



Effectiveness of stent graft versus balloon angioplasty for failing arteriovenous dialysis graft—a single center retrospective cohort experience

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Background: Evaluating stent graft (SG) and balloon angioplasty for the treatment of failing arteriovenous dialysis graft (AVG).

Methods: Retrospectively analyze the clinical variables, treatment methods, and follow-up results of 43 patients, whose AVG was failed from March 2014 to December 2016. According to whether to carry out SG implantation, patients were classified into two groups. Then we compare the clinical feature between the two groups.

Results: The stenosis rate of target lesion ($79.79\% \pm 9.58\%$ vs. $78.65\% \pm 10.20\%$, $P=0.709$), target lesion length (2.78 ± 0.91 vs. 3.29 ± 1.02 cm, $P=0.090$) and reference vessel diameter (5.68 ± 0.59 vs. 5.76 ± 0.77 mm, $P=0.696$) were similar in the two groups. Both the 6- and 12-month postintervention primary patency rate of target lesion in SG group were superior compared with percutaneous transluminal angioplasty (PTA) group (60% vs. 30.34% , $P=0.037$; 20% vs. 0% , $P=0.037$). The postintervention 6-month assisted primary patency rate was 70% in SG group and 34.78% in PTA group ($P=0.037$). The postintervention 6-month secondary patency rate in both SG and PTA were 100% , and the postintervention 12-month secondary patency rate were similar in the two groups (90% vs. 95.65% , $P=0.491$). The 12-month postintervention index of patency function was 6.90 ± 2.71 (months/intervention) for SG group and 4.96 ± 1.15 for PTA group ($P=0.003$).

Conclusions: SG is superior to solely PTA regarding 6- and 12-month patency rate in treating AVG failure. Whether routine surveillance and pharmacological treatment for AVG should be carried out need further investigation.

Keywords: Arteriovenous graft (AVG); stent graft (SG); percutaneous transluminal angioplasty (PTA)

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Introduction

The overall prevalence of chronic kidney disease in China has reached 10.8% by 2012 (1). Hemodialysis is essential for end stage renal disease. Though autogenous arteriovenous fistula (AVF) is recommended as the first

choice for patients undergoing hemodialysis because of its fewer complication and longer durability (2). Prosthetic arteriovenous graft (AVG) has the advantage of short maturation time and multiple potential puncture sites, so AVG is still widely used for many patients with

inappropriate vessels (3). The amount of falling AVG remains large and the treatment for failing AVG remains important.

Percutaneous endovascular balloon angioplasty has been widely used as an alternative treatment strategy to surgical revision for failing AVG (4). but the patency rate remains poor because of restenosis caused by elastic recoil and intimal hyperplasia (5). To prevent elastic coil, bare-metal stent was introduced in treating failing AVG, but the restenosis rate is still high because of intimal hyperplasia.

Stent graft (SG) can cover the lesion site to prevent elastic recoil and intimal hyperplasia. Some studies have reported superior patency rate of SG over balloon angioplasty (6,7). We have tried to carry out both balloon angioplasty and SG for the treatment of failing AVG, so the aim of the present study is to report our own experience on the treatment strategy for failing AVG with balloon angioplasty or subsequent SG. We present the following article in accordance with the STROBE reporting checklist (available at <http://dx.doi.org/10.21037/jxym-21-9>) (8).

Methods

Patients selection criteria

The study population consisted of consecutive hemodialysis patients admitted because of failing AVG between March 2014 and December 2016 at our department. All the patients received ultrasonography examination when admitted and digital subtraction angiography (DSA) before endovascular intervention to evaluated the AVG. And were treated with balloon angioplasty or subsequent SG implantation. The data was collected retrospectively. The study was approved by the institutional ethics committee of our hospital and all patients have signed informed consent. The work has been reported in line with the STROCCS criteria.

The inclusion criteria was: (I) patients with arm AVG for hemodialysis aged 18–80 years old; (II) the AVG has achieved ≥ 1 successful hemodialysis; (III) AVG failed because of insufficient blood flow or thrombosis formation. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Ethics Board of China-Japan Friendship Hospital (2013-KY-85) and individual consent for this retrospective analysis was waived.

