



Comparison of Helical Interwoven Nitinol Stent Placement Versus Balloon Angioplasty for Arteriovenous Dialysis Graft Malfunction Caused by Stenosis of the Venous Anastomosis Site

정맥 문합부 협착에 의한 인조혈관 동정맥루의
기능부전에 나선형으로 결합된 니티놀 스텐트 설치와
풍선 혈관 확장술의 비교연구

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Purpose The study aimed to compare the differences in patency between helical interwoven nitinol stents and balloon angioplasty in patients with arteriovenous graft (AVG) malfunction caused by venous anastomosis stenosis.

Materials and Methods This retrospective study included patients who underwent helical interwoven nitinol stent placement ($n = 15$) or balloon angioplasty ($n = 25$) between January 2016 and September 2021. The primary and secondary patency rates were compared between the two groups.

Results Dialysis was possible post-intervention in all patients who showed no specific complications, including stent fracture. The average primary patency of the stent placement group was longer than that of the balloon angioplasty group but did not differ significantly (8.5 vs. 6.3 months, $p = 0.319$). The mean secondary patency period was 17.6 months in the stent placement group, which was shorter than that in the balloon angioplasty group (18.8 months); however, this difference was also not statistically significant ($p = 0.660$).

Conclusion Helical interwoven nitinol stents could maintain patency in patients with AVG

malfunction caused by venous anastomosis stenosis, but they did not improve patency compared to balloon angioplasty.

Index terms Arteriovenous Shunt, Surgical; Self Expandable Metallic Stent; Angioplasty, Balloon

INTRODUCTION

Chronic renal failure is a disease with a high prevalence rate of 11%–13% worldwide. Patients with chronic renal failure require treatment procedures such as dialysis or renal transplantation (1). An access path is required for hemodialysis, and arteriovenous grafts (AVG) are used in cases where native arteriovenous fistulas cannot be created. After the AVG is created, an increase in blood flow and a configurational change in the outflow vein occur. Wall shear stress caused by the altered flow pattern may lead to neointimal hyperplasia resulting from damage and inflammatory reactions of the vessel wall and is associated with venous anastomosis stenosis (2-4). The aims of interventional treatment in patients with AVG malfunction include thrombus removal and the expansion of narrowed blood vessels using balloon angioplasty to restore sufficient blood flow for dialysis. Several studies have reported that approximately 50% of patients who undergo balloon angioplasty achieve primary patency for more than 6 months, but they often require reintervention due to restenosis (5-7). Among patients requiring reintervention, stent placement is recommended instead of balloon angioplasty alone for those experiencing complications such as elastic recoil or vascular rupture and those developing restenosis within 3 months (8, 9). Because AVG is mainly performed in the elbow or axillary areas, stents in these areas may fracture due to frequent folding. The helical interwoven nitinol stent (SUPERA; 3200 Lakeside Drive, Santa Clara, CA, USA) is more flexible than conventional laser-cut nitinol stents (10). Helical interwoven stents are commonly used in the femoral and popliteal arteries because of their high flexibility in the joint areas and demonstrate good patency (10, 11). Thus, the use of a highly flexible helical interwoven stent in cases of AVG malfunction is expected to prolong patency and reduce the incidence of side effects including stent fracture. In one such instance, a helical interwoven stent was implanted in a patient with AVG, and dialysis was successfully performed for six months without any complications (11).

Therefore, this study compared helical interwoven stent placement and balloon angioplasty in patients with AVG malfunction caused by venous anastomosis site stenosis to determine the patency rate and factors influencing it in these two groups.

MATERIALS AND METHODS

This retrospective study was approved by the Institutional Review Board of Jeju National University Hospital, which waived the requirement for written consent (IRB No. 2022-11-012).

A total of 104 patients who underwent balloon angioplasty or stent placement for AVG malfunction at the hospital between January 2016 and September 2021 were included in this

study. AVG patency was analyzed using two years of medical, procedural, and interventional records for these patients. After excluding cases with follow-up records of less than 2 years after the procedure ($n = 44$) or a history of interventional treatment at another hospital within 2 years ($n = 20$), 40 patients were finally selected. The patients' age, sex, the shape, location, and duration of AVG; presence or absence of hypertension and diabetes; and the use of anti-coagulant and antiplatelet agents were determined from the medical records.

