Stent and Stent-Graft Use in Arteriovenous Dialysis Access

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Abstract

Keywords

- ▶ AV graft
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Dialysis access failure is a major cause of mortality and morbidity among dialysis patients. Preservation of access is critical to maintaining hemostasis, avoiding uremia, and managing the complications of kidney failure. While angioplasty remains the most common method of managing arteriovenous (AV) access stenoses, the use of stents and stent grafts to manage venous stenoses associated with AV access has become more prominent. There have been several prospective randomized trials that have demonstrated the benefit of these devices in maintaining the target lesion patency of the treated areas. In this article, the author reviews the data relating to stent and stent-graft use at the venous anastomosis and outflow veins for pseudoaneurysms of grafts, at the cephalic arch, and for central venous stenoses.

Objectives: Upon completion of this article, the reader will be able to discuss the current indications and outcomes for stent and stent-graft use in AV accesses.

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Treatment of malfunctioning arteriovenous (AV) dialysis access is still primarily based on surveillance and angioplasty. Early small prospective studies performed prior to 2000 failed to demonstrate an advantage of noncovered stents over angioplasty.^{1–3} Since that time, new stent design and the development of covered stents have provided devices that have allowed the possible uses of stents and stent grafts in AV accesses. Furthermore, because of the Fistula First Breakthrough Initiative, the prevalence of AV grafts has decreased,

while native fistula has increased. This demographic change has altered the landscape in which interventional radiologists (IR) operate, and has provided new locations in which to intervene with stents and stent grafts.

The purpose of this review is to highlight the current state of clinical data with respect to stents and stent-graft placement in patients with malfunctioning AV access. The dialysis circuit includes everything from the left ventricle through the artery, into the AV fistula or graft, and into the outflow vein and back to the right heart. This article will cover the common applications of stents and stent-graft use in the most common dialysis circuits. A discussion of arterial stent and stent grafting in the arterial system upper extremities and aortic arch is beyond the scope of this article.

In this article, four major situations in which a stent or stent graft may be considered are focused upon: (1) venous outflow stenosis, (2) pseudoaneurysms, (3) cephalic arch stenoses, and (4) central vein stenosis.

Venous Outflow Stenosis

Venous outflow is defined starting at the graft to vein anastomosis or artery to vein anastomosis, and ending at the subclavian vein where the central veins begin. The earliest stent used to treat the venous outflow stenosis were Gianturco self-expanding

Z stents (Cook Medical, Bloomington, IN). Randomized studies of the Z stent versus angioplasty demonstrated no improvement with stent placement when compared with angioplasty alone in dialysis grafts with venous outflow stenoses.^{1,2} Subsequent evaluation of the Wallstent (Boston Scientific, Natick, MA) again demonstrated no significant difference between Wallstent use and angioplasty alone for venous outflow stenoses associated with dialysis graft (except for a significant increase in the cost of the procedure).³ Nitinol stents were evaluated, in small studies, and primary patency was noted to be improved with the use of a SMART stent when compared with angioplasty alone. The sample size in this study, however, was extremely small with only 35 patients receiving angioplasty and 25 patients receiving stents.^{4,5} The use of stents in this patient population was also noted to decrease the number of interval interventions until graft thrombosis.

In a follow-up study, in a retrospective evaluation of SMART stents to angioplasty alone in 211 patients, Chan et al described an increase in AV graft flow after the use of nitinol stents. In this study, the authors found an increase in access flow and primary patency in AV grafts, but no differences in primary patency of AV fistulae.⁶

Building upon the success of the more flexible nitinol stent in reducing interventions in dialysis access failure, covered stents were evaluated with the concept that the covering would reduce the impact of the medial-intimal hyperplasia that plagues dialysis access interventions. Based on favorable safety data in animals,⁷ a prospective randomized study of 190 patients was completed which demonstrated significant improved outcomes following primary placement of a covered stent (Flair, Bard, Tempe, AZ). In this investigation, the stent graft was placed as a graft extension (of synthetic AV grafts) in patients with venous anastomotic stenoses. In this study, Haskal et al demonstrated a primary 6-month patency rate of 51% with stent grafts compared to only 23% with angioplasty alone. There was also improvement of access circuit patency (32 vs. 20%) and freedom from repeat interventions (32 vs. 16%).⁸