Ultrasonography examination

Most of the patients was admitted for thrill disappear in AVG or increased venous pressure during hemodialysis. Ultrasonography was routinely carried out with a commercially available machine (SSA-660A, Toshiba) using a 10-MHz linear array transducer. Patients were in supine position with arm abducted to about 45°. The blood flow in access circuit, morphological characteristic of the AVG and anastomosis, the inflow artery and outflow vein conduit were examined. All ultrasonography was carried out by the vascular surgeon who carry out the operation.

Endovascular intervention

All procedures were performed using an angiographic machine (Allura Xper FD20, Phillips). For patients with AVG thrombosis, a 2-cm longitudinal incision was made at the lowest part of the ‘U shaped’ AVG. Then the AVG was exposed and controlled with vessel loops. After cutting open AVG, thrombectomy was carried out with Fogarty catheter. Then we carried out the angiography to evaluated the AVG circuit. Balloon angiography with or without SG implantation was carried out if stenosis exist (*Figures 1,2*). Less than 30% residual stenosis was defined as technical success. One hundred mg aspirin per day was taken for patients after intervention.

Endpoints

Six- and 12-month target lesion primary patency was defined as primary endpoint. Target lesion assisted primary patency, secondary patency, and index of patency function was defined as second endpoint.

Target lesion primary patency was defined as continuous patency after intervention from 10 mm proximal to 10 mm distal of the target lesion (9). Target lesion assisted primary patency was defined as continuous patency after intervention or preventive treatment before occlusion. Target lesion secondary patency was defined as patency after intervention until the AVG was abandoned. Index of patency function was defined as the ratio of days from initial intervention to AVG abandonment and times of intervention.

Adverse events

Adverse events of both peri-operative and 30-day were also recorded and compared between the two groups (*Table 1*).

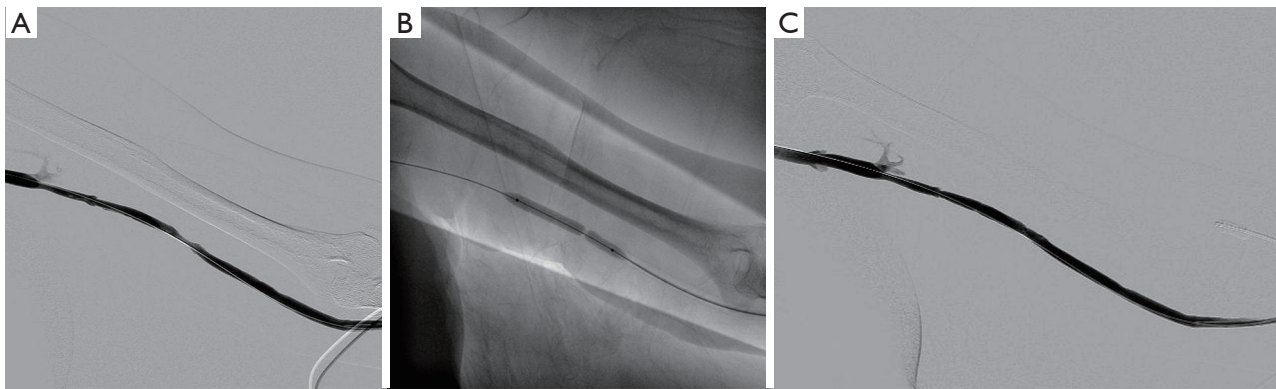


Figure 1 A typical case for PTA. (A) Pre-operative angiography showed stenosis at the graft/venous anastomosis; (B) balloon angioplasty; (C) angiography after treatment. PTA, percutaneous transluminal angioplasty.

