovenous fistulae resulting in the loss of vascular access for hemodialysis is an important complication in patients with chronic renal failure. Dysfunction of AVFs occurs frequently in haemodialysis patients and contributes significantly to morbidity and hospitalization in the dialysis population. Percutaneous transluminal angioplasty is being used more frequently in the treatment of stenosis aiming at increasing the patency of arteriovenous fistulae. The purpose of this article is to report our experience with drug-eluting balloons for the treatment of failing hemodialytic arteriovenous fistulas and to evaluate the primary patency rates.
Methods and materials

We performed 22 interventions in 22 patients on hemodialysis AVFs stenosis. The angioplasties were performed in the angiology service between January 1 and November 31, 2013. There were 17 men and 5 women with a mean age of 63.8 years (range, 6-82 years). Patients with malfunctioning arteriovenous access who presented at the Internal Medicine Service.

The angioplasties were performed in all cases by proximal catheterization of the fistulae with the insertion of introductory sheaths (varying from 5 to 7 Fr) and regional anticoagulation using 2000 IU of heparin. Diagnostic angiography was performed through the sheath. A hydrophilic-coated, steerable, 0.035-inch Terumo guidewire (Terumo Corp., Tokyo, Japan) was passed. A balloon catheter was then passed over the guidewire and advanced to the most central lesion. According to the size of the veins, drug eluting balloons with a diameter 1 mm greater than the normal size of the venous segment (varying from 4 to 8 mm) were used. Balloon size was determined based on the findings on fistulography. The balloon was allowed to remain inflated for 1 minute with each inflation. A post-procedural fistulography was performed to assess and document the results of the therapy. Following the removal of the vascular sheath, hemostasis was achieved by manual compression. All patients were observed in the day surgery ward for two to three hours and discharged if no acute complications (bleeding or thrombosis) were detected.
Results

In the study period, 22 angioplasties were performed in 22 fistulae of 22 patients. Of these fistulae, 20 were the radiocephalic and 2 were brachiocephalic. Immediate postprocedural technical and clinical success was 100% for all the 22 patients at the first treatment.

The main objective was to evaluate primary patency (PP) defined, in accordance with the Kidney Disease Outcomes Quality Initiative recommendation, as the absence of dysfunction of the vascular access, patent lesion or residual stenosis <30% and no need for further reintervention.

Patients were followed routinely at 6 months and 12 months after balloon angioplasty. Primary patency at 6 and 12 months were evaluated with echo color doppler for arteriovenous fistulae. During the follow-up, 7 cases of restenosis were diagnosed. And were successfully treated with PTA.

The primary patency (PP) of the 22 fistulae evaluated after angioplasty was 72.7% at 6 months (16/22) and 68.1% at 12 months (15/22)
Conclusion

The AVF is regarded as the vascular access of choice for hemodialysis because of its superior patency and lower complication rates. Vascular access complications are one of the main causes associated with an increase in morbidity and mortality in stage 5 chronic kidney disease patients (1). Thrombosis is the most frequent complication of arteriovenous fistulae that results in the loss of the access for hemodialysis. Most episodes of thrombosis coincide with the development of stenosis (in more than 85% of cases), generally located in the venous segment proximal to the arteriovenous anastomosis [2-4]. In the past, surgical treatment performing correction of the stenotic lesion using a bypass or a patch was the only option.

In recent years, percutaneous interventional techniques have been tried and established as a viable alternative means in the management of fistula dysfunction. Angioplasty is efficacious with some advantages compared to the conventional surgical treatment such as a shorter time needed to perform the procedure and shorter hospitalization, less discomfort for the patient, and lower infection rates. Additionally, it enables dialysis immediately after the procedure without the necessity of using a central venous catheter. Percutaneous transluminal angioplasty (PTA) is the mainstay of treatment in stenosed hemodialysis access. With current techniques, PTA is a safe and useful intervention to restore access patency and preserve venous capital for future AVF creation. (5) PTA restores the luminal diameter of venous fistula by stretching and dissection of the vessel wall. This induces vascular damage and may cause subsequent restenosis. (6) After balloon dilatation, the pathways of the biological tissue response are regarded to be generally similar in arteries and dialysis access vessels.

The concept of developing a balloon-based drug delivery system to prevent arterial restenosis was based on the hypothesis that a durable effect on neointimal proliferation could be achieved following the single-time delivery of paclitaxel into the vessel wall (7,8,9). This early hypothesis contradicted previous experimental and clinical data suggesting that sustained tissue exposure to paclitaxel was necessary to effectively decrease restenosis. After balloon dilatation, the pathways of the biological tissue response are regarded to be generally similar in arteries and dialysis access vessels. The advantages of drug-eluting balloons (DEBs) could offer a valuable alternative in treating dialysis access stenosis, as they were found to decrease the 6-month restenosis rate from approximately 45.5% to about 18.7% in femoropopliteal arteries (10).

Our results show promising higher 12 months PP (68.1%) than the literature (11,12,13) this shows the effectiveness of treatment with DEB in preventing restenosis AV fistulas, increases PP and decreases the rate of repeated procedures.
Fig. 1: A 70 year-old man presented with a stenosis of his radiosefalic fistula vein

References: radiology, adnan menderes university, university hospital - Ayd#n/TR
Fig. 2: stenosis of radiosefalic fistula vein was dilated with 4/20mm DEB

References: radiology, adnan menderes university, university hospital - Ayd#n/TR
**Fig. 3:** After DEB, stenosed fistula vein successfully dilated

*References:* radiology, adnan menderes university, university hospital - Aydın/TR

A 70 year-old man presented with a stenosis of his radiosefalic fistula vein which was dilated successfully with an 4/20 mm DEB
References


