

Use of the Viabahn stent graft for the treatment of recurrent cephalic arch stenosis in hemodialysis accesses

Gregg A. Miller, MD,^a Dean C. Preddie, MD,^a Yevgeny Savransky, MD,^a and Lawrence M. Spergel, MD,^b
Brooklyn, NY; and San Francisco, Calif

ABSTRACT

Objective: Cephalic arch stenosis (CAS) is a frequent and challenging failure mode of brachiocephalic fistulas. Natural tortuosity of the cephalic arch requires special consideration in selecting a treatment modality. Typical percutaneous angioplasty and bare-metal stent (BMS) treatments provide a short-term treatment solution for CAS without a durable effect. This study assessed Viabahn (W. L. Gore & Associates, Flagstaff, Ariz) stent grafts (SGs) as a first-line percutaneous option to provide a durable treatment for CAS.

Methods: SG data were collected at a free-standing physician office between July 10, 2009, and January 26, 2011. A single-arm, prospective, observational study was conducted of 50 consecutive CAS patients treated with angioplasty followed by deployment of Viabahn SGs. Outcomes included target lesion primary patency and reintervention rates as well as secondary access patency. Results were compared with historic cohorts of percutaneous balloon angioplasty (N = 50) and angioplasty followed by BMS deployment (N = 50). The cohorts were treated between May 5, 2005, and May 20, 2010, and assessed in chronologic order.

Results: The SG cohort target lesion primary patency reported at 3, 6, and 12 months was $90\% \pm 7\%$, $74\% \pm 12\%$, and $60\% \pm 14\%$ ($\pm 95\%$ confidence interval), respectively. Compared with historic cohorts, the SG cohort demonstrated statistically superior target lesion primary patency ($P < .001$), with a reduced reintervention rate per access-year ($P < .001$). Secondary access patency was statistically superior compared with the percutaneous balloon angioplasty cohort ($P = .034$) but not statistically different from the BMS cohort when assessed during a 2.5-year period. The secondary access patency for the SG cohort at 5 years was $80\% \pm 15\%$.

Conclusions: In treatment of a CAS, the Viabahn SG study group demonstrated superior target lesion primary patency and required fewer subsequent interventions compared with historic cohorts treated with angioplasty or angioplasty followed by BMS placement. Given the significant improvement in target lesion primary patency, future studies should challenge Viabahn SGs as a primary percutaneous treatment modality vs durable surgical alternatives. (J Vasc Surg 2017;■:1-7.)

Cephalic arch stenosis (CAS) is one of the most prevalent and significant challenges in maintaining brachiocephalic fistula function.¹⁻⁶ Tortuous anatomic features of the cephalic arch vein segment make it more prone to the development of aggressive flow-restrictive lesions.^{4,5,7} That same anatomy also creates treatment difficulties that must be managed through careful device selection and procedural technique. Thus far, an optimal percutaneous treatment for CAS has yet to be demonstrated.

Management of CAS with percutaneous transluminal angioplasty (PTA) or PTA followed by bare-metal stent (BMS) deployment has long been the mainstay of

therapy because of the relatively low cost and satisfactory technical success observed during the procedure. Both therapies are fraught with issues. PTA of the cephalic arch has low primary patency, requires frequent reintervention,^{8,9} and is associated with a high incidence of vein rupture during dilation of venous stenosis.^{2,5} After suboptimal angioplasty, elastic recoil of the vein wall may necessitate a BMS to provide structural support. The BMS will often form in-stent stenosis, creating a lesion reinforced by a metal scaffold, which tends to be resistant to percutaneous treatment. The incidence of in-stent stenosis, at various anatomic locations, has been reported as high as 85%, with patency rates at 1 year equivalent to those of PTA.¹⁰⁻¹³ In this location, BMSs are also known to cause axillary vein stenosis and occlusion.⁴

Stent grafts (SGs) offer a potential solution to the shortcomings of PTA and BMS in treating CAS. Several large, multicenter, randomized controlled studies have established that treatment of dysfunctional grafts or fistulas with SGs can demonstrate improved lesion patency and reduced reintervention rate compared with PTA.¹³⁻¹⁵ None of these large studies included treatment of CAS. A few small studies focused on CAS treatment have demonstrated positive outcomes in patients treated

From American Access Care of Brooklyn, Brooklyn^a; and Founder and Clinical Consultant, A-V Fistula First Breakthrough Initiative, San Francisco.^b

Author conflict of interest: G.A.M. has been a paid consultant for W. L. Gore & Associates.

