대 한 투 석 혈 관 학 회 지 : 제 4 권 제 1 호
Journal of Korean Dialysis Access 2021;4(1):16-20

Original Article

Impact of a Cuffed Extended Polytetrafluoroethylene Graft at the Venous Anastomosis for Hemodialysis Vascular Access

Chang Hun Lee[1], Jun Gyo Gwon[2]

[1]Department of Vascular Surgery, Hyundae General Hospital, Namyangju, Korea
[2]Division of Transplantation and Vascular Surgery, Department of Surgery, Anam Hospital, Korea University College of Medicine, Seoul, Korea

Introduction: Consensus is lacking on evaluations of the effect of cuffed expanded polytetrafluoroethylene (ePTFE) grafts on the long-term patency of the vascular access conduit. This study aimed to confirm the patency of non-cuffed ePTFE versus cuffed ePTFE grafts for vascular access.
Methods: Patients who underwent brachioaxillary vascular access surgery were divided into a group using a cuffed prosthetic graft and a group using a non-cuffed prosthetic graft, and the graft patency of the two groups was compared.
Results: A total of 36 patients were selected for the study according to the inclusion and exclusion criteria over 2 years. There was no difference in the primary patency rate between the cuffed and non-cuffed graft groups (p=0.064). The re-intervention survival rate showed improved outcomes in the cuffed graft group (p=0.003).
Conclusion: The re-intervention survival rate was better in the cuffed graft vascular access group. Therefore, using a cuffed vascular access graft can help improve graft patency.

Key Words: Cuffed extended polytetrafluoroethylene graft, Patency, Vascular access

INTRODUCTION

Most vascular access–related guidelines recommend that the hemodialysis route for patients with chronic kidney disease prioritize autologous arteriovenous fistulas over prosthetic grafts [1-3]. However, in patients lacking adequate superficial veins to enable autologous vein vascular access surgery, prosthetic graft vascular access surgery is usually required. Expanded polytetrafluoroethylene (ePTFE) grafts are currently the most widely used prosthetic grafts for vascular access surgery [4]. Unlike autologous vein vascular access, ePTFE graft vascular access is susceptible to proliferation of the graft outlet site intimal hyperplasia, which can lead to graft exit stenosis and thrombosis. Accordingly, the patency of ePTFE grafts is significantly lower than that of vascular access using autologous veins. A commercial ePTFE graft, a cuffed outlet site prosthetic graft, was launched to improve hemodynamic performance and reduce exit stenosis by adding a cuff design to the tip. The cuffed design successfully demonstrated improved patency through experimental analysis to reduce flow turbulence at the vein anastomosis site [5]. On the other hand, one animal study showed a model of lumen narrowing due to intimal proliferation at the anastomosis site of the cuff graft [6]. Therefore, long-term patency of cuffed prosthetic grafts must be clinically proven. Consensus is lacking on the evaluation of the effect of cuffed ePTFE grafts on the long-term patency of the vascular access conduit. This study aimed to confirm the patency of non-cuffed ePTFE versus cuffed ePTFE grafts for vascular access.

Received: Mar 15, 2021, Revised: Mar 27, 2021, Accepted: Apr 5, 2021
Corresponding Author : Jun Gyo Gwon
Division of Transplantation and Vascular Surgery, Department of Surgery, Korea University College of Medicine, Goryeodae-ro 73, Seongbuk-gu, Seoul 02841, Korea
Tel: 82-2-920-5978, Fax: 82-2-928-1631, E-mail: sojinb612@korea.ac.kr

| eISSN: 2635-8603

MATERIALS AND METHODS

1. Patients and outcomes

This study is a retrospective study examining the clinical results of vascular access surgery performed by a single surgeon in single center. Patients who underwent brachio-axillary prosthetic graft vascular access surgery at our institution between January 2018 and December 2019 were included in this study. All patients underwent prosthetic graft vascular access surgery because of poor superficial veins or inability to undergo forearm prosthetic graft vascular access surgery. Before hemodialysis patients were excluded from the study, as were study subjects who previously underwent dialysis using a central venous catheter. Patients who underwent right-sided surgery were also excluded from the study. After that, the graft patency was compared between patients by dividing them into a group using a cuffed prosthetic graft (Venaflo® II ePTFE; Bard Peripheral Vascular, Inc., Tempe, AZ, USA) as a conduit and a group using a non-cuffed prosthetic graft (Advanta VXT; Atrium Medical Corporation, Merrimack, NH, USA) as a conduit. Both prosthetic graft types had a graft diameter of 6 mm just before the vein anastomosis. All patients underwent surgery performed by the same surgeon, and perioperative management and follow-up were performed using the same protocol (Fig. 1). We verified both the vascular access primary patency rate and the re-intervention survival rate. Vascular access primary patency was defined as the interval from the time of access placement to any intervention designed to maintain or re-establish patency or access thrombosis or to the time of the patency measurement [7]. Re-intervention survival was defined as the date from one intervention to the next intervention; if re-intervention was not performed, it was defined as equal to the vascular access primary patency period.