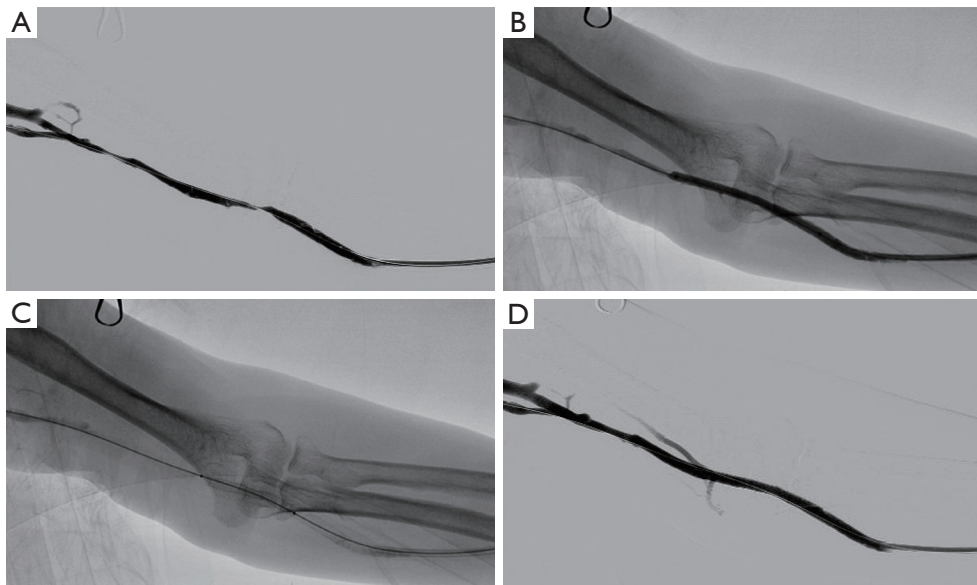


Figure 2 A typical case for SG placement. (A) Pre-operative angiography showed severe stenosis at the graft/venous anastomosis; (B) balloon angioplasty; (C) SG placement; (D) angiography after treatment. SG, stent graft.

Statistical analysis

Continuous variables and discrete variables were present as mean \pm standard deviation and percentages, respectively. Student *t*-test was performed to compare means for continuous variables. Fisher's exact test or Chi-square test was carried out for discrete variables. Kaplan-Meier survival estimates was carried out to analyze the patency rate. Log-rank test was used for the comparison between the two groups. Data analysis was performed with SPSS software, (version 22, SPSS Inc., Chicago, IL, USA). A P value of

<0.05 was considered statistically significant.

Results

Demographics and clinical data

The study population consisted of 43 consecutive patients (17 men; mean age 62.23 ± 12.45 years) with AVG failure due to thrombosis or increased venous pressure between March 2014 and December 2016 at our hospital. Among these patients, 23 received balloon angioplasty with/

Table 1 Adverse events

Variables	Balloon angioplasty	SG	P value
Infection	1	2	0.590
Pseudo-aneurysm	3	3	0.999
Hemorrhage	2	1	0.999
Vessel rupture	0	1	0.465
Thrombosis	2	1	0.999
Death	0	0	0.999

SG, stent graft.

Table 2 Demographics and clinical characteristics

Characteristics	Balloon angioplasty	SG	P value
No.	23	20	–
Age	61.17±10.61	63.45±14.46	0.556
Male sex (%)	8	9	0.494
hypertension	18	16	0.999
Diabetes	10	7	0.511
Coronary artery disease	2	3	0.650
Congestive heart failure	3	5	0.440
Cerebrovascular accident	3	1	0.610
Year on dialysis	5.57±4.83	3.17±3.06	0.144
Age of graft	1.72±0.83	1.84±0.76	0.616
History of AVF	20	20	0.491
Anticoagulant agent	2	3	0.650
Antiplatelet agent	10	8	0.999

SG, stent graft; AVF, arteriovenous fistula.

without thrombectomy and 20 received subsequent SG implantation. There were no significant differences between the two groups regarding demographic characteristics, clinical features or medical history (*Table 2*).

Angiographic characteristics of the lesion

Among all the 43 AVGs, 40 were established at left arm and 3 at right arm, 15 were at forearm and 28 at upper arm. All arterial anastomoses were brachial artery. In SG group, the venous anastomoses including 12 basilic, 7 cephalic and 1 median cubital veins. In percutaneous transluminal

Table 3 Angiographic data for target lesions

Characteristics	Balloon angioplasty	SG	P value
Stenosis rate of target lesion (%)	79.79±9.58	78.65±10.20	0.709
Target lesion length (cm)	2.78±0.91	3.29±1.02	0.090
Reference vessel diameter (mm)	5.68±0.59	5.76±0.77	0.696
Lesion site			0.536
Venous anastomosis	18	14	
Puncturing site	5	6	
Location of AVG			
Right arm	1	2	0.590
Left arm	22	18	0.590
Forearm	4	2	0.988
Upper arm	19	18	0.988
Arterial anastomosis			
Brachial	23	20	0.999
Venous anastomosis			0.424
Basilic	13	12	
Cephalic	6	7	
Median cubital vein	4	1	

SG, stent graft; AVG, arteriovenous graft.

angioplasty (PTA) group, the venous anastomosis including 13 basilic, 6 cephalic and 4 median cubital veins.

