Vascular Specialist International
Vol. 35, No. 4, December 2019
pISSN 2288-7970 • eISSN 2288-7989

Original Article

Use of Paclitaxel Eluting Stents in Arteriovenous Fistulas: A Pilot Study

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Purpose: We report short-term patency outcomes of a proof of concept study conducted to determine the efficacy of drug-eluting stent (DES) for the treatment of arteriovenous fistula (AVF) stenosis in hemodialysis patients.

Materials and Methods: This is a single-center, retrospective observational study involving 10 patients with AVF dysfunction treated with DESs between January 2017 and December 2017. The primary outcome was AVF patency confirmed by sonographic and clinical assessment at 1 month and 6 to 9 months after treatment.

Results: A total of 12 DESs were deployed in 10 patients with dysfunctional AVF (radiocephalic: 7, brachiocephalic: 3). During the early follow up (mean: 28.6 days), primary access circuit and DES patency was 100%, with an average volume flow rate of 886.4 mL/min. Nine patients were available for short-term follow up (mean: 202.4 days; 1 unrelated death), with a mean volume flow rate of 1,048.9 mL/min. The primary DES patency was 7/9 (77.8%), and 3 patients required angioplasty at other parts of the circuit (primary access circuit patency: 4/9 [44.4%]). The assisted primary access circuit patency was 77.8%. In 2 patients, the ultrasound revealed that the DESs were thrombosed without any antecedent stenosis; they were salvaged with angioplasty. Both patients previously underwent 2 DESs implanted and recently stopped dual antiplatelet therapy. B-mode sonographic assessment at all timepoints showed minimal intimal ingrowth on the stent struts.

Conclusion: This study demonstrates acceptable short-term patency for DESs in the treatment of AVF stenosis. Dual antiplatelet therapy is probably mandatory in the short term.

Key Words: Arteriovenous fistula, Fistula, Vascular access, Drug-eluting stents

Received September 5, 2019
Revised November 17, 2019
Accepted November 21, 2019

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Oral presentation at Australia and New Zealand Society for Vascular Surgery 2018 Annual Scientific Conference 29th Sept-1st Oct 2018.

Vasc Specialist Int 2019;35(4):225-231 • https://doi.org/10.5758/vsi.2019.35.4.225

INTRODUCTION

Hemodialysis is a renal replacement therapy option for patients with end-stage renal failure. Patients dependent on hemodialysis require a reliable conduit that allows high flow vascular access. With superior patency and lower reintervention rates, the autogenous arteriovenous fistula (AVF) is the preferred form of vascular access [1,2]. However, AVF is prone to restenosis [3,4].

Neointimal hyperplasia may be pronounced in AVFs for multiple reasons [5,6]. To detect early signs of access dysfunction, the National Kidney Foundation Kidney Dialysis

Outcomes Quality Improvement guidelines recommends judicious follow up of patients with a newly created AVF as part of an AVF surveillance program involving both clinical examination and evaluation by duplex ultrasound [7].

Percutaneous transluminal angioplasty (PTA) is increasingly being accepted as the first-line treatment for restoring luminal diameter [1]. However, PTA has variable technical success rates and high rates of restenosis [3,4,8]. Drug-eluting balloons (DEBs) have been shown to improve patency, particularly in recurrent stenosis [9,10]. The DEB delivers an antiproliferative agent that inhibits smooth muscle cell proliferation and migration. Therefore, it prevents or delays the recurrence of stenosis and has superior patency rates to the standard non-DEB 6 and 12 months after the procedure [2,9,10]. However, neither PTA nor DEB addresses the problem of post-angioplasty elastic recoil, a problem that is effectively treated by the insertion of a self-expanding nitinol Stent. The presence of a stent also improves the ease with which the fistula can be needled [11]. Stent placement has been safely and successfully used to salvage failing AVFs [12,13]. The use of stents may prevent elastic recoil and allow for a larger acute lumen to facilitate needle access. However, stents in AVFs are prone to restenosis [14].

