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Promising results of stent graft placement for cephalic arch stenosis after repeated failure of angioplasty in patients on hemodialysis

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Abstract

Objective: Cephalic arch stenosis (CAS) causes repeated dysfunction and failure of arteriovenous access. Percutaneous transluminal angioplasty is the standard initial treatment for CAS, but its outcome is unsatisfactory. This study aimed to evaluate the outcome of stent graft placement for CAS in patients on hemodialysis.

Methods: A retrospective chart review from a tertiary medical center was performed in patients receiving stent graft placement for CAS between January 2012 and 2016. Patency was analyzed using the Kaplan–Meier method.

Results: Twenty-one patients received stent graft placement for CAS. Technical and clinical success rates were 100%. Primary target lesion patency was 95% (95% confidence interval [CI], 86%–100%), 76% (95% CI, 58%–94%), and 43% (95% CI, 22%–64%) at 3, 6, and 12 months, respectively. No significant difference in patency was observed between the arteriovenous fistula and arteriovenous graft groups. Assisted primary patency was 95%

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(95% CI, 86%–100%), 71% (95% CI, 52%–91%), and 57% (95% CI, 36%–78%) at 3, 6, and 12 months, respectively. Secondary patency was 100% at 3, 6, and 12 months.
Conclusions: After repeated failed angioplasty for cephalic arch stenosis, patients on hemodialysis who receive stent graft placement have effective and durable outcomes.

Keywords
Cephalic arch, stent graft, hemodialysis, arteriovenous access, angioplasty, lesion patency

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Introduction

Maintaining arteriovenous (AV) access function is crucial for the quality of life of patients undergoing hemodialysis.[1] Venous outflow stenosis is the leading underlying cause of dysfunction of AV access.[2] The cephalic vein is one of the upper limb AV access outflow conduits and is a part of the superficial venous system, which makes it easy to approach.[3,4] However, the cephalic arch's unique anatomy makes it susceptible to development of venous stenosis.[5,6] Currently, percutaneous transluminal angioplasty (PTA) is the standard initial treatment for venous outlet stenosis of AV access.[7] The primary patency rate after PTA for cephalic arch stenosis (CAS) is as low as 11% in 1 year and is the worst outcome in patients on hemodialysis.[8] Previous studies have shown a bare metal stent used for CAS treatment does not show more satisfactory outcomes than PTA.[1,9] Bare metal stents and PTA do not lead to a reliable outcome compared with stent grafts.[10]

Satisfactory outcomes of stent graft placement for treating AV access outflow have been reported, especially in arteriovenous graft (AVG) outlet anastomosis stenosis.[11,12] Little is known about stent graft placement in CAS. Therefore, we conducted a retrospective follow-up study on the outcome of patients on hemodialysis who had failure of angioplasty and received a stent graft to treat CAS compared with the outcome in patients who had PTA.

Materials and methods

This was a retrospective study of stent graft placement for treating symptomatic patients with CAS who were undergoing dialysis in a tertiary medical center between 2012 and 2016. This study was approved by the institutional review board of Chang Gung Memorial Hospital (Taoyaun, Taiwan; Approval No. 201900162B0). Individual informed consent was waived because only data from medical chart records were analyzed.

Patients

All patients had AV access with the cephalic vein as the single venous outflow, with poor function and CAS (>50%). Six patients had an AVG and 15 had arteriovenous fistula (AVF). The cephalic vein was the single outflow for all patients. The medical records were reviewed to collect data on comorbidities, morphology of cephalic lesions, treatment procedure, and outcomes. Patients who experienced easy recoil or vein rupture of the cephalic arch lesion after pre-dilation were all included and treated with stent grafts through

elective or salvage procedures (elective and salvage groups, respectively). A cephalic arch lesion was defined as >50% stenosis over the distal portion of the cephalic vein within 5-cm insertion to the axillary vein and without axillary vein involvement. These lesions were all recurrent lesions and the patients received PTA before stent graft placement for a median of three times and a mean of 3.9 times.