The stenotic lesion distributed at the graft/venous anastomosis and puncturing site (*Table 3*). The stenosis rate of target lesion (79.79%±9.58% *vs.* 78.65%±10.20%, $P=0.709$), target lesion length (2.78±0.91 *vs.* 3.29±1.02 cm, $P=0.090$) and reference vessel diameter (5.68±0.59 *vs.* 5.76±0.77 mm, $P=0.696$) were similar in the two groups.

Intraoperative variables

Technical success rate was 100% in both groups (*Table 4*). Operation time was a little longer in SG group, but the difference was not statistically significant (74.35±21.28 *vs.* 83±17.12 mins, $P=0.154$). In PTA group, 18 patients were treated with one PTA balloon, 3 patients with two balloons and 2 patients with three balloons. Five patients were treated with high pressure balloons. The residual stenosis

Table 4 Intra-operation variables and endpoints for the two groups

Variables	Balloon angioplasty	SG	P value
Technical success	23/23 (100.00%)	20/20 (100.00%)	0.999
Residual stenosis	18.78±3.81	18.20±4.12	0.633
Operation time	74.35±21.28	83.00±17.12	0.154
6-month primary patency of target lesion	7/23 (30.43%)	12/20 (60.00%)	0.034
12-month primary patency of target lesion	0/23 (0.00%)	4/20 (20.00%)	0.005
6-month assisted primary patency of target lesion	8/23 (34.78%)	14/20 (70.00%)	0.019
6-month secondary patency of target lesion	23/23 (100.00%)	20/20 (100.00%)	0.999
12-month secondary patency of target lesion	22/23 (95.65%)	18/20 (90.00%)	0.491
Index of patency function (months/interventions)	4.96±1.15	6.90±2.71	0.003

SG, stent graft.

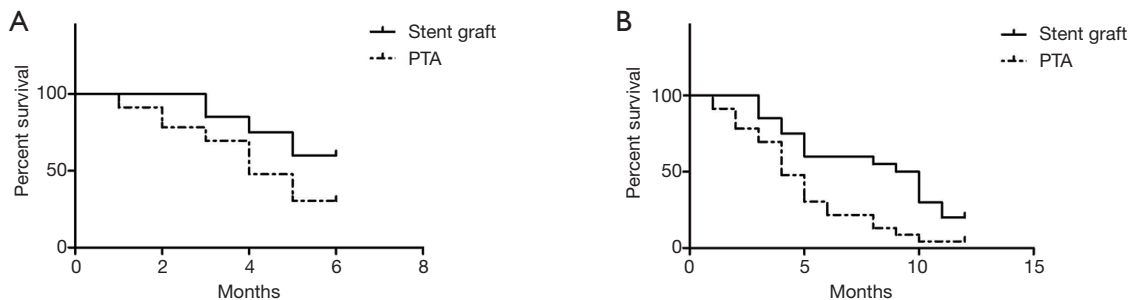


Figure 3 Kaplan-Meier curves for postintervention primary patency rate. (A) Six-month primary patency rate; (B) 12-month primary patency rate. PTA, percutaneous transluminal angioplasty.

after treatment was 18.78%±3.81%. In SG group, 24 Viabahn (Gore, USA) SGs were implanted. Sixteen patients received one stent and 4 patients received two stents. The diameter of the stents including 5 mm (10%), 6 mm (70%) and 7 mm (20%). The residual stenosis was 18.20%±4.12%.

Endpoints

Both the 6- and 12-month postintervention primary patency rate of target lesion in SG group were superior compared with PTA group (60% *vs.* 30.34%, $P=0.037$, HR: 0.40, 95% CI: 0.16–0.95; 20% *vs.* 0%, $P=0.037$, HR: 0.34, 95% CI: 0.12–0.72; *Figure 3*). The 6-month postintervention assisted primary patency rate was 70% in SG group and 34.78% in PTA group ($P=0.037$, HR: 0.33, 95% CI: 0.13–0.84). The 6-month postintervention secondary patency rate in both SG and PTA were 100%, and the 12-month postintervention secondary patency rate was similar in the

two groups (90% *vs.* 95.65%, $P=0.491$, HR: 2.22, 95% CI: 0.23–21.43). The 12-month postintervention index of patency function was 6.90±2.71 (months/intervention) for SG group and 4.96±1.15 for PTA group ($P=0.003$).