Primary patency was defined as the period from stent placement or balloon angioplasty to reintervention due to stenosis of the venous anastomosis site or obstruction of the AVG. Secondary patency was defined as the period after the initial procedure until the AVG was unavailable. The follow-up period was set to 24 months.

AVGs were approached prospectively and retrospectively. In cases where a thrombus was present, it was removed by aspiration thrombectomy using a 7-Fr Desilets-Hoffman Sheath (Desilets-Hoffman Introducer Set; Cook; Bloomington, IN, USA) or a 7-Fr guiding catheter (Guider Softip XF; Boston Scientific, Marlborough, MA, USA). For balloon angioplasty, a 6-mm balloon catheter (Boston Scientific) was used, and the balloon was inflated to 15–24 atmospheric pressure for 3–5 min repeated twice until it was fully unfolded. In cases showing residual restenosis of more than 30% and the absence of thrill on physical examination due to elastic recoil or vessel rupture after balloon angioplasty, a 6.5 mm \times 60–80 mm helical interwoven nitinol stent (SUPERA; 3200 Lakeside Drive) was placed depending on the length of restenosis. Following stent placement, balloon dilatation for stent expansion was performed for 1 min using a 6-mm balloon catheter (Fig. 1).

Kaplan–Meier survival analysis and the Tarone–Ware test were used to determine the differences in primary and secondary patency between the groups that underwent stent placement or balloon angioplasty. The differences were analyzed using SPSS (version 25.0; IBM Corp., Armonk, NY, USA) employing the Mann–Whitney U test and Fisher's exact test for clinical variables affecting patency. Multiple linear regression analysis was used to analyze the degree of influence of clinical variables in all patients, regardless of stent placement or balloon angioplasty. Statistical significance was set at $p < 0.05$.

RESULTS

Of the 40 patients, 15 underwent stent placement, and 25 underwent balloon angioplasty. The diameter of all AVGs was 6 mm. Hemodialysis was successful in all patients, and no complications were observed after the procedure, including stent fractures. The two patient groups showed no differences in age, sex, presence of hypertension and diabetes, use of antiplatelet or anticoagulant agents, or the duration, location, and shape of AVGs. Stent placement was performed in 13 patients due to recoiling stenosis and in 2 patients due to vessel rupture (Table 1).

The average primary patency period was 8.5 months in the group undergoing stent placement, which was slightly longer than that in the balloon angioplasty group (6.3 months); however, the difference was not statistically significant ($p = 0.319$). The average secondary patency period was 17.6 months in the stent placement group, shorter than that in the balloon angioplasty group (18.8 months); however, this was also not statistically significant ($p = 0.660$).

