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The role of endovascular stents in dialysis access maintenance

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Abstract

Vascular stenosis is most often the culprit behind hemodialysis vascular access dysfunction, and while percutaneous transluminal angioplasty (PTA) remains the gold standard treatment for vascular stenosis, over the past decade the use of stents as a treatment option has been on the rise. Aside from the two FDA approved stent-grafts for the treatment of venous graft anastomosis (VGA) stenosis, use of all other stents in vascular access dysfunction is off-label. KDOQI recommends limiting stent use to specific conditions, such as elastic lesions and recurrent stenosis; otherwise, additional adapted indications are in procedure-related complications, such as grade 2 and 3 hematomas. Published reports have shown the potential use of stents in a variety of conditions leading to vascular access dysfunction; such as VGA stenosis, cephalic arch stenosis, central venous stenosis, dialysis access aneurysmal elimination, Cardiac Implantable Electronic Device induced stenosis, and thrombosed arteriovenous grafts (AVG). While further research is needed for many of these conditions, evidence for recommendations has been clear in some; for instance, we know now that stents should be avoided along cannulations sites and should not be used in eliminating dialysis access aneurysms.

In this review article, we evaluate the available evidence for the use of stents in each of the aforementioned conditions leading to hemodialysis vascular access dysfunctions.

Keywords

Stents; Dialysis access dysfunction; Cephalic arch stenosis; Aneurysms; CIED; Central venous stenosis

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Introduction

Although the tools and equipment used in endovascular treatment of hemodialysis vascular access dysfunction have seen important advances over the last decade, we strongly believe that the road of discovery and innovation is still in the early stages. Hemodialysis vascular access complications contribute to End Stage Renal Disease (ESRD) patients' morbidity and mortality¹ and significantly add to their cost of care². Hemodialysis vascular access is the lifeline of ESRD patients on hemodialysis, which is essentially a life sustaining treatment. Arteriovenous fistulas (AVF) are the preferred hemodialysis access due to superior patency rates, longevity, and lower rates of complications³, with AVGs coming in second in preference, although AVGs do have occasional unique advantages over AVFs^{4,5}. Vascular (arterial and venous) stenosis is the main culprit for arteriovenous access dysfunction, and neointimal hyperplasia (NIH) is the main pathology behind the development of venous stenosis⁶.

Advances in endovascular procedures for hemodialysis vascular access, improved outcomes, and the convenience of performing these procedures in the outpatient settings, make PTA the gold standard treatment for hemodialysis vascular access dysfunctions. Stents, however, have emerged as a potential additional therapeutic intervention in vascular access dysfunction and have been the subject of retrospective and prospective studies examining their efficacy as compared to PTA. The role of stents in treating vascular access dysfunction has been debated, and evidence is clearer in some specific clinical conditions as compared to others. Flair endovascular stent grafts⁷ (Bard Peripheral Vascular, Inc., Tempe, AZ) and Viabahn endovascular stent grafts⁸ (W.L. Gore & Associates, Inc., Flagstaff, AZ) are the only known stents approved by the FDA for use in the hemodialysis vascular access for VGA stenosis, while use of other stents in dialysis access dysfunction has been mostly off-label.

Indications for stent use in hemodialysis vascular access procedures

In addition to the above-mentioned indications for Flair and Viabahn graft stents for venous graft anastomosis stenosis, there are other indications that were adapted based on clinical practice guidelines and position paper recommendations. One such indication is the use of stents as treatment for procedure related grade 2 and 3 hematomas^{9,10}. It is important to mention that grade 1 hematomas usually respond to balloon tamponade intervention. The recommendation for stent use in grade 2 and 3 hematomas came from clinical practice committee position papers due to the major advantage of salvaging arteriovenous access and avoiding the need for urgent surgery. Another indication for stent use is elastic lesions (recoil) after angioplasty¹¹. This recommendation was based on the evidence that median access survival was inversely related to the residual stenosis in both elective angioplasty and thrombectomy¹². A third indication is rapid recurrence of stenosis, which is defined by KDOQI as recurrence of the lesion in a period of less than three months¹¹.

Complications associated with stent use

There are several reported complications associated with stent placement. Stent migration has been reported as one of the complications; migration can be local, i.e., *displacement*

migration (at time of placement or delayed after placement) or distal, i.e., *major migration*. Local migration can result in obstruction of downstream vessels. A example for such scenario is a stent placed at the cephalic arch migrating into the subclavian vein, which can result in partial or total occlusion, impeding future creation of an AVF or AVG using the basilic or axillary vein (Image-1). Distal migration, which has also been reported¹³, can involve the pulmonary artery or intra-cardiac vessels, which are common locations for distal migrations¹⁴⁻¹⁶. This requires extensive procedures to remedy, in addition to procedures for the removal of the migrated stent.