There is an increasing body of evidence demonstrating that the patency of a drug-eluting stent (DES) is superior to that of a bare metal stent and plain balloon angioplasty in various vascular beds [15-17]. DES has reduced rates of in-stent stenosis through the elution of an anti-proliferative drug into the blood vessel wall. The elution profile of a DES allows for prolonged delivery of a drug to the neointima, thus preventing restenosis over a longer period of time compared to DEB angioplasty. This profile would be suitable for AVFs. However, DESs have not been studied in AVF stenosis patients.

This study aimed to assess the safety and efficacy of DESs for the treatment of AVFs to obtain enough evidence to support the need for a larger clinical trial.

MATERIALS AND METHODS

1) Study population and data collection

Ethical approval was obtained from the local Human Research Ethics Committee before the study was conducted (approval number: LNR/17/POWH/564).

We treated 10 failing AVFs that were previously treated with an Eluvia DES (Boston Scientific, NJ, USA) at a single center between January 2017 and December 2017. Data was extracted retrospectively from medical records and clinical databases. Patient demographics and comorbidities, clinical presentation, history of vascular access, operative and stent details, previous salvage procedures, and treatment outcomes were recorded in a Microsoft Excel Spreadsheet database (Microsoft, Palo Alto, CA, USA).

2) Indication for intervention

Patients with problematic dialysis were identified during hemodialysis and were referred to a dedicated vascular access clinic [18]. Clinical assessment and sonography were performed to determine the underlying cause of problematic dialysis. Details of the AVF lesions of patients were recorded, including location and length of stenosis, as well as flow rate volumes. The indication for a DES placement was based on the criteria previously established by Swinnen et al. [10], which include the presence of either a luminal ultrasound diameter <2 mm (with or without symptoms/problems) or a luminal ultrasound diameter between ≥2 and 4 mm with other evidence of fistula malfunction related to the stenosis.

3) Procedure

① Access, deployment, and imaging

All procedures were performed in a hybrid operating theatre under local anesthesia. Ultrasound-guided percutaneous access was gained. A 6-Fr Brite Tip Sheath (Cordis Cardinal Health, Dublin, OH, USA) access sheath was introduced, and diagnostic angiography was performed through the sheath to visualize the stenotic lesions (Fig. 1). All patients were given 5,000 IU heparin. An Eluvia DES was deployed to extend across the most central part of the lesion. All lesions were pre-dilated using a 6-mm plain balloon angioplasty (Armada; Abbott Vascular, Abbott Park, IL, USA). A post-procedural fistulogram was performed to ensure a good angiographic result (Fig. 2). Following the removal of the vascular sheath, hemostasis of the puncture site was achieved. All patients were observed during recovery for approximately 3 hours and examined for acute complications. The patients then underwent dual antiplatelet therapy (DAPT) and were subsequently discharged following the

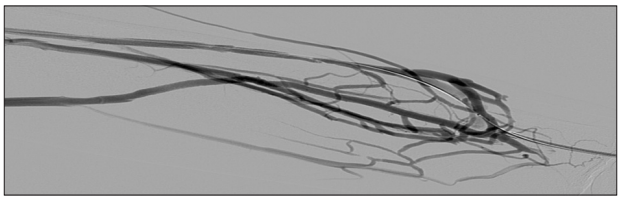

Fig. 1. Forearm angiogram taken via radial artery puncture demonstrated multiple small superficial veins prior to placement of Eluvia stent.

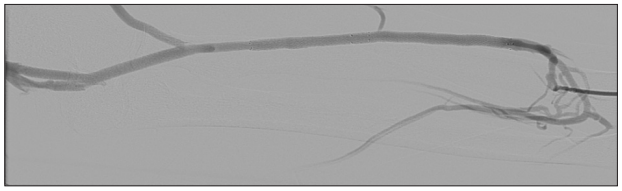

Fig. 2. Forearm angiogram taken via radial artery sheath after placement of Eluvia stent demonstrated flow mainly through the stent.

administration of a regular dose. Patients were maintained on dual anti platelets for 1-year post-implantation of the stent.