It should be emphasized that these data are explicitly related to AV fistula grafts. Initial reports using a polytetrafluoroethylene (PTFE)-covered stent initially approved for endobronchial use (Fluency, Bard, Tempe, AZ) demonstrated primary patency in 17 patients with AV fistulae of 94.1, 88.2, and 88.2% after 3, 6, and 12 months of follow-up, respectively. This suggests that reasonable patency rates could be achieved when stent grafts are used in arteriovenous fistula.⁹

Finally, innovative approaches to evaluating graft materials other than PTFE have also been assessed. Chan et al evaluated the use of the Viabil device (Gore Medical, Flagstaff, AZ) which has a much lower porosity than the Viabahn or Flair devices; these investigators reported a primary patency rate of 85% at both 2 and 6 months in a small 20-patient pilot trial.¹⁰

Pseudoaneurysm

Pseudoaneurysms are dilations of blood vessels or synthetic grafts. In dialysis access, pseudoaneurysm management is mostly considered a method of managing the degeneration of

synthetic graft material. They tend to occur after multiple punctures in the same general area of a graft, with dilation occurring due to weakness in the wall of the material and the overlying fibrotic response. Based on the 2006 dialysis outcomes quality initiative (K-DOQI) recommendations, pseudoaneurysms should be surgically repaired when the number of cannulation sites is limited; when the pseudoaneurysm threatens the overlying skin; when it is symptomatic; or when there is evidence of infection.¹¹

Most aneurysmal dilations in fistula and outflow veins are due to downstream stenosis. The mainstay of management of aneurysmal dilation in access was and remains managing the downstream stenosis that leads to increased pressure in the access.

When dealing with pseudoaneurysm formation in grafts, the use of PTFE-covered stents has the appeal of theoretically relining the graft material and thereby excludes the pseudoaneurysm; this allows an endovascular in situ replacement of the graft material. Early case series in select patients demonstrated successful exclusions of pseudoaneurysms in grafts with reasonable patency over 3 to 6 months. Najibi et al found that 9 of 10 patients treated in such a manner maintained functioning access while excluding the pseudoaneurysm over a follow-up of 3 months.¹² In 2005, Vesely reported primary patency rates in 11 patients of 71 and 20% at 3 and 6 months, respectively, after Viabahn placement in grafts with pseudoaneurysms.¹³ Of these 11 patients, 2 still required surgical revision due to loss of cannulation sites, and another 2 patients had recurrence of pseudoaneurysms from puncture holes in the stent graft.¹³ In a small study of Wallgrafts (Boston Scientific), used in six patients for pseudoaneurysm exclusion ($n = 3$) or intragraft stenosis ($n = 3$), repeated punctures were able to be performed between 8 and 29 months post-stent-graft placement. In one of these six patients, the repeated punctures did result in fraying of the stent graft near the puncture site, but this was access maintained without further treatment. In one of the patients with pseudoaneurysm, surgical resection of one of the Wallgrafts in the circuit was required for an infected segment, but the access was maintained with a new jump graft.¹⁴ These examples emphasize the importance of an interdisciplinary approach to the management of dialysis access. Just because IRs can exclude a pseudoaneurysm does not mean that appropriate surgical revisions should be avoided. More recently, a slightly larger series of 23 patients was reported that echoed earlier results with Wallgrafts yielding primary patency rates of 82% at 30 days and 28% at 6 months. In this patient population, continued use of the grafts was achieved.¹⁵ To date, however, no prospective randomization of endograft use to surgical revision has been published.