Procedural details

After patients were placed in the supine position, the upper limb was stretched and the shoulder was abducted. A complete fistulogram was obtained under local anesthesia and digital subtraction venography was performed, which showed cephalic arch lesions. The cephalic arch was defined as the terminal part of the cephalic vein with a horizontal segment and insertion into the axillary vein.[13] Imaging data on the length and diameter of the cephalic arch and the lesion were collected before PTA. The lesion length and diameter were measured and the cephalic vein upstream and outflow vein diameters were also recorded. Subsequently, PTA was performed using a high-pressure balloon (Conquest; C.R. Bard, Covington, GA, USA). A stent graft (VIABHAN, W. L. Gore & Associates, Flagstaff, AZ, USA) was indicated for deployment if there was a rapid recoil of the lesion >30% after angioplasty (Figure 1) or vessel rupture after angioplasty (Figure 2). We placed the stent graft over the cephalic arch, and it did not protrude into the axillary vein within 1 cm to avoid coverage of the axillary vein and preserve the chance of further outlet bypass. The diameters of the balloon and stent graft were 10% larger than the diameter of an adjacent normal segment of the cephalic vein. We choose the lengths of 50 mm (19.1%), 100 mm (61.9%), and 150 mm (19%) for coverage of lesions according to the length of the lesion and a healthy landing zone in emergent vessel rupture cases. After the PTA procedure and stent graft deployment, final angiography or digital subtraction angiography was performed,

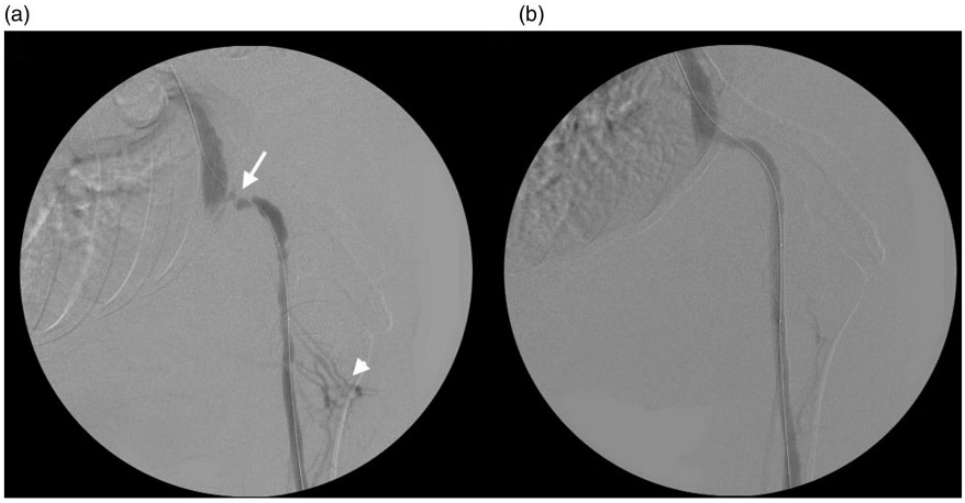

Figure 1. Digital subtraction angiography of the cephalic arch: (a) cephalic arch stenosis (arrow) with collateral branches (arrow head) present because of the stenosis; and (b) placement of a stent graft (VIABHAN) at the cephalic arch.

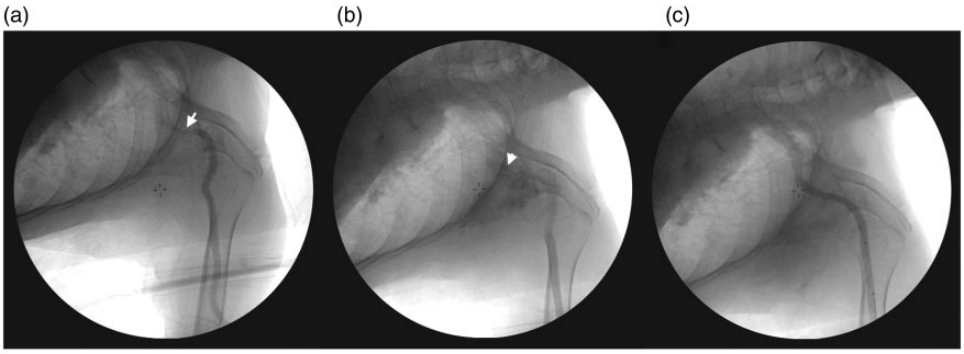

Figure 2. Digital subtraction angiography of the cephalic arch: (a) cephalic arch stenosis (arrow); (b) a vessel has ruptured with extravasation of contrast media (arrow head) after balloon angioplasty; and (c) placement of a stent graft (VIABHAN) for endovascular repair.

and hemostasis was conducted using purse string sutures.