Peri-operative and 30-day adverse events

There was no significant difference between the occurrence of adverse events in the two groups (*Table 1*). The most common adverse event is pseudo-aneurysm. Infection, hemorrhage, vessel rupture and thrombosis also occurred. No death occurred in the two groups.

Discussion

AVG remains an important vascular access for patients in whom native fistulas is unsuitable to be created (10). However, long-term maintenance of AVG remains a

problem in clinical practice, mostly due to recurrent stenosis and thrombosis (11). A natural history study of AVG showed that 96% need salvage procedure at 24 months after the construction (12).

The optimal management of AVG failure remains controversial. Balloon angioplasty has been recommended as a first-line treatment for AVG dysfunction, but the reported 6-month primary patency rate is less than 50% (13). The low patency rate, associated complications and costs of repeated balloon angioplasty has promoted clinicians to look for better treatment strategy. Cutting balloon, high-pressure balloon, cryoplasty, brachytherapy and bare-metal stent have been tried in the past decades (14-16), but few has achieved good long-term patency. Drug-coated balloon has recently been reported to be superior to standard angioplasty of stenotic lesion in dysfunctional hemodialysis AVFs (17). AngioJet is reported to be an effective option in the treatment of thrombosed AVF and AVG, but the quality of the current evidence is relatively poor (18). Cellular or gene therapy is under investigation and may have good curative effect (19).

SG provide an endoluminal support to prevent elastic recoil and a polytetrafluoroethylene (PTFE) barrier to prevent intimal hyperplasia. And when implanted in graft/venous anastomosis, turbulence can be changed to laminar flow. So, SG is theoretically superior than PTA or bare-metal stent. It has been used in AVG/venous anastomosis and cephalic-arch stenosis, the treatment area primary patency (TAPP) at 6 months is reported to be 51% vs. 23% with PTA alone in AVG/venous anastomosis and 100% vs. 0% with PTA alone in cephalic-arch stenosis (3,20). In our study, we included AVG failure due to puncture site and graft/venous anastomosis stenosis. The cumulative postintervention primary patency rate at 6 months was 60% for SG and 30.43% for PTA. The 12-month postintervention primary patency rate was 20% for SG and 0% for PTA. And the complications in the two groups were similar. These results showed that SG is superior to PTA in the treatment of AVG failure. But SG placement could also preclude a future endovascular intervention in case of AVG failure. In-stent restenosis may easily occur at both bare ends of the SG (21). So, SG should cover the lesion completely with PTFE barrier. The longitudinal lifespan beyond 12 months may be higher with angioplasty approach first, followed by SG placement later as opposed to primary stent placement.

Vascular access surveillance is important for maintaining patency. A randomized controlled trial showed that access

blood flow surveillance with ultrasound and prophylactic intervention can reduce thrombosis and improves AVF patency (22). This may also be applied to AVG. Contrast-enhanced ultrasound may also helpful in routine surveillance (23). In the present study population, most patients admitted because of thrombosis. Only two patients in SG group underwent routine ultrasonic surveillance and was admitted because of increased venous pressure.

Pharmacological treatment is essential during or after the establishment of arteriovenous access. Whether anticoagulation or antiplatelet treatment is better is still controversial. Nee *et al.* think that aspirin alone is the most cost-effective strategy for preventing AVG failure (24). A systematic review and meta-analysis showed that anticoagulation during arteriovenous access establishment may improve the patency rate of AVF instead of AVG (25). In our study series, patients routinely received 100 mg aspirin after PTA or SG implantation. More randomized controlled trials need to be carried out to evaluate the impact of anticoagulation or antiplatelet therapy, especially for novel oral anticoagulant agents (26,27).

In conclusion, SG is superior to solely PTA regarding 6- and 12-month postintervention patency rate in treating AVG failure. Whether routine surveillance and pharmacological treatment for AVG should be carried out need further investigation.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <http://dx.doi.org/10.21037/jxym-21-9>

Data Sharing Statement: Available at <http://dx.doi.org/10.21037/jxym-21-9>

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was

conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional ethics board of China-Japan Friendship Hospital (2013-KY-85) and individual consent for this retrospective analysis was waived.

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