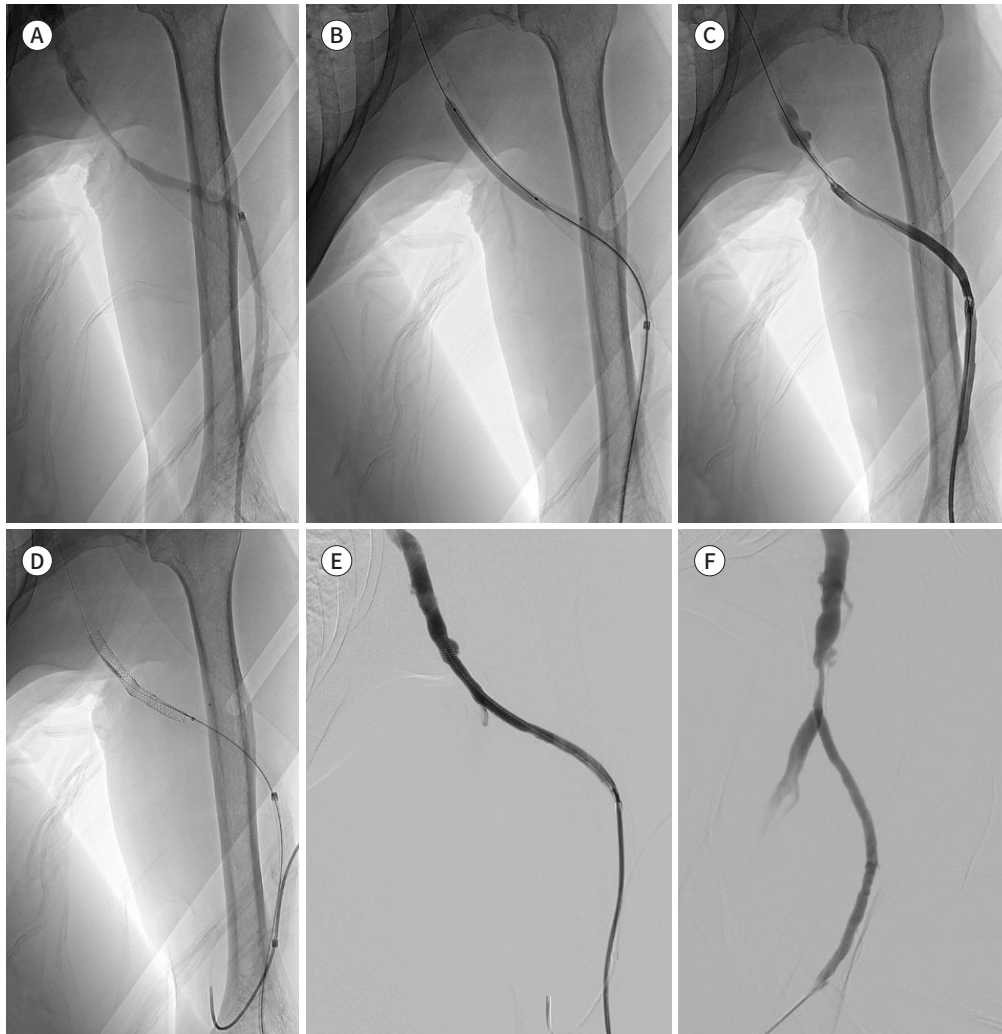
Fig. 1. An 85-year-old male with malfunction of arteriovenous graft.

A. Fistulogram after aspiration thrombectomy shows stenosis in the venous anastomosis site.

B, C. After balloon angioplasty, recoiling stenosis is observed at the venous anastomosis site.

D, E. Fistulogram after placement of a 6.5 × 60 mm helical interwoven nitinol stent reveals complete restoration of the luminal diameter at the venous anastomosis site.

F. In-stent restenosis is observed on a follow-up fistulogram after 244 days. Despite repeated interventions, the arteriovenous dialysis graft was no longer available 1009 days later.



The primary patency rates in the stent placement and balloon angioplasty groups were as follows: 3 months, 80.0% vs. 88.0%; 6 months, 53.0% vs. 48.0%; 9 months, 26.7% vs. 20.0%; and 12 months, 20.0% vs. 8.0%, respectively. The rates in the two groups did not differ significantly ($p = 0.385$) (Fig. 2). Secondary patency rates in the two groups were as follows: 3 months, 93.3% vs. 100%; 6 months, 86.7% vs. 95.7%; 12 months, 80.0% vs. 82.6%; and 24 months, 45.0% vs. 39.0%, respectively, with no significant intergroup differences ($p = 0.897$) in the overall comparison (Fig. 3).

In the stent placement group, the 3-month primary patency rate was similar between patients who received antiplatelet or anticoagulant agents ($n = 9$, 77.8%) and those who did not ($n = 6$, 83.3%). However, the average primary patency in the medication group was longer

than that in the group who did not receive medication (9.64 months vs. 6.78 months; $p = 0.14$). Although the 12-month secondary patency rate was higher in the medication group than that in the non-medication group, the difference was not statistically significant (87.5% vs. 70%;

Table 1. Characteristics of the Patients and Access Grafts

Characteristics	Balloon Angioplasty ($n = 25$)	Stent ($n = 15$)	p -Value
Age	74.9 \pm 12.0	72.5 \pm 10.3	0.505
Sex, male	15 (60.0)	11 (63.3)	0.143
Hypertension	20 (80.0)	11 (73.0)	0.635
Diabetes mellitus	14 (56.0)	4 (27.0)	0.074
Graft age (months)	12.8 \pm 12.2	15.2 \pm 13.6	0.342
Stenosis location			
Axilla	7 (28.0)	5 (33.3)	0.673
Elbow	18 (72.0)	10 (66.7)	0.673
U shape looped	18 (72.0)	12 (80.0)	0.583
Graft thrombosis	18 (72.0)	12 (80.0)	0.583
Rupture	0 (0.0)	2 (13.0)	0.064
Antiplatelet or Anticoagulant agent	9 (36.0)	9 (60.0)	0.153
Primary patency (months)	6.3 \pm 4.1	8.5 \pm 7.6	0.319
Secondary patency (months)	18.8 \pm 7.3	17.6 \pm 9.0	0.660

Data are mean \pm standard deviation or n (%) values.