Follow-up and surveillance

All of the patients returned to outpatient clinics for follow-up 2 weeks after the procedure. Subsequently, the interval between follow-up visits was adjusted according to patients' clinical conditions and extended to every 2 to 3 months. There was no routine use of antiplatelet or anticoagulant agents. A physical examination and ultrasound were conducted for evaluating AVF or AVG function. Venography was arranged in case of dysfunction of AV access, and if the findings of the physical examination and ultrasound techniques were not compatible.

Definitions and statistical analysis

Technical success, clinical success, primary target lesion patency, and assisted primary patency and secondary patency were defined according to the Society of Interventional Radiology guidelines for dialysis access intervention.[14] Technical success was defined as an adequate stent graft location and sufficient lesion coverage. Clinical success was defined as restoration of normal function of AV access and improvement in symptoms. Primary target lesion patency was defined as the time interval between stent graft deployment and the time point of the next intervention for the target lesion. Primary assisted patency was defined as the time interval from stent graft deployment to thrombosis of AV access with salvage thrombectomy, PTA, or another stent graft extension over the original stent graft edge. Secondary patency was defined as the time interval between stent graft deployment and the abandonment date of AV access.

Data were collected using Microsoft Excel (Microsoft Corp., Redmond, WA, USA). All analyses were conducted using the commercially available SPSS statistics software program for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA). Patency curves over time were calculated using the Kaplan–Meier method. P values <0.05 were considered statistically significant.

Results

Patient demographics

The demographic data are shown in Table 1. Twenty-one patients with AV access using the cephalic vein as the single

Table 1. Demographics of patients with cephalic arch stenosis who received stent graft implantation

Characteristics	No. (%)
Age (years, mean ± SD)	64.5±14.6
Sex, female	17 (81)
Diabetes mellitus	12 (57.1)
Hypertension	14 (66.7)
Coronary artery disease	2 (9.5)
Congestive heart failure	2 (9.5)
Peripheral artery disease	3 (14.3)
Anti-platelet therapy	3 (14.3)
Access type	
AVF	15 (71.4)
AVG	6 (28.6)
Lesion	
Side, left	16 (76.2)
Length (mm)	19.3 ± 9.4
Focal, CAS only	11 (52.4)
Indications	
Vessel rupture after PTA	5 (23.8)
Poor outcome after PTA	16 (76.2)
Stent graft size (mm)	
6 × 50	2 (9.5)
7 × 50	1 (4.8)
7 × 100	9 (42.9)
7 × 150	2 (9.5)
8 × 50	1 (4.8)
8 × 100	4 (19)
8 × 150	2 (9.5)

SD, standard deviation; CAS, cephalic arch stenosis; AVF, arteriovenous fistula; AVG, arteriovenous graft; PTA, percutaneous transluminal angioplasty

outflow were identified. Fifteen (71.4%) patients had an AVF and six (28.6%) had AVG. Among the 15 patients with an AVF, three had radiocephalic fistulae, and the other 12 patients had brachiocephalic fistulae. The mean age of the patients was 64.5±14.6 years (range, 23–86) and 17 (81%) patients were women. Five (23.8%) patients received stent grafts because of vessel rupture after PTA and 16 (76.2%) received stent grafts through elective procedures because of poor outcomes after PTA. The most common comorbidity was hypertension, followed by diabetes mellitus,

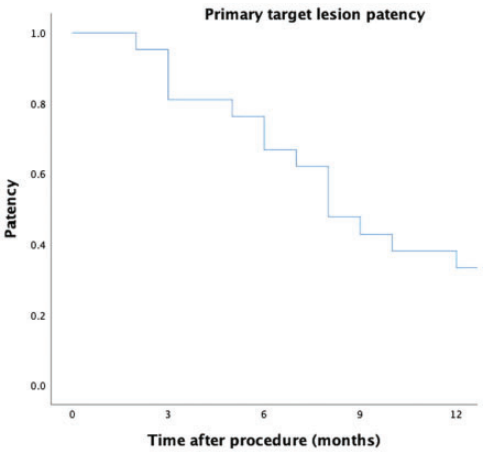

Figure 3. Kaplan–Meier survival estimate of primary target lesion patency of stent graft implantation for cephalic arch stenosis.

peripheral artery disease, and coronary artery disease (Table 1).