Stent fracture is another complication, which is usually seen on follow up angiograms¹⁷. Stents placed at the Subclavian-Brachiocephalic junction, i.e. at the costo-clavicular junction, are commonly reported locations for stent fractures, probably due to the fact that the stent is crushed between the clavicle and the body of the first rib. Stent fracture, however, can occur at other locations (Image-2).

Infection is another major complication that can lead to catastrophic outcomes. The combination of the immunocompromised status of patients with ESRD and repetitive cannulations for dialysis treatments are likely contributing factors to infection. Stent infections have been reported in case series¹⁸ and in large retrospective analysis¹⁹. It has been reported that up to 16.3% of stents placed in arteriovenous accesses are surgically removed at some point due to stent infection¹⁹.

One unique complication, stent struts protrusion, results from placing stents in cannulation sites¹⁸. Repetitive cannulation can damage the metal part of the stents (struts), which might protrude through the skin and create a hazardous situation for dialysis patients' healthcare providers¹⁸. (Image-3).

Stent use in special conditions

Cephalic arch stenosis

Cephalic arch stenosis (CAS) is a common cause of brachiocephalic arteriovenous fistula (AVF) dysfunction²⁰. The use of various types of stents as a treatment of cephalic arch stenosis has been reported²¹. A study was performed on patients with recurrent cephalic arch stenosis comparing bare stents to stent grafts²². Six month primary patency for bare stents and stent grafts were 39%, and 82%, respectively; one year primary patency was 0%, and 32%, respectively, with a significant statistical difference of $p = 0.0023$ at one year. The study results were markedly limited by the small sample size ($n=13$) and by the fact that groups were not compared to the gold standard therapeutic method of angioplasty (PTA). Additionally, many stents were used in the study patients, adding significantly to the cost of such therapy. Another retrospective cohort analysis of 45 patients was recently published comparing stent placement to PTA²³. The authors concluded that stent placement resulted in a better patency rate as compared to angioplasty alone. The retrospective design of the study, the small sample size of patients evaluated (stent $n=20$ and PTA $n = 25$), and lack of control for stent type were identifiable weaknesses of this review. The fact that CAS is a common complication of brachiocephalic AVFs highlights the need for a well-designed randomized control trial (RCT) comparing specific types of stents (and not all stents

together) to PTA alone. Such a study should use primary patency, secondary patency, complication rates, and associated treatment costs as outcome measures. Until such a study is performed, PTA alone remains the gold standard treatment option for cephalic arch stenosis.

Surgery is another modality that can be considered as a treatment option for recurrent cephalic arch stenosis as it has yielded excellent patency rates²⁴.

Venous graft anastomosis (VGA) stenosis

Despite the decline in the overall rate of AVGs among hemodialysis patients, AVG dysfunction is still a common presentation to vascular access centers, with VGA stenosis being the most common cause of this dysfunction²⁵. As previously mentioned, Flair and Viabahn stents are approved for placement at VGA stenoses^{7,8}. Numerous studies were published investigating the role of stents at VGA sites with variable results²⁶⁻²⁸. In a multicenter RCT comparing PTA alone to angioplasty with stent graft placement²⁹, 190 patients with VGA stenosis were randomized to both groups. The stent graft group had significantly better primary patency at 6 months (51% for stent graft group and 23% for PTA group, $p < 0.001$) and better access circuit patency (38% for stent graft group and 20% for PTA group, $p = 0.008$). There was no significant difference between the two groups in access circuit assisted patency and access circuit cumulative patency rates. A follow up two year study (RENOVA) was initiated and 270 patients were enrolled, with 138 patients randomized to the PTA with stent graft group and 132 patients to PTA group alone³⁰. The mid-term (12 month period) results of this study showed that Access Circuit Primary Patency (ACPP) and Index of Patency Function (IPF) were significantly better in the PTA with stent graft group than the PTA alone group, and final results are expected to be published in the near future.