Correspondence: Gregg A. Miller, MD, American Access Care of Brooklyn, 577 Prospect Ave, Brooklyn, NY 11215 (e-mail: vascular1@att.net).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

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<http://dx.doi.org/10.1016/j.jvs.2017.08.018>

with SGs; however, optimal procedural technique, durability, and potential failure modes for SGs have yet to be described.^{10,16-18}

The purpose of this study was to prospectively evaluate the short-term clinical outcomes as well as long-term durability of an SG in treating CAS. Historic cohorts of PTA and BMS treatment modalities from the same center were used as statistical comparators. This study also explores a unique implantation technique to best navigate the tortuous anatomic features of the cephalic arch.

METHODS

Study design. The study was a 50-patient, single-arm, prospective, observational study carried out at a free-standing physician office between July 10, 2009, and January 26, 2011. An Institutional Review Board did not exist at the authors' free-standing physician office when the study was initiated; therefore, the principles of the Declaration of Helsinki were followed. All patients consented for the procedure had a dysfunctional or thrombosed native fistula due to CAS. Patients who experienced elastic recoil or vein rupture at the cephalic arch after predilation with PTA were treated with an SG and included in the study. Patients were excluded if a persistent "waist" was visible on an ultrahigh-pressure PTA balloon in treating the target lesion. The visible waist indicated the presence of an intractable stenosis that required a surgical referral for patch angioplasty or new access creation. Fifty consecutive patients who met inclusion criteria received a Viabahn (W. L. Gore & Associates, Flagstaff, Ariz) SG to treat CAS. Patients were observed for 12 months, with visits scheduled at 3, 6, and 12 months per the standard protocol of the study site.

Historic BMS and PTA cohorts were collected retrospectively between May 5, 2005, and May 20, 2010. Patients were considered in chronologic order until 50 patients in each historic cohort were identified. To optimize effectiveness comparisons, patients were selected from the same center with procedures performed by the same operators. A minimum of 12 months of data after PTA or BMS treatment was required to be part of the historic cohorts. Similar inclusion and exclusion criteria applied to the prospective arm were also applied to the historic cohorts. Elastic recoil or vein ruptures, managed by prolonged balloon inflation, were included in the PTA cohort. If a BMS was required to treat the elastic recoil or rupture, those patients were eligible to be included in the BMS cohort. Historic cohorts had recorded similar visits at 3, 6, and 12 months per standard protocol of the study site.

The primary outcomes of this study were target lesion primary patency, postimplantation reintervention rate, and incidence of juxtastubclavian stenosis (JSS) during the 1-year study period. Study patients continued to be observed during a 5-year period to determine secondary access patency.

ARTICLE HIGHLIGHTS

- **Type of Research:** Prospective cohort study with historic controls
- **Take Home Message:** In 50 dialysis patients with cephalic arch stenosis treated with Viabahn stent grafts, significantly higher primary patency rates were observed at 12 months than in historic controls treated with angioplasty or bare-metal stents. Reintervention rate was lower in the Viabahn group, but secondary patency rates were not different from the bare-metal stent group.
- **Recommendation:** These data support use of Viabahn stent grafts for treatment of cephalic arch stenosis in dialysis patients.

Procedural technique. All patients were assessed by physical examination and Doppler ultrasound (Terason T3000, 5 MHz probe; Teratech Corp, Burlington, Mass) on referral for inability to deliver adequate dialysis. Based on the findings of the physical examination and ultrasound study, patients could be referred for venography.

A complete fistulogram was obtained under local anesthesia, with the arm in the supine position lying parallel to the body. The arm position allowed the natural tortuosity of the cephalic arch anatomy to be appreciated, as evident in Fig 1, A. Direct access was gained by a 4F micropuncture (Cook Medical, Bloomington, Ind). An 8F sheath was inserted initially in preparation for the placement of the SG. The access circuit from the arterial anastomosis to the central circulatory system was visualized by a hand injection of >50 mL of iopamidol (Isovue; Bracco Diagnostics, Cranbury, NJ) contrast dye (300 parts per million) at a 50/50 dilution. The arterial anastomosis was visualized by occluding the arteriovenous access and force refluxing contrast dye.