Procedural outcomes

The technical and clinical success rates were 100%. The primary target lesion patency rate was 95% (95% confidence interval [CI], 86%–100%), 76% (95% CI, 58%–94%), and 43% (95% CI, 22%–64%) at 3, 6, and 12 months (Figure 3). The assisted primary patency rate was 95% (95% CI, 86%–100%), 71% (95% CI, 52%–91%), and 57% (95% CI, 36%–78%) at 3, 6, and 12 months, respectively. The secondary patency rate was 100% at 3, 6, and 12 months.

The primary target lesion patency rate at 6 and 12 months was 66.7% (95% CI, 43%–91%) and 20% (95% CI, 0%–40%) in the AVF group, and 0% and 0% in the AVG group, respectively. No significant difference in primary target lesion patency was observed between the two groups. Additionally, no significant differences were observed in primary target lesion patency, assisted primary patency, and

secondary patency between the elective and salvage groups.

No complications related to stent graft placement developed during the procedure or follow-up. The mean follow-up time was 51.7 ± 20.1 months. During this period, no AV access-related death occurred.

After stent graft deployment, stenosis of the stent graft edge was observed in 15 patients. Therefore, the rate of restenosis was 71.4% during follow-up. Specifically, nine (60%) patients had proximal edge stenosis, three (20%) had distal edge stenosis, and three (20%) had bilateral edge stenosis. PTA was the initial treatment for these patients.

Four patients required further stent graft extension because of development of edge stenosis in the follow-up period following poor PTA outcomes.

Discussion

CAS causes dysfunction of AV access and leads to high venous pressure, difficult hemostasis of puncture sites, incomplete hemodialysis, or thrombosis of AV access that is difficult to treat. CAS in AV access can be explained by multiple hypotheses. These hypotheses include the natural anatomy of the cephalic vein within the deltopectoral groove, wall shear stress resulting from curvature of the cephalic arch promotes endothelial proliferation and intimal hyperplasia, the presence of valves in this area reduces the lumen diameter, and a high flow rate of the shunt causes remodeling of vessels.[15,16] Previous studies have shown that 77% of patients with dysfunctional brachiocephalic AVF and 15% of patients with AVF have CAS.[1,17]

Rajan and Falk[18] compared the outcomes of stent grafts with those of PTA for CAS. The primary target lesion patency rate at 6 and 12 months was 100% and 29% in the stent graft group, and 0% and 0% in the PTA group, respectively, with a significant difference between groups. Miller et al.[8] compared stent grafts and PTA for CAS and showed increased target lesion primary patency and a reduced reintervention rate in the stent graft group. These results indicate that stent graft deployment for CAS provides durable and satisfactory outcomes. Another study showed that primary patency of stent grafts for CAS were not different between the prior PTA group and the *de novo* lesion group.[19]

Previous studies have reported stent graft insertion for CAS in brachiocephalic AVF, but the patency of the stent graft varied. Rajan and Falk[18] reported nine cases of VIABHAN stent graft placement for CAS, and the primary target lesion patency rates were 100% and 29% at 6 and 12 months, respectively. Jones et al.[19] reported 39 cases of VIABHAN stent graft deployment for CAS from 2012 to 2015. The primary target lesion patency rates were 67% and 42% at 6 months and 12 months, respectively. Miller et al.[8] reported 50 cases of stent graft placement over CAS, and the primary target lesion patency rates were 74% and 60% at 6 months and 12 months, respectively. In the present study, the primary target lesion patency rate at 6 and 12 months was 76% and 43%, respectively. A summary of outcomes of stent grafts for CAS from previous studies is shown in Table 2. Our result for stent graft placement for CAS is consistent with the results of previous studies.[8,18,19] However, our study group is different from that in previous studies. We included the AVG group in our study to observe whether clinical performance was different in that group. Six patients had an AVG with the cephalic vein as the single outflow in our study, and five of them had the brachial artery as the inflow and one had the radial artery as the inflow. The primary target lesion patency in the AVF group appeared to be better than that in the

Table 2. Summary of outcomes of cephalic arch stenosis in previous studies

Author	Year	Number of patients	Access	Primary patency		
				3 months	6 months	12 months
Rajan and Falk[18]	2015	9	BC AVF	100%	100%	29% (9–93)
Jones et al.[19]	2017	39	BC AVF	85% (69–93)	67% (50–80)	42% (25–57)
Miller et al.[8]	2018	50	BC AVF	90% (80–97)	74% (59–84)	60% (45–72)
Feng et al.*	2020	21	AV access with the cephalic vein as single outflow	95% (86–100)	76% (58–94)	43% (22–64)

Values in parentheses are confidence intervals. *Current study. BC AVF, brachiocephalic arteriovenous fistula; AV arteriovenous.