Another RCT that led to the FDA approval of the Viabahn stent is the REVISE clinical trial³¹, which is pending publication. The literature from abstracts and the FDA, however, indicates that 295 patients were enrolled and randomized, and 293 patients comprising the Intent-To-Treat (ITT) analysis group. Reportedly, 145 patients were randomized to the stent group and 148 subjects to the PTA group, although 24 patients were later excluded from the effectiveness analysis. At the 24-month period of the study, there were 65 patients who completed the study in each arm. Primary patency at 6 months, 12 months, and 24 months was 52.9%, 30.2% and 15.7%, respectively, for the stent group and 35.5%, 18.2%, and 9.9%, respectively, for the PTA group ($p = 0.008$). Access circuit primary patency was 21.4% and 9.6% for stent group and 15.2% and 6.8% for the PTA group, at 12 and 24 months respectively ($p = 0.035$). There was no statistically significant difference between the groups in assisted primary patency, access secondary patency, or treatment site secondary patency.

While these trials deserve a compliment, as RCTs are very much needed in our field, stent placement at VGA sites is not without issues. One concern is the fact that stents might occupy part of the outflow vein, jeopardizing future possibilities of creating a secondary fistula using the outflow vein. Secondary fistulas constitute an excellent option for patients with failing AVGs with excellent primary and secondary patency rates³². The high cost of

stents is another factor of consideration, raising concern into whether the benefits obtained by placing stents at VGA stenosis sites outweigh the costs associated with such treatment²⁰. Careful thought should be given to the option of creating a secondary AVF as an alternative treatment to placing a stent at a VGA stenosis site.

Thrombosed Arteriovenous access

Arteriovenous access thrombosis is the most troublesome complication. Patency rates of arteriovenous access after thrombectomy procedures are significantly less than the rates of routine angiogram and angioplasty¹². Stent placement, one of the limited options for intervention in these situations, has been used to prolong patency rates. Maya et al.³³ compared stent placement after thrombectomy procedures (n = 14 patients) to thrombectomy alone (n=34 patients) in arteriovenous grafts (AVGs). Primary patency for AVGs that received stenting was significantly better than thrombectomy alone (median of 85 vs. 27 days respectively, p = 0.02). Similarly, secondary patency rates were better (1215 vs. 46 days for the thrombectomy group, p = 0.049). The limitation of this study is the small sample size. Due to the well-known fact of poor patency rates after thrombectomy procedures, we are in need of a randomized study comparing specific types of stents to thrombectomy procedures with primary and secondary patency rates as outcome measures. Until such a study is conducted, the routine use of stents post thrombectomy procedures cannot be endorsed.

Pseudo-aneurysms

Pseudo-aneurysms are a relatively common complication of hemodialysis vascular access, occurring most frequently at the cannulation site. It is believed that this occurs as a result of the frequent cannulations for dialysis treatment, especially if no cannulation site rotation is performed, and seems to be independent of the presence of outflow vein stenosis. Even though the traditional therapy for dialysis access related aneurysms has been surgical repair, stents have been used to eliminate aneurysms³⁴. The author of this report was able to place stent grafts to eliminate aneurysms in 11 patients, with only 2 of which continued to have problematic aneurysms requiring additional surgical repair. Another study reported the successful elimination of aneurysms in 10 patients³⁵. One major complication of such therapy is infections¹⁸, which can be catastrophic and may require major surgeries or may even limit the patient's longevity. A retrospective study by Kim et al. on stent elimination of aneurysms in AVGs has ended the debate as it showed clearly that infections occur at a higher rate than previously expected¹⁹. The authors of the aforementioned retrospective study reviewed 235 stent placements for the purpose of eliminating aneurysms, in a total 174 patients, and found that 16.3% of the stent-implanted AVGs were surgically removed due to graft infection. Stent grafts used to eliminate intra-graft aneurysms had subsequent graft infections at a significantly higher rate (42.1%) than bare stents or stent grafts that were deployed for other reasons combined (18.2%) (p = 0.011), clearly indicating that stent grafts should not be used for intra-graft aneurysmal elimination. Additionally, due to the high rate of infections elsewhere, stents should not be used to eliminate aneurysms unless surgical intervention is not possible. Therefore, surgical repair remains the gold standard therapy for dialysis access related aneurysms when indications for such treatment arise.

One additional risk of stent placement that is specific to stent placement at cannulation sites has been reported, and that is the protrusion of stent material through the patient's skin¹⁸. This carries risks to dialysis patients' healthcare providers, further supporting the KDOQI recommendation that stents should be avoided along cannulation sites¹¹.