2. Operation and follow-up

The operation was performed according to the following procedure. First, the brachial artery above the antecubital fossa and axillary vein was exposed. The prosthetic graft was tunneled in a slightly curved shape through the subcutaneous fat layer Subsequently, venous anastomosis was performed first, followed by arterial anastomosis. Each anastomosis was performed with a parachute suture technique using a single thread on both sides using Prolene 7-0. Follow-up was performed at the outpatient clinic at 1 week after the surgery, and every 3 months thereafter. Patients began dialysis through the graft at 2-4 weeks after the surgery.

3. Statistical analysis

The characteristics of the study subjects are summarized as median (interquartile range) for continuous variables and

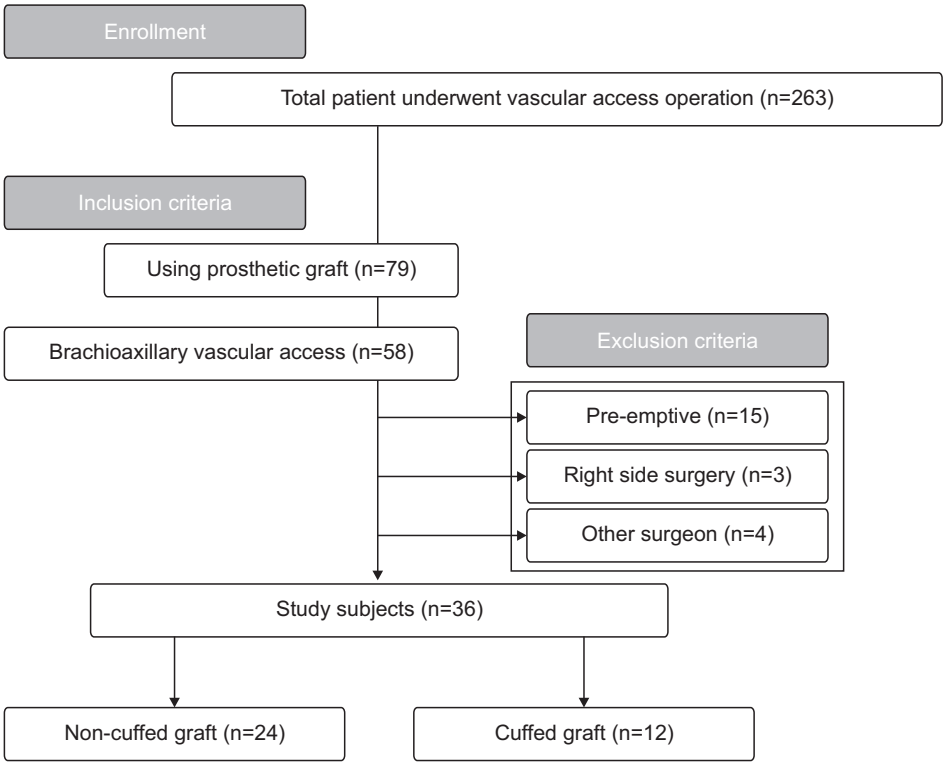

Fig. 1. Flowchart of the study population selection process.

Table 1. Baseline characteristics of the study subjects

	Total (n=36)	Cuffed graft (n=12)	Non-cuffed graft (n=24)	p
Age (years), median (IQR)	74.9 (66.5-77.5)	73.5 (60.5-73.5)	75.5 (68.5-79.0)	0.231
Male, n (%)	14 (38.9)	4 (33.3)	10 (41.7)	0.727
Body mass index (kg/m^2), median (IQR)	22.7 (19.7-25.3)	24.6 (19.7-29.9)	22.2 (19.5-24.3)	0.194
Hypertension, n (%)	30 (83.3)	11 (91.7)	19 (79.2)	0.640
Diabetes mellitus, n (%)	22 (61.1)	8 (66.7)	14 (58.3)	0.727
Smoking, n (%)	8 (22.2)	2 (16.7)	6 (25.0)	0.691
Stroke, n (%)	10 (27.8)	2 (16.7)	8 (33.3)	0.438
Coronary artery disease, n (%)	9 (25.0)	2 (16.7)	7 (29.2)	0.686
Peripheral artery disease, n (%)	3 (8.3)	0 (0)	3 (12.5)	0.536
Previous AVF or AVG, n (%)	8 (22.2)	4 (33.3)	4 (16.7)	0.397
Cancer, n (%)	6 (16.7)	3 (25.0)	2 (12.5)	0.378
Artery size (mm), median (IQR)	4.3 (3-5)	4.1 (3-4.5)	4.3 (3-5)	0.074
Vein size (mm), median (IQR)	6.1 (4-6.5)	5.8 (4.5-6)	6.2 (4-8)	0.302