4) Follow-up procedure

Patients were clinically evaluated at approximately 1 month (early) and 6 to 9 months (short term) post DES deployment as part of the standard care for AVFs. A full assessment of the AVFs of patients included physical fistula assessment and duplex ultrasound imaging with a review of the hemodialysis performance parameters of patients. Volume flow rates and recurrent dysfunction were recorded during these assessments. If a patient experienced fistula or dialysis problems in between clinic visits, he or she was referred for urgent duplex ultrasound and clinical assessment. Dialysis problems included decreased dialysis flow rates, cannulation difficulty, alteration in intra-access pressure, recirculation, and abnormal pain and swelling.

5) Outcome endpoints

Previously described standards by Sidawy et al. [19] were used to report post-intervention patency. The primary endpoint for this study was primary patency of the AVF. A significant stenosis was defined as a luminal diameter of <2.7 mm during B-mode and color duplex imaging. Swinnen et al. [3] previously verified this criterion. In addition, secondary endpoints included access circuit patency, assisted primary patency, and secondary patency. Access circuit patency loss was defined as the development of a stenosis in any region of the AVF circuit. Assisted primary patency was defined as the patency of the AVF until thrombosis or loss of the AVF, regardless of the number of endovascular repeat interventions. The brachial blood flow rate was also analyzed.

RESULTS

Ten patients were treated with the Eluvia Paclitaxel Eluting Stent (7 radiocephalic and 3 brachiocephalic AVFs). Indications for AVF DES implantation intervention were complete occlusion (20.0%) and stenosis (80.0%). Baseline demographics are presented in Table 1. The mean access age at time of failure was 1,061.5 days (range: 14-3,475 days), with a mean patient age of 69.3 years (range: 53-79 years). Six patients had previously undergone endovascular salvage of their fistula (angioplasty alone: n=1, stent: n=5).

Table 1. Baseline patient and access characteristics (n=10)

Characteristic	Value
Sex (male)	5 (50.0)
Age (y; at time of DES insertion)[a]	69.3 (53-79)
Comorbidities	
Diabetes	5 (50.0)
Hypertension	7 (70.0)
High cholesterol	6 (60.0)
Ischemic heart disease	6 (60.0)
Peripheral vascular disease	5 (50.0)
CVA	1 (10.0)
Smoker	1 (10.0)
Access type	
Radiocephalic	7 (70.0)
Brachiocephalic	3 (30.0)
Previous intervention	6 (60.0)
PTA	1 (10.0)
Stent and PTA	5 (50.0)
Indication for DES	
Occlusion	2 (20.0)
Stenosis	8 (80.0)
Stent details	
Age of access at the time of failure[a]	1,061.5 (14-3,475)
Diameter[b]	6 (6-7)
Length[b]	60 (40-80)
Additional stents	5 (50.0)

Values are presented as number (%) unless otherwise indicated.
DES, drug-eluting stent; CVA, cerebrovascular accident; PTA, percutaneous transluminal angioplasty.
[a]Mean (range). [b]Median (range).

A total of twelve stents were successfully deployed. Two patients required 2 DESs to completely cover their lesion. Further interventions were required to maintain patency in 4 patients. Those interventions involved the use of a bare metal stent on each occasion. The median stent length was 60 mm (range: 40-80 mm) and the median diameter was 6 mm (range: 6-7 mm). No procedural complications were reported. Following DES intervention, all patients were able to undergo dialysis immediately.

All patients were available for the first follow-up visit (mean: 28.6 days; range: 12-40 days). Primary patency was 100%, with an average flow rate 886.4 mL/L. Only 9

https://doi.org/10.5758/vsi.2019.35.4.225

patients were available for the short-term follow up (mean: 202.4 days; range: 112-284 days). One patient died from influenza. Seven patients had patent AVFs (77.8%) with an average volume flow rate of 1,048.9 mL/min. Primary and assisted primary access circuit patency was 44.4% and 77.8%, respectively.