All clinically significant stenoses (flow-limiting stenosis >50% stenosed) were treated with balloon angioplasty before deployment of the SG at the cephalic arch. A 0.35-inch Bentson wire with a 4F Berenstein catheter (AngioDynamics, Queensbury, NY) was used to cross all lesions and extended centrally. The Blue Max angioplasty balloon (Boston Scientific, Marlborough, Mass) was used as the standard angioplasty treatment. In 8% of patients, a visual waist persisted with use of the standard treatment balloons, but full dilation of the lesion was achieved by an ultrahigh-pressure Conquest angioplasty balloon (Bard Peripheral Vascular, Tempe, Ariz).

Before dilation of the cephalic arch, the fistula was depressurized using manual compression of the inflow to minimize potential extravasation after angioplasty. Dilation of the lesion was performed before device deployment, typically with an 8- × 80-mm high-pressure angioplasty balloon. Elimination of all balloon visual waist was required for the patient to be eligible for placement of the SG.

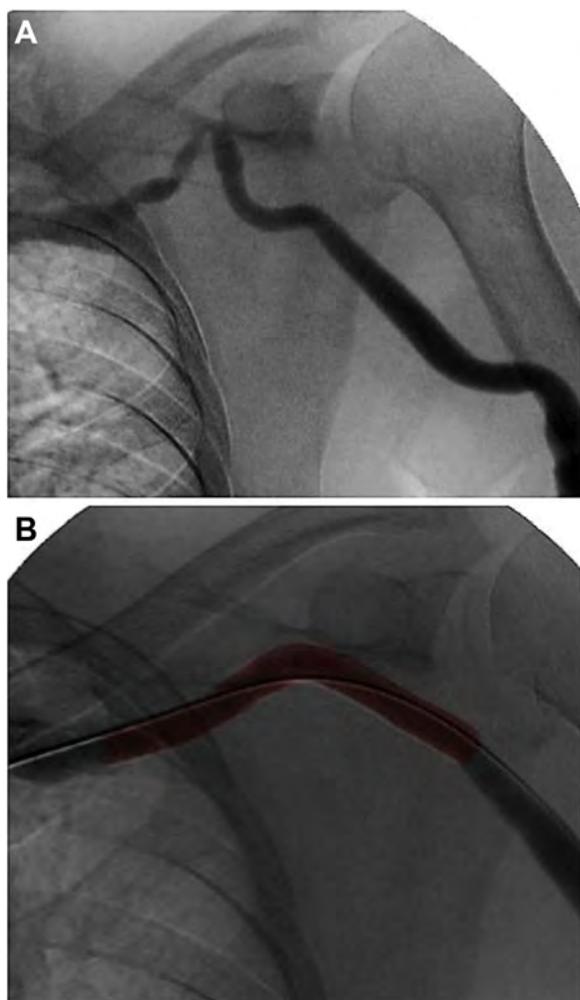


Fig 1. Angiographic images of the cephalic arch with the arm in the supine position. **A**, Representative image of a dilated brachiocephalic fistula as it tapers down and becomes tortuous as it crosses the deltopectoral groove, stenotic at the cephalic arch. **B**, Representative image of placement of the Viabahn device (highlighted in red) in the cephalic vein, at the cephalic arch, and crossing the ostium into the subclavian vein.

Implantation of the SG involved landing the medial edge at least 1 cm into the subclavian vein as shown in Fig 1, B. Extension into the subclavian vein was intended to help prevent misplacement of the device during deployment due to string tension causing tip retraction. SG diameter was chosen to allow adequate flow-carrying capacity and to limit obstruction of venous return.

Application of the angioplasty balloon in historic cohorts followed similar procedural protocols. PTA and BMS cohorts underwent standard and ultrahigh-pressure balloon angioplasty, as needed. BMSs were deployed with the medial edge extending into the axillary vein by an estimated 1 to 2 mm in most cases (Protege EverFlex Self-Expanding Stents; Medtronic, Minneapolis, Minn).

Patient follow-up. All study patients returned at 3, 6, and 12 months per the standard protocol of the center.

The follow-up consisted of a physical examination and ultrasound study to evaluate function of the fistula. Ultrasound measurements assessed both diameter and flow characteristics. Patients were referred for venography if the physical examination detected abnormalities, such as high intra-access pressure, pulsatile flow, outflow dysfunction, and distal ischemia. If angiography was warranted, a 12- or 14-mm-diameter balloon was inflated in the subclavian vein, testing for JSS by contrast dye reflux into the axillary vein for all cohorts per standard protocol of the center for patients previously treated for CAS.