Finally, one concern about using stent grafts for pseudoaneurysm exclusion in synthetic accesses is the risk of infection by excluding a pseudoaneurysm sac, which could become a milieu for bacterial growth. Kim et al retrospectively evaluated 235 stent and stent-graft deployments in 174 patients, and reported a significantly increased risk of infection in patients who had covered stents to treat pseudoaneurysms compared with bare or covered stents placed

for other reasons (42.1 vs. 18.2%, respectively¹⁶). Also, location within the graft itself was associated with a greater infection rate than at the venous anastomosis (26.9 vs. 6.9%, respectively).¹⁶ For these reasons, it is important to have good communication with surgical colleagues with regard to trying to select appropriate cases for placement of stent grafts in the management of pseudoaneurysms in grafts.

Cephalic Arch

The cephalic arch represents an anatomical hinge at the end of cephalic outflow AV fistulae (►Fig. 1). As such, the mechanical stresses placed on the terminal cephalic arch are altered by the high flow of the fistula, which can lead to intimal-medial hyperplasia at the end of the cephalic arch. In a cohort of 177 patients with arteriovenous fistula, cephalic arch stenosis was found in 26 (15%). Brachiocephalic fistulas had a significantly higher incidence of cephalic arch stenoses than radiocephalic fistulae (39 vs. 2%, respectively), suggesting higher flow presentation to the cephalic arch may predispose to stenosis formation. In that study, 50 angioplasties were performed; 29 (58%) required high-pressure balloons and 3 (6%) experienced rupture. Following angioplasty, the primary patency rate was 76, 42, and 23% at 3, 6, and 12 months, respectively.¹⁷ In another study of 127 patients with arteriovenous fistula, 77% of patients with brachiocephalic fistulae had cephalic arch stenosis, while only 20% of patients with radiocephalic fistulae had cephalic arch stenosis. In this report, diabetes was found to be a negative predictor of cephalic arch stenosis. Furthermore, cephalic arch stenosis was associated with a higher rate of arteriovenous fistula thrombosis.¹⁸

To test if flow reduction would reduce cephalic arch stenosis, Miller et al performed a retrospective analysis of 33 patients identified from a cohort of 183 patients, who had undergone banding with the MILLER procedure for steal or hypervolemia. The number of interventions before and after banding was noted to decrease from 3.34 to 0.9/access-year, suggesting that flow rates from brachiocephalic fistulae may be contributory to cephalic arch stenosis.^{19,20}

In response to the poor outcomes of angioplasty of the cephalic arch, the role of surgery in the treatment of cephalic arch stenoses was reported in 2008. In 13 patients with frequent angioplasty, the cephalic arch was ligated and the

upstream cephalic vein was anastomosed to the adjacent basilic vein. Angioplasty was required in 100% of the patients after surgery; however, the authors failed to report the intervals of the angioplasties or the primary patency of the surgery. The primary patency of angioplasty after surgery increased from 23, 8, and 0% to 92, 69, and 39% at 3, 6, and 12 months, respectively, after angioplasty. This suggests that removing the diseased arch from the circuit and altering the configuration of the cephalic vein anastomosis to the basilic vein may be helpful.²¹

When stent grafts (Fluency) were compared with bare stents (Luminex, Bard, Tempe, AZ), stent placement in cephalic arch stenoses recurred within 3 months following a successful angioplasty. Stent grafts had an 18% restenosis rate as compared with a 70% restenosis in the bare metal stent group. Furthermore, at an interim analysis of this prospective randomized trial, 13 stent grafts had a primary patency of 82, 82, and 32% after 3, 6, and 12 months, respectively, while the 12 bare metal stents had primary patency rates of 39, 39, and 0% at the same time intervals. These favorable outcomes resulted in early termination of the trial.²²

Subsequent evaluation of the Viabahn in the cephalic arch was reported in a small case series of 11 patients, who had primary patency rates of 82 and 73% at 6 and 12 months, respectively, after use.²³ Furthermore, a small prospective randomized trial of 14 patients with cephalic arch stenoses demonstrated significantly improved access patency and primary target lesion patency at 3, 6, and 12 months. In this study, five patients were randomized to Viabahn use and nine were randomized to angioplasty only; in these patients, the 6-month primary patency rate in the Viabahn group was 100%, while it was 0% in the angioplasty group. Despite this initial advantage, even the Viabahn group had only a 29% 1-year primary patency rate, indicating the need for further surveillance in these patients.²⁴