Two thrombosed DESs were identified. The patients with these DESs had recently stopped DAPT. All the other patients continued their DAPT, classified as aspirin and clopidogrel, for at least 1 year. The discontinuation of DAPT was, therefore, considered a contributing factor to AVF thrombosis. Each of the 2 patients underwent angioplasty and AVF salvage successfully (100% secondary patency). Both patients had 2 DESs implanted to treat their original stenosis.

DISCUSSION

The AVF is the preferred type of access for patients who require hemodialysis. In this single-center, proof of concept study, we describe the use of DESs for maintaining AVF patency in failing AVFs. Even though 2 patients developed AVF thrombosis, the remaining 7 (77.8%) patients demonstrated DES patency during the short-term follow up. This study provides proof of concept for the use of DES in AVF, and emphasizes the need for further studies to investigate the benefits of using DESs to salvage the failing AVF.

All DESs were implanted using percutaneous techniques and were discharged on the same day as their procedure. All patients successfully underwent hemodialysis immediately after the procedure. Dialysis nurses were allowed to puncture the DES to enable needle placement after the procedure. There were no major adverse events and no hematomas in the arm after DES placement.

The literature strongly supports endovascular salvage over surgery as a first-line approach for treating AVF dysfunction in hemodialysis patients [7]. The advantages of endovascular techniques include reduced operating times and days in hospital, less discomfort, lower infection rates, and immediate post-operative use of the AVF. Further, given the body's limited available anatomical access sites, endovascular salvage also prevents the surgical creation of a new AVF, hence allowing for the preservation of potential future access sites. Although a number of different endovascular approaches have already been established, AVF dysfunction is still prevalent in patients who have already undergone some type of salvage procedure.

The current endovascular options for treating AVF stenosis include the use of PTA, DEB, or bare metal stents. Although PTA has traditionally been used as the first-line intervention for restoring luminal diameter, the results of recently published data favor treatment with DEB. A randomized controlled trial by Swinnen et al. [10] demonstrated a significant delay in restenosis in lesions treated with a Paclitaxel DEB compared to standard non-coated balloon (10.14 months for standard PTA vs. 42.39 months for DEB). This finding was also supported by Katsanos et al. [20], who reported significantly superior primary patency rates in patients treated with DEB compared to treatment with standard PTA (70% for DEB vs. 25% for standard PTA) 6 months after the procedure. A small number of randomized controlled studies also support this finding [21-23]. Regardless of these results, conduit restenosis is still high in patients treated with DEB, and Boitet et al. [24] reported dysfunction in up to 60% and 70% of patients 6 and 12 months, respectively, after the procedure. Non-DESs have also been successfully used to treat stenosis, however, with variable primary patency rates ranging from 27% to 69.3% after 6 months. In the literature, studies on this topic are scarce [13,25]. With primary and assisted primary access circuit patencies of 44% and 78%, our results are comparable to those obtained following the use of other methods of endovascular salvage. Finally, a recent study conducted by Dinh et al. [26] showed no increased risk for all-cause mortality in patients treated with DEB angioplasty compared to those treated with PTA for dialysis access dysfunction during short-term and mid-term follow up.

During B-mode ultrasound imaging, no intimal growth was observed in the stents. This suggests that the stent struts may remain exposed. This may explain the conduit thrombosis that occurred in the 2 patients who discontinued the DAPT. We noted that both patients had undergone 2 stent placement. This suggests that DAPT may be more important in these patients with longer treated segments. It is also possible that remnant thrombus had formed within these stents leading to occlusion. The type and optimal duration of antiplatelet therapy in patients after the deployment of a DES in a peripheral vessel remains the subject of ongoing debate. Current clinical practices were extrapolated from data on the coronary and lower extremity vessels [27-29]. These studies suggest that long-term single agent antiplatelet therapy with aspirin in patients undergoing PTA with or without stenting improves patency outcomes. Additionally, in a study by Sharma et al. [30] that involved coronary stents, it was proposed that the discontinuation of antiplatelet therapy remains the most important independent predictor for the development of stent thrombosis. Although the study by Sharma et al. [30] involves coronary arteries, the results inform physicians about the potentially important role antiplatelet therapy may play in preventing stent thrombosis elsewhere in the body.