Outcomes assessment. Technical success was defined as complete dilation of the lesion with <50% residual stenosis. Clinical success was defined as resolution of symptoms of a dysfunctional native fistula. Outcomes were assessed by patency rates and rate of reintervention.

Primary and secondary patency rates were defined in accordance with the Society of Interventional Radiology's reporting standards for percutaneous interventions in dialysis access.¹⁹ Target lesion primary patency was the time interval from the initial procedure to the next intervention performed. Secondary access patency was the time interval from the initial procedure to abandonment of the access circuit. The reintervention rate was calculated for each patient during the first year of follow-up and defined as the number of treatments necessary to maintain a patent cephalic arch as a function of access-year. JSS was defined as a stricture of >50% of the axillary vein within 3 cm downstream of the cephalic-axillary vein ostium.

Statistical analysis. Patency and incidence of JSS were determined by Kaplan-Meier survival probability estimates, and the log-rank test was used for comparison of the survival curves during the defined follow-up period. Intervention rate was calculated as the frequency of interventions for the duration of access patency during the 1-year follow-up period. Statistical significance between the three cohorts was determined by Kruskal-Wallis H test. The χ^2 tests were used to assess differences between demographic proportions. A pairwise Mann-Whitney U test was used in a post hoc analysis to compare the SG cohort with the PTA and BMS cohorts, individually. Statistical significance was set at $P = .05$. Patency, JSS, and intervention rates are reported with 95% confidence intervals.

RESULTS

Patient demographics. No statistical difference was detected for age, race, gender, body mass index, diabetes, hypertension, or congestive heart failure between cohorts as shown in the Table.

Procedural outcomes. Both technical and clinical success for implantation of the SG was 100%, with no device

Table. Demographics

Cohorts	SG (n = 50)	BMS (n = 50)	PTA (n = 50)	P
Age, years	60 (30-89)	57 (38-84)	65 (33-87)	.594
Male sex	50	56	48	.707
BMI	27.5 (21-59)	27.0 (22-40)	29.0 (22-44)	.184
Race				.159
African American	52	50	46	
White	44	46	38	
Asian	4	4	16	
Diabetic	54	54	38	.181
Hypertensive	74	76	82	.61
Congestive heart failure	22	18	6	.069

BMI, Body mass index; BMS, PTA followed by bare-metal stent deployment cohort; PTA, percutaneous transluminal angioplasty cohort; SG, stent graft cohort.

Categorical variables are presented as %. Continuous variables are presented as median (range).

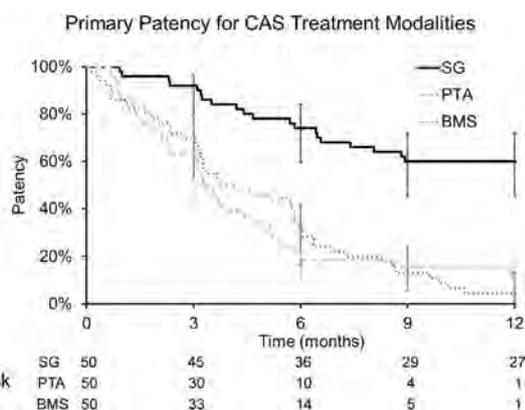


Fig 2. Kaplan-Meier survival estimate of primary patency rates with 95% confidence intervals. The stent graft (SG) cohort demonstrated statistically greater survival probability during the 1-year study period based on log-rank statistical analysis compared with the other cohorts ($P < .001$). BMS, Bare-metal stent; CAS, cephalic arch stenosis; PTA, percutaneous transluminal angioplasty.

migration. Each procedure required a single SG. The most common device size used was 8 × 100 mm (43/50). The other device sizes were 10 × 100 mm (6/50) and 10 × 50 mm (1/50). The BMS cohort included 8 × 100-mm devices (50/50). Placement of the SG across the cephalic-axillary vein ostium and into the subclavian vein did not result in any swollen limbs due to obstructed venous return.