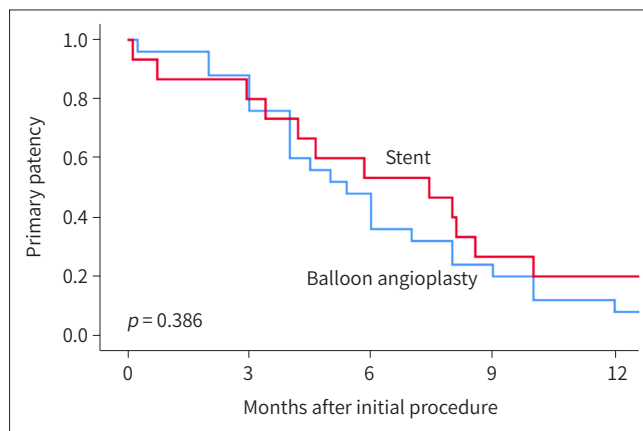


Fig. 2. Percentages of patients showing primary patency in each treatment group. The p -value was calculated using the Tarone–Ware test.

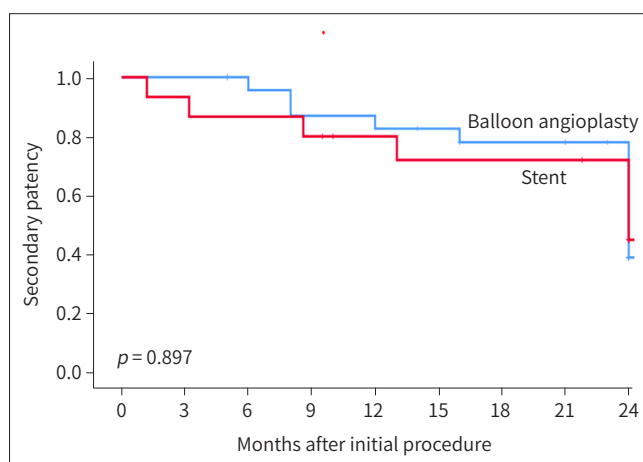


Fig. 3. Percentages of patients showing secondary patency in each treatment group. The p -value was calculated using the Tarone–Ware test.

$p = 0.468$). Comparative analysis of patients receiving anticoagulants or antiplatelet agents in the stent placement and balloon angioplasty groups also revealed no statistically significant differences ($p = 0.287$).

Regression analysis was performed to identify the factors affecting primary and secondary patency. However no significant statistical correlations with age, sex, hypertension, diabetes, AVG duration, location of AVG, shape of AVG, presence of thrombus, rupture status, or the use of antiplatelet or anticoagulant agents was observed.

DISCUSSION

Studies on the treatment of AVG stenosis at venous anastomosis sites have been actively conducted. Although the primary patency with stainless-steel stent placement was lower than that with balloon angioplasty, nitinol stents, which exhibit a shape-memory effect and high elasticity, yielded good patency (12). Unlike other nitinol stents used in previous studies, the interwoven nitinol stent consisted of six pairs of nitinol wires woven into a spiral structure. Because of this spiral structure, the radial force of the stent is strong, flexible, and resistant to bending, thereby ensuring that blood vessels are not obstructed by external pressure. No stent fracture-related bending was reported for 1 year in the 3-year SUPERB trial of the femoral artery. Additionally, the high shear pressure prevented restenosis, yielding a high 1-year primary patency rate of 86.3% (10). In comparison, this study showed a relatively low patency. This difference is due to the AVG anastomosis site being more vulnerable to stenosis than the other vessels. Neointimal hyperplasia, caused by shear stress from the anastomosis or from the wound healing process after suturing the anastomosis site, is the major reason for stenosis at the AVG anastomosis site (13).