Central Venous Stenosis

Central vein stenosis (CVS) is a relatively common complication of hemodialysis access. Hemodialysis catheters, Cardiac Implantable Electronic Devices (CIED), and peripherally inserted central catheters (PICC) are the most common causes of CVS. In spite of its variable results, angioplasty remains the gold standard treatment for CVS^{36,37}. It is well known that elastic lesions (recoil) are more common in CVS when compared with peripheral vein lesions³⁸. Available studies report a wide range in patency rates after CVS angioplasty with primary patency rates ranging between 23% to 63% at 6 months and 12% to 50% at 12 months^{37,39-42}. The variation among studies has occurred over time and may be due to the advancing technology as it is used, e.g. high-pressure balloons. In fact, a recent study using higher-pressure balloons showed primary patency rates of 60% at 6 months and 30% at 12 months, which is better than what was previously reported⁴³. Notably, the indications for stent placement in CVS are not different from indications for stent placement in peripheral veins.

Several reports have been published on outcomes of stenting in CVS with variable primary and secondary patency rates⁴⁴⁻⁴⁹. An adequately powered RCT comparing specific types of stents to PTA in the case of CVS is necessary. Until such a study is performed, PTA remains the gold standard treatment for CVS and stent placement indications remain as recommended by KDOQI guidelines in elastic lesions (recoil) and recurrent stenosis.

Cardiac Implantable Electronic Devices (CIED)

The rate of CIED use in patients with chronic kidney disease (CKD) and ESRD is on the rise. It is well known that CKD and ESRD patients with CIED experience more complications than the general population and that these patients constitute a high percentage of patients requiring removal of these devices^{50,51}. A high percentage of patients who receive CIED will develop CVS, reportedly even as high as 64% at 6 months after placement⁵². In a multi-center study looking at angioplasty alone as a treatment option for CIED induced CVS that included 28 patients, the primary patency rates were 18% at 6 months and 9% at 12 months. Secondary patency was 95% at 6 months, 86% at 12 months, and 73% at 24 months⁵³. This study confirms angioplasty as the gold standard treatment for CIED induced CVS. Other studies have reported the use of stents as treatment for CIED induced CVS. One such retrospective study of 14 patients who received stents as treatment for CIED induced CVS reported a primary patency rate to of 45.5% at 6 months and 9% at 12 months, with a secondary patency rate at 100% and 90% at 6 and 12 months respectively⁵⁴. It is important to note that there are official recommendations from the Heart Rhythm Society indicating that CIED leads should be removed if stent placement is needed prior to stent placement in order to avoid entrapment of CIED leads by the stent⁵⁵. Therefore, stent placement should be avoided when CIED leads are still present. As such, PTA remains the gold standard treatment for CIED induced CVS. Epicardial CIED can be

considered when patients with advanced CKD or ESRD meet the indication for CIED placement⁵⁶. Epicardial CIED leads completely bypass the central venous system and may reduce the specific CIED lead associated complications in CKD and ESRD patients⁵⁷.

Conclusions

PTA remains the gold standards treatment for hemodialysis vascular access dysfunction caused by vascular stenosis. While the FDA has approved two stents to be placed at VGA stenosis sites, these stents should be used carefully in order not to jeopardize future secondary fistula creation. Stents should be avoided along cannulation sites and should not be used to eliminate dialysis access aneurysms. Stents should also be avoided in CIED induced CVS to avoid entrapment of CIED leads.

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Clinical Summary

- Percutaneous Transluminal Angioplasty (PTA) remains the therapeutic gold standard option for the majority of vascular stenoses resulting in hemodialysis vascular access dysfunction.
- The FDA has approved two stent grafts for the treatment of venous graft anastomosis stenosis; use of any other stents in vascular access dysfunction would be off- label.
- Stent placement should be avoided along cannulation sites.
- Stents should not be used to eliminate aneurysms due to the high risk of subsequent infections.
- Stent placement should be avoided in central venous stenosis when CIED leads are present to avoid entrapment of leads.

Image - 1.

Stent migration. This is local migration of a stent that was previously placed at the cephalic arch, inducing subclavian vein stenosis. This migration was discovered during a vessel mapping procedure for new access creation. The arrow points to the location of the stenosis.

Image - 2.

Stent fracture. This is a fractured stent in the outflow vein of a brachiocephalic AVF. The arrow points to the location of the fracture.

Image - 3.

Stent protrusion. The stent material (struts) was cut by the repetitive cannulation from hemodialysis needles. The injured struts may protrude through the skin, which will carry risks to dialysis patients' healthcare providers. The arrows point at the damaged stent struts.