Central Vein Stenosis

Central veins include the subclavian vein, innominate vein, and the superior and inferior vena cava (SVC and IVC), respectively. While the earliest IVC and SVC stents were reported with balloon-expandable Palmaz stents (Cordis Corporation, Miami Lakes, FL),²⁵ current technologies have advanced to use self-expanding bare metal stents and covered stents in hopes of reducing in-stent restenosis in the central veins. Some of the earliest work consisted of a small series of Wallstent use in central veins associated with dialysis access and symptoms such as arm swelling, prolonged bleeding, or high venous pressures.²⁶⁻²⁹ While technical success and 3-month primary patency were promising, 1 year patency rates with Wallstent ranged from 19 to 56% (►Table 1).

When approaching the dialysis patient, it is critically important to understand the imaging found during fistulography and to correlate the stenoses with the patient's symptoms. Based on early work, it is known that prophylactic angioplasty does not alter the natural history of dialysis access use.³⁰ For this reason, the National Kidney Foundation K-DOQI does not support angioplasty in the absence of

Fig. 1 Representative image of cephalic arch confluence with the axillary vein. A mild stenosis is noted in this patient (arrow).

Table 1 One-year patency rates with Wallstents

Author	Year	Device studied	n	3 mo	6 mo	12 mo
Vesely et al ²⁶	1997	Wallstent	20	67%	42%	25%
Haage et al ²⁷	1999	Wallstent	50	92%	84%	56%
Maya et al ²⁸	2007	Wallstent	23	56%	33%	19%
Bakken et al ²⁹	2007	Wallstent	26	76%	46%	21%
Jones et al ³²	2011	Viabahn	30	97%	81%	67%

Notes: This table is a summary of early studies focused on Wallstent use for central vein stenosis. The primary patency rates at 3, 6, and 12 months are listed. The study of Jones et al relating to Viabahn use is presented in contrast. Note that all of these are small retrospective studies and thus are subject to selection bias.

symptoms or physical findings associated with dialysis access failure. The same approach is important in evaluating central venous stenoses. In 35 patients with 86 asymptomatic central venous stenoses, the 62% of patients who were treated with angioplasty were compared with those who were not treated; patients were evaluated for central vein stenosis progression by dividing the change in percentage stenosis by the time interval between interventions. While the untreated group showed a slight improvement in stenosis ($-0.08\%/day$), the treatment group had a mean *progression* of $0.21\%/day$, with many patients demonstrating escalation of the stenosis to symptoms, including arm swelling, additional stenoses, and interventions requiring stents.³¹ This study should serve as a cautionary note that a central stenosis without clinical indication for treatment should not be treated.

Finally, there has been one retrospective study of stent grafts used to treat central venous stenoses that evaluated the patency of the Viabahn stent graft (W.L. Gore, Flagstaff, AZ) over 2 years in 30 patients. These 3-, 6-, and 12-month patency rates were 97, 81, and 67%, respectively, with a 2-year primary patency of 45%. Despite this, even the stent grafts required additional procedures over time to maintain patency, with a 2-year assisted patency rate of 75%.³² To date, there have been no prospective randomized trials that produce level 1 evidence that stents or stent grafts in the central circulation can be used as a single point of therapy for long-term access maintenance and freedom from symptoms. However, the alternatives are poor and the existing data we have suggest that stent grafts are better than bare metal stent when they need to be used. Close follow-up and intervention for recurrent symptoms will be necessary once a stent is deployed.

Summary

Stents and stent grafts are being used with increased frequency. It has been shown in at least one randomized controlled trial and multiple observational studies that stents and stent grafts used at the venous anastomosis and cephalic arch improve patency over angioplasty alone. Data after 1-year follow-up, however, show a diminishing return of this advantage. The evidence suggesting the use of stents and stent grafts in the remainder of the access circuit is less clear, and further evidence is needed. The use of these devices in

any particular patient should always be weighed against angioplasty, surgery, and doing nothing; however, in select populations, their use is likely advantageous in maintaining access patency for this difficult population.

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