In this study, helical interwoven stent placement did not extend primary and secondary patency compared to balloon angioplasty at the venous anastomosis site of the AVG. In studies on other metallic stents, the average primary patency rate at 6 months was reported to be 25%–67% (12, 14–16). A 2018 study by Kouvelos et al. (17), a meta-analysis of eight studies, also reported that the average 6-month primary patency rate was 58.3% in the stent placement group, which was significantly higher than the corresponding value in the group that underwent balloon angioplasty alone (27.2%). However, the primary patency rate of the balloon angioplasty group in our study (6-month primary patency rate, 48.0%) was as high as that of the group that underwent stent placement, in contrast to the findings presented in previous studies. We performed balloon angioplasty twice for 3–5 min each time. However, the balloon inflation time has not been reported in other studies. Zorger et al. (18) reported that a 3-minute inflation time improved immediate angioplasty results in infra-groin lesions compared to shorter inflation times. In dialysis access venous anastomoses, Forauer et al. (19) showed that the 3-minute inflation group was 4.7 times more technically successful than the 1-minute inflation group, but there was no significant difference in primary patency rates. Although there is insufficient evidence to make recommendations on appropriate balloon inflation times, it is possible that this study showed better results than other studies on post-intervention access patency because of the longer balloon inflation times. Therefore, while other studies showed significant results for patency in the stent placement group compared with the balloon angioplasty

group, our study appeared to indicate no significant differences. Nevertheless, the 6-month primary patency rate in our study was similar to that reported in other studies using metallic stents (6-month primary patency rate, 53.0%). Therefore, helical interwoven stent placement can be considered useful for patients who cannot be treated with balloon angioplasty alone.

After placement, the stent is easily exposed to bending or stretching near the joint. Therefore, care should be taken to avoid stent fractures in the joint areas that may frequently result in-stent dysfunction. When a venous anastomosis site is in the elbow or axillary regions, a stent is placed over the joint. A study by Vogel and Parise (16) showed no significant difference in patency in relation to location in the stent placement group; however, one patient showed stent fracture in the follow-up assessment. In this regard, the interwoven nitinol stent is thought to be resistant to deformities and shows fewer side effects. No fractures were observed in the patients who underwent stent placement in the present study, and these patients showed no significant differences in primary and secondary patency rates based on the location.

Antiplatelet and anticoagulant agents were administered after the stent placement to prevent restenosis or thrombus occlusion. In this study, the average primary patency in the anticoagulant and antiplatelet-agent group was longer than that in no-agents group (9.64 months vs. 6.78 months), and the 12-month secondary patency rate differed between patients taking or not taking medication after stent placement (87.5% vs. 70.0%), although the difference was not statistically significant. In a study by Yoon et al. (12), patency showed no difference with the use of antiplatelet agents in the stent placement group. Therefore, additional studies are required to evaluate the effectiveness of anticoagulants and antiplatelet agents in patients with stents.

In cases of thrombotic occlusion in the AVG, surgical or interventional thrombectomy and balloon dilatation are often performed together. However, despite these treatments, the long-term patency rate with thrombosis is known to be poor. In fact, 65%–85% of all dialysis vascular abandonment cases are due to thrombosis (2). Maya and Allon (20) reported that stent placement was more effective than balloon angioplasty, with 6-month primary patency rates of 19% and 3% in the patient group with thrombosis and median primary patency periods of 85 and 27 days, respectively. Although these low primary patency periods showed a low therapeutic effect in the thrombosis patient group, it indicates that stent placement is more effective than balloon angioplasty in these patients. However, the present and other studies showed no significant difference in the opening period in relation to thrombosis (12, 21).