Primary outcome: target lesion primary patency. The 3-, 6-, and 12-month target lesion primary patency rates were calculated for all groups. The median follow-up was 1007 days, 495 days, and 345 days for the SG, BMS, and PTA cohorts, respectively. The SG cohort target lesion primary patency was 90% (80%-97%), 74% (59%-84%), and 60% (45%-72%), respectively (Fig 2). Similarly, the historic PTA cohort reported target lesion primary patency rates of 61% (44%-72%), 27% (9%-30%), and 11%

(3%-24%), respectively, and the historic BMS cohort reported target lesion patency rates of 68% (53%-79%), 29% (17%-42%), and 4% (1%-13%), respectively. The target lesion primary patency for the SG cohort was statistically superior to both historic cohorts during the entire 12-month period ($P < .001$).

Reinterventions. The SG cohort demonstrated a statistically significant reduction in reinterventions compared with either historic cohort within the first year of follow-up as shown in Fig 3 ($P < .001$). The SG cohort required only 1.0 (0.5-1.5) reintervention per access-year as opposed to the reported 2.5 (1.8-3.2) reinterventions per access-year for PTA and 2.7 (2.0-3.4) reinterventions per access-year for BMS. Less than half of the patients in the SG cohort (23/50) required reintervention to maintain access patency as opposed to the majority of the PTA (43/50) and BMS (47/50) patients in the first year.

Secondary access patency. The SG cohort demonstrated consistently greater secondary access patency during a 2.5-year period compared with the historic PTA cohort but similar patency to the historic BMS cohort, as shown in Fig 4. The SG cohort was observed for up to 5 years, and 1-, 2.5-, and 5-year secondary access patency rates were reported as 98% (86%-99%), 96% (81%-99%), and 80% (59%-90%), respectively. Secondary access patency rates for the historic cohorts were calculated during a 2.5-year period. Data out to 5 years were not available because of censored events before that time primarily due to loss to follow-up. The PTA cohort reported 1- and 2.5-year secondary access patency of 86% (68%-94%) and 81% (60%-91%), respectively, and the BMS cohort reported a 1- and 2.5-year secondary access patency of 98% (86%-99%) and 98% (86%-99%). The SG cohort demonstrated secondary access patency superior to that of the PTA cohort during the 2.5-year period ($P = .034$). No statistical difference was detected compared with the BMS cohort.

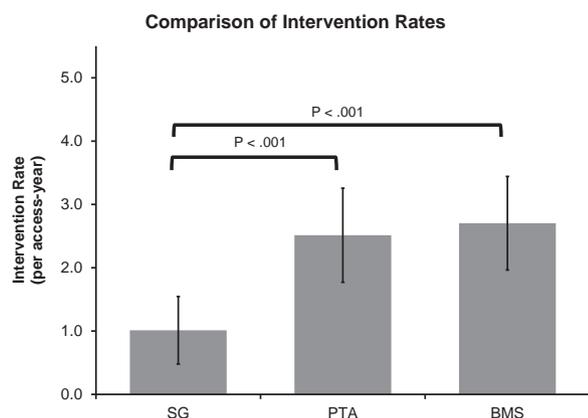


Fig 3. Intervention rates reported for the three treatment modalities for the first year of follow-up. The stent graft (SG) cohort showed a statistically significant lower intervention rate than the other two cohorts. BMS, Bare-metal stent; PTA, percutaneous transluminal angioplasty.

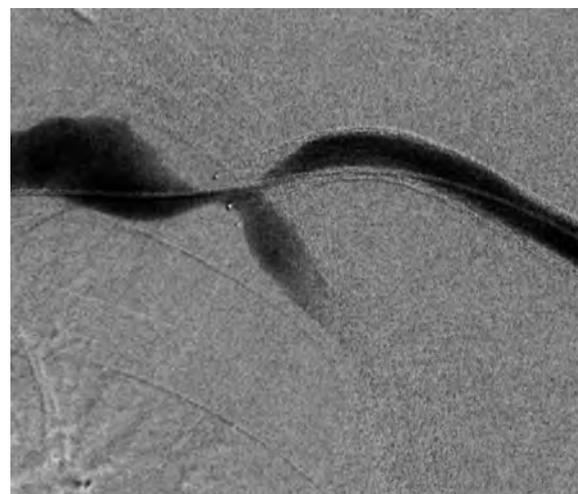


Fig 5. Representative image of juxtastubclavian stenosis (JSS) associated with the placement of a bare-metal stent (BMS) in the cephalic arch and a "tenting" axillary vein.