AVG group, but this was not significant. This lack of significance may be related to the small number of the patients in this study. Further prospective studies are required to confirm this finding.

In our study, the indications for stent graft placement included early recoil of lesions after PTA and vessel rupture after PTA. No significant difference was found in primary target lesion patency, assisted primary patency, or secondary patency between the elective and salvage groups. Therefore, in case of cephalic arch rupture after PTA, stent graft placement appears to an effective approach to control bleeding and maintain patency of AV access.

Furthermore, selecting the appropriate placement technique and stent graft size are challenging because this may affect primary target lesion patency. The first concern is location of the device. Because the terminal portion of the cephalic arch joins the axillary vein, devices may need to protrude into the axillary vein to cover the lesion and offer landing, and they may offer a better flow vector to the subclavian vein. However, a protruding stent graft may also impede venous return and cause axillary–subclavian stenosis. In our practice, we avoid protruding stent grafts >1 cm from the ostium of the cephalic arch to the axillary vein. Jones et al.[19] had a <1- to 3-mm protrusion policy and Miller et al.[8] had a protrusion length within 1 to 2 cm. No central vein lesions or venous return problems were observed in our patients during follow-up.

Another concern is the choice of the stent graft size. In our study, the stent graft diameter was selected to be 10% larger than the diameter of an adjacent normal segment of the cephalic vein. According to a review of stent graft sizes used in previous studies, Jones et al.[19] used a stent graft size from 6 to 13 mm for CAS and Miller et al.[8] used a stent graft size ranging from 8 to 10 mm. The 8-mm stent graft was the most commonly used (86%). In the current study, we used a smaller stent graft size compared with that used in previous studies.[8,18] An oversized stent graft may cause more intimal hyperplasia[20] and impair the patency of AV access and the target lesion. Jones et al.[19] reported that stent graft edge stenosis mostly occurred over the lateral side. In this study, a small proportion of patients had distal edge stenosis, and the diameter of the stent graft selected might have been a factor involved in this stenosis.

In addition to PTA and stent graft placement, other endovascular methods can be used to treat stenotic lesions of AV access, including drug-eluting balloons and drug

eluting-stents. Tang et al. used the helical SUPERA™ stent (Abbott Vascular, Santa Clara, CA, USA) and a drug-coated balloon to treat recurrent CAS, with a primary patency rate of 83.3% at 1 year.[21] COVERA (Bard Peripheral Vascular, Tempe, AZ, USA) is another stent graft with a helical structure and it provided a primary patency rate of 75% at 6 months over CAS in a previous study.[22] The helical structure of a stent and stent graft offer flexibility and may provide reliable patency over the cephalic arch with minimal intimal hyperplasia. Therefore, additional trials should be conducted to compare the performance of devices that are available. With regard to the open approach, previous studies have obtained adequate, but variable, results for cephalic vein transposition and bypass.[23–25] However, these studies had small sample sizes. Randomized studies and comparisons of historic cohorts with surgical revision are insufficient and more should be conducted in the future. Nonetheless, there are still disadvantages to surgical revision. The first disadvantage is outflow neo-anastomosis stenosis, which occurred in 15.3% of cases of CAS in a previous study.[23] The second disadvantage is the type of invasive procedure and risks of regional or general anesthesia of the operation. The third disadvantage is the use of ipsilateral-side vein assets, which can be preserved in the endovascular approach without manipulation of the ipsilateral basilic vein.

PTA is our first-line treatment strategy for CAS. Stent grafts are indicated in case of rescuing vessel rupture and poor outcomes of PTA. There is no role of bare metal stents in our practice because of a poor outcome over the cephalic arch.[10] As a further step, surgical revision can be considered in case of abandonment of cephalic outflow after thrombosis or repeated failure.

In conclusion, stent graft placement for treating CAS of AV access using the cephalic vein as the single outflow provides durable outcomes for patients with an AVF or AVG. This method is also a safe and effective approach for salvaging AV access in case of vessel rupture after PTA. However, a larger study is warranted to identify the optimal strategy and algorithm for CAS.

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Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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