IQR, interquartile range; AVF, arteriovenous fistula; AVG, arteriovenous graft.

number (percentage) for binary variables. To compare the characteristics between groups by graft material, we used the Mann-Whitney U-test or Fisher's exact test, as appropriate. The primary patency, assisted patency, and secondary patency rates by follow-up time were calculated using the Kaplan-Meier curve. To compare the patency time between the two groups, we used the log-rank test; the results are presented as median patency time and corresponding 95% confidence interval. Statistical significance was set at $p<0.05$. All statistical analyses were performed using SAS software (version 9.4; SAS Institute Inc., Cary, NC, USA) and R (version 4.0.3; R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Over the 2-year study period, 36 patients who underwent brachial axillary vascular access surgery were selected for the study according to the inclusion and exclusion criteria. Among the patients who underwent surgery, 24 were treated with a cuffed prosthetic graft and 12 were treated with a non-cuffed prosthetic graft. There were no significant intergroup differences in patient characteristics (Table 1). The mean follow-up period was 23.6±18.8. months in the cuffed graft group and 30.1±22.4. months in the non-cuffed graft group (p=0.033). For the cuffed and non-cuffed graft groups, the 1-year primary patency rates were 85.1% and 71.6%, respectively, while the 2-year primary patency rates were 63.6% and 37.9%, respectively, showing no intergroup difference (p=0.064) (Fig. 2). For the cuffed and non-cuffed graft groups, the 1-year vascular access survival rates were 93.2% and 78.6%, respectively, while the 2-year survival rates were 64.1% and 41.3%, respectively, showing better re-intervention free outcomes in the cuffed graft group (p=0.003) (Fig. 3).

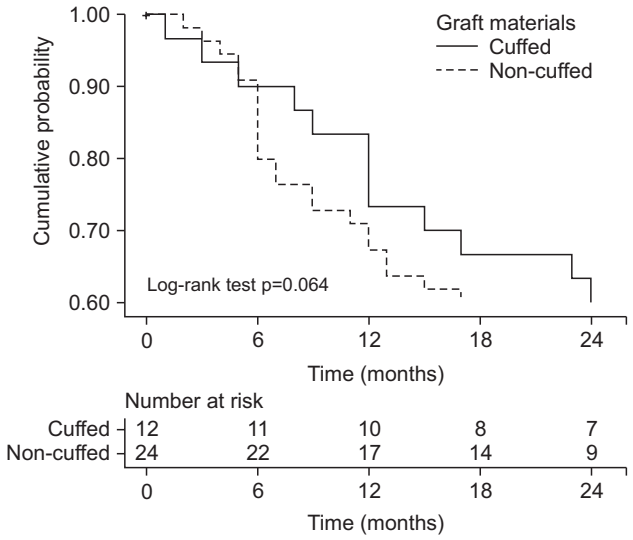

Fig. 2. Kaplan-Meier curve of primary patency rate of vascular access by graft type.

DISCUSSION

In this study comparing the cuffed prosthetic graft and the non-cuffed prosthetic graft at the vein anastomosis site, we confirmed two findings. First, the two graft types had the same primary patency rates. Second, the period until re-intervention

was longer when cuffed versus non-cuffed grafts were used.

1. Primary patency rate

In prosthetic graft vascular access surgery, outlet stenosis is an important factor that decreases the patency rate. Therefore, it is important to prevent intimal hyperplasia at the graft outlet to extend vascular access patency [8]. However, the comparison of primary patency between the two groups in this study suggests that the cuffed outlet could not reduce outlet intimal hyperplasia, possibly due to excessive turbulent flow (Fig. 4). In an experimental animal study, Michael et al. examined a cross-section of the cuffed graft and noted that the larger the angle between the mainstream blood flow and the cuff wall, the more turbulent the flow. This turbulent flow induces intimal hyperplasia because of the shear stress of the graft wall [6].