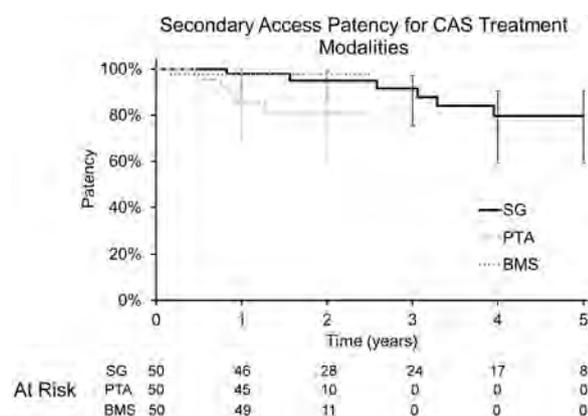


Fig 4. Kaplan-Meier survival estimate of secondary access patency for each treatment group with 95% confidence intervals. The percutaneous transluminal angioplasty (PTA) cohort demonstrated statistically lower survival probability at 2.5 years based on log-rank statistical analysis compared with the stent graft (SG) cohort ($P = .034$). BMS, Bare-metal stent; CAS, cephalic arch stenosis.

Incidence of failure. The reported incidence of JSS at 12 months for the SG cohort was 6% (5%-7%) of patients, whereas the historic BMS and PTA cohorts reported 55% (39%-68%) and 11% (10%-12%), respectively. The SG cohort demonstrated a lower incidence of JSS compared with the BMS cohort ($P < .001$). No statistical difference was detected compared with the PTA cohort. These results suggest that JSS as a failure mode, shown in Fig 5, was unique to BMS treatment.

During the first year of follow-up, placement of Viabahn SGs with the medial portion 1 to 2 cm into the subclavian vein did not appear to result in any adverse events, such as arm swelling, venous hypertension, subclavian vein thrombosis, or pulmonary embolus. During the 5-year follow-up period, secondary access patency was

significantly improved compared with the PTA cohort, as shown in Fig 4. Of the six SG patients who lost secondary access patency, one patient received a new transposed basilic vein fistula in the same arm with no outflow complications. Two patients continued to use the failing cephalic vein for dialysis at low pump speeds as a bridge to a new fistula in the contralateral limb, thus avoiding catheter placement. Another two patients elected to receive forearm fistulas in the contralateral arm instead of a basilic vein fistula. One patient had chronic low blood pressure and became catheter dependent. None of the six patients exhibited compromised outflow through the axillary vein due to JSS. Whether the remaining patients with patent cephalic vein fistulas would be candidates for a new access in the same arm is unknown.

DISCUSSION

This study demonstrated that treatment of CAS with an SG provides a high target lesion primary patency and low rates of reintervention. Comparisons with historic BMS or PTA cohorts suggest a statistically significant improvement in outcomes for the SG cohort. In addition, the long-term outcomes of the SG cohort demonstrated sustained secondary access patency $>80\%$ during a 5-year period. Secondary access patency comparison at 2.5 years also suggested that the SG cohort is superior to the PTA cohort, whereas no difference was observed compared with the BMS cohort.

SGs demonstrate superior clinical benefit, presumably by providing both a scaffold to prevent elastic recoil and graft material to prevent tissue ingrowth through interstices of the stent.^{13,14,16,17} Unique properties of the selected device, including device conformability, long length, and implantation technique, appear to be additional critical factors to the outcomes of this study.

The cephalic arch has been generically defined as the perpendicular vein segment that connects the superficial peripheral veins with the deep central veins.² More specifically, the cephalic arch could be defined as the vein segment starting at the transition from a free-floating, superficial position to a deep subcutaneous position, terminating at the junction with the axillary vein. The point of transition, from a superficial free-floating position to a tethered, deep location, occurs before the curve, primarily at the lateral portion of the deltopectoral triangle.^{20,21} The natural constriction of the cephalic arch at the transition zone limits diametric expansion of the vein, which results in hypertrophic tissue remodeling inward and amplification of the wall shear stress, presumably associated with the development of flow-restrictive lesions.²²⁻²⁵

Tortuosity and dense surrounding tissue create challenges for PTA. BMS is also challenged in this location as it is postulated but yet to be clinically demonstrated that inward remodeling results in tissue ingrowth through the interstices of the stent structure, with resulting in-stent stenosis.¹⁰⁻¹³ The tethering to dense subcutaneous tissue is a key consideration in both failure and treatment of CAS, as it limits dilation of the vein.