As the use of DESs in AVFs has not yet been studied, the

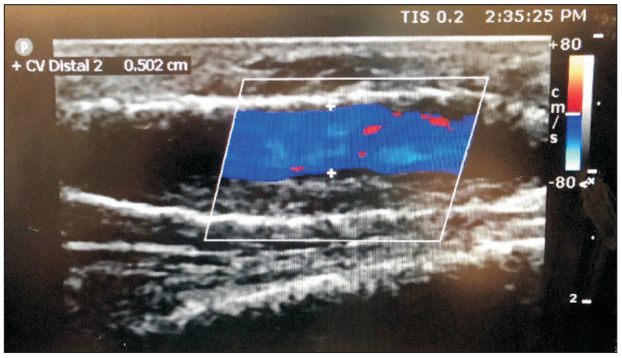

Fig. 3. Standard nitinol stent 6 months post implantation demonstrated color fill in the lumen of the stent with outlining neointimal hyperplasia within stent.

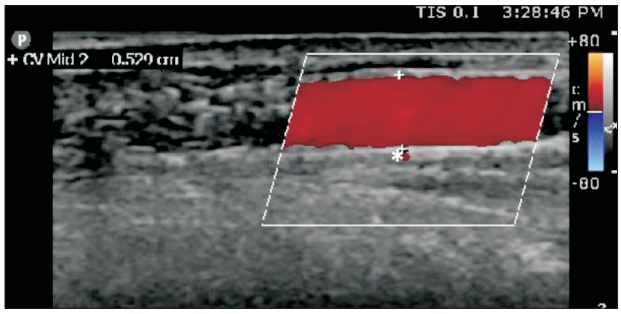

Fig. 4. Eluvia stent 6 months post implantation demonstrated no significant neointimal hyperplasia. *: Indicating colour flow seen to the edge of the stent on duplex ultrasound.

importance and course duration of antiplatelet therapy post deployment is unknown. The preliminary results of this study suggest that continuous antiplatelet therapy may be important in preventing early and short-term thrombotic events. Long-term antiplatelet therapy may be contraindicated in some hemodialysis patients, especially potential renal transplant recipients. Antiplatelet therapy at time of renal transplant increases the risk of post-operative bleeding complications and subsequent allograft rejection. The general applicability of the use of DES in managing patients with dysfunctional AVFs is therefore limited and judicious patient selection is crucial. Long-term hemodialysis patients who do not have the option of receiving a transplant are likely to benefit from DES.

The appearance of the stent during ultrasound imaging at the follow up was different in patients treated with DESs (Fig. 3, 4) compared to that in patients treated with nitinol stents. DES stents did not show any evidence of neointimal growth within the stent during B-mode ultrasound imaging during the study period. In our experience, a thin lining of intimal tissue typically develops on standard nitinol stents. This lining often becomes thicker over time and can lead to hemodynamically significant stenosis. The appearance of the stent and the lack of intimal growth on the stent did not change throughout the follow-up period.

Critical limitations to this study include the study type and the small number of participants. Further, a longer follow-up period is needed to assess long-term AVF viability. Nonetheless, the results of this study will serve as a basis to conduct a larger multi-centered, randomized control trial.

CONCLUSION

The efficacy of DESs in maintaining failing AVF and preventing restenosis during the short-term follow-up period is promising. Further studies are required to investigate the role of DESs in AVF and its benefit, if any, over standard endovascular treatments.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHOR CONTRIBUTIONS

Concept and design: SDT. Analysis and interpretation: JS, SDT. Data collection: KD, SDT. Writing the article: KD, SDT, RLV. Critical revision of the article: TC, JS, RLV, PC. Final approval of the article: all authors. Overall responsibility: SDT.

https://doi.org/10.5758/vsi.2019.35.4.225

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