In cases involving bare metal stents, the proliferated intima inside the stent can directly cause vascular stenosis, limiting the ability of such stents to prevent restenosis. In contrast, stent grafts are composed of polytetrafluoroethylene, which prevents intimal hyperplasia (22). Several studies have shown that balloon angioplasty with additional stent graft placement had better results than balloon angioplasty alone, including: 1) higher freedom from reintervention (32% vs. 16%, $p = 0.03$), 2) lower restenosis (RR 0.52; 95% confidence interval), and 3) longer primary patency periods (2013 days vs. 108 days) (2, 22, 23). Kavan et al. (21) reported superior results with stent graft placement compared with bare metallic stent placement (65% vs. 18%, $p < 0.0001$). However, the primary patency rate of bare metallic stent placement in their study was 18%, which was lower than that in the present study. The 6-month primary patency rate in the stent graft placement group in their study was approximately 75%, while it was 53.0% in the present study. Compared to bare metallic stents, stent grafts are expensive, and

stent grafts of appropriate size and length may not be readily available.

The limitations of this study are as follows. First, because this was a retrospective study, the results may have reflected a selection bias. Second, the sample size was small with only 40 patients included in the analysis. Third, there is a limitation in comparison with other studies because the evaluation of the severity of the patient group undergoing intervention treatment was not conducted. Qualitative and quantitative analyses of the degree of obstruction, excluding length, were not performed.

In conclusion, as an intervention treatment for venous anastomosis stenosis of the AVG, interwoven helical stent placement effectively extended patency in patients who could not be treated with angioplasty alone. However, in comparison to cases in which balloon angioplasty alone was successful, the primary and secondary patency could not be extended.

Availability of Data and Material

The datasets generated or analyzed during the study are available from the corresponding author on reasonable request.

Author Contributions

Conceptualization, all authors; data curation, H.J.H., K.D.R., L.J.S., K.J.J., K.H., K.M.; formal analysis, H.J.H., K.D.R., N.I.C., K.J.J.; investigation, H.J.H., K.D.R., K.M.; methodology, all authors; project administration, K.D.R., N.I.C.; resources, H.J.H., K.D.R., K.J.J., K.H.; software, H.J.H., K.D.R., L.J.S., K.M.; supervision, K.D.R., N.I.C., L.J.S., K.J.J.; validation, H.J.H., K.D.R., N.I.C., K.M.; visualization, H.J.H., K.D.R., N.I.C., K.J.J., K.H.; writing—original draft, H.J.H., K.D.R., N.I.C.; and writing—review & editing, H.J.H., K.D.R., L.J.S.

Conflicts of Interest

The authors have no potential conflicts of interest to disclose.

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정맥 문합부 협착에 의한 인조혈관 동정맥루의 기능부전에 나선형으로 결합된 니티놀 스텐트 설치와 풍선 혈관 확장술의 비교연구

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목적 본 연구는, 정맥 문합부 협착에 의한 인조혈관 동정맥루 기능부전 환자에서 helical interwoven 니티놀 스텐트 삽입 혹은 풍선확장술을 시행한 경우를 비교하여 개통기간과 개통률의 차이 및 이에 영향을 주는 요인들에 대하여 알아보하고자 한다.

대상과 방법 본 연구는 후향적 연구로, 정맥 문합부 협착에 의한 인조혈관 동정맥루의 기능 문제로 2016년 1월부터 2021년 9월까지 본원에서 풍선확장술($n = 25$)과 풍선확장술만으로 충분하지 않아 추가로 helical interwoven 니티놀 스텐트 삽입술을 시행 받은 환자($n = 15$) 40명을 대상으로 하였다. 두 그룹 간 일차 및 이차 개통기간 및 기간별 개통률 차이를 비교하였다.

결과 시술 후 모든 환자에서 투석이 가능하였고, 스텐트 골절을 포함한 관련 합병증은 발생하지 않았다. 스텐트 삽입과 풍선확장술을 시행 받은 환자군 간의 평균 일차 개통기간 비교에서는 스텐트 삽입군에서 풍선확장술 시행군 6.3개월보다 약 2개월 긴 8.5개월로 기간 연장을 보였으나 통계적으로 유의한 차이는 없었다($p = 0.319$). 이차 개통기간에서는 스텐트 삽입군이 17.6개월로 풍선확장술 18.8개월보다 약간 짧았으나 통계적으로 유의한 차이는 없었다($p = 0.660$).

결론 정맥 문합부 협착에 의한 인조혈관 동정맥루 기능부전 환자에서 helical interwoven 니티놀 스텐트 삽입으로 개통기간을 유지할 수 있었다. 그러나 풍선확장술만 시행한 경우와 비교하여 개통기간에 차이는 없었다.

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