BMS placement demonstrated a strong correlation to JSS compared with the other two treatment cohorts. This stenosis is potentially a result of the BMS's altering the anatomy of the cephalic arch by straightening the natural curvature. Straightening of the cephalic arch results in a subsequent "tenting" effect at the cephalic-axillary vein junction, as observed in Fig 5. This abnormal vascular morphology and anatomy, combined with the trauma from the high fistula flow rates, potentially explains the high incidence of JSS.

The BMS cohort reported a secondary access patency similar to that of the SG group but tended to require more frequent interventions. Nearly all of the BMS patients required at least one additional intervention procedure within the first year after implantation, leading to a significantly greater intervention rate compared with the SG cohort as described in Fig 3. These data suggest that use of a BMS to treat CAS may provide adequate secondary access patency but will require frequent procedures to achieve this clinical benefit. By contrast, the use of an SG provided long-term clinical benefit with fewer required reinterventions.

Although other SGs are available, the Viabahn SG was specifically selected for its unique mechanical properties that enable it to conform to tortuous vessels and for its availability in 10-cm lengths. The SG conformed well to the vessel and maintained the natural anatomy months after implantation, as shown in Fig 1, B. Shemesh et al described device flexibility as well as device covering as being critical to successful treatment of CAS. They reported a 12-month "primary stent patency" of 75% for the conformable SG compared with 32% for a less

conformable SG.^{10,16} The conformability and covering offered by the Viabahn SG seem to provide important clinical benefits in treating the highly tortuous anatomy of the cephalic arch.

In addition to device design, implantation technique was also an important consideration to maximize the duration of patency in treating CAS. The technique used in this study was to extend the device past the deltopectoral groove laterally and 1 to 2 cm past the cephalic-axillary vein ostium medially. In doing so, long segments of diseased vein known to have high-frequency restenosis were covered by the SG to avoid treatment failure.²⁶ As a secondary benefit, extending 1 to 2 cm past the cephalic-axillary vein ostium allowed alignment of flow vectors with the subclavian vein. As shown in Fig 1, B, angiography demonstrates how alignment of flow vectors mitigates turbulent flow as highlighted by the absence of recirculation typically observed within the axillary vein.

Whereas this technique may enhance primary patency, operators need to be actively concerned with the risk of axillary vein stenosis and occlusion. SG diameter should be chosen to avoid impedance of flow in the axillary vein. The most common device chosen was 8 mm in diameter (86%) with the goal of mitigating risk of stenosis and occlusion. This study suggests that the technique is safe out to 1 year, but it was not designed to assess long-term adverse events frequently seen with BMSs, such as chronic occlusion limiting ipsilateral access creation, arm swelling, and potentially pulmonary embolism.

Limitations. This prospective study for treatment of CAS with SG was limited by the lack of randomization to comparator groups. In addition, we tested for target lesion primary patency and reintervention rates, which does not necessarily translate into a decrease in total circuit interventions. Finally, the risk of primarily placing an SG 1 cm into the subclavian vein is uncertain as too few patients required revisions or new accesses for this technique to be adequately evaluated in the long term.

CONCLUSIONS

In treatment of CAS, Viabahn SGs demonstrated superior target lesion primary patency and required fewer subsequent interventions compared with alternative percutaneous treatments. Based on these findings, the Viabahn SG should be considered a primary treatment option to limit the burden on the patient to undergo frequent procedures for CAS. Future studies to evaluate the appropriate treatment algorithm for patients with CAS should challenge Viabahn SG as the primary percutaneous modality against surgical alternatives with comparisons to total circuit intervention rates, long-term access survival, and potential risk of limiting future options due to JSS.

The authors would like to acknowledge Dr Aleksandr Khariton for his significant contribution to this work. His unique talents as an interventionalist helped develop the implantation technique and the study protocols. He beat all the odds and survived 10 years past a diagnosis of metastatic renal cell carcinoma. Medicine has advanced as a result of his attention to detail and pursuit of truth against dogma.

AUTHOR CONTRIBUTIONS

Conception and design: GM, DP, YS, LS

Analysis and interpretation: GM, DP, YS, LS

Data collection: GM, DP, YS, LS

Writing the article: GM, DP, YS, LS

Critical revision of the article: GM, DP, YS, LS

Final approval of the article: GM, DP, YS, LS

Statistical analysis: GM, DP, YS, LS

Obtained funding: Not applicable

Overall responsibility: GM

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Submitted Dec 15, 2016; accepted Aug 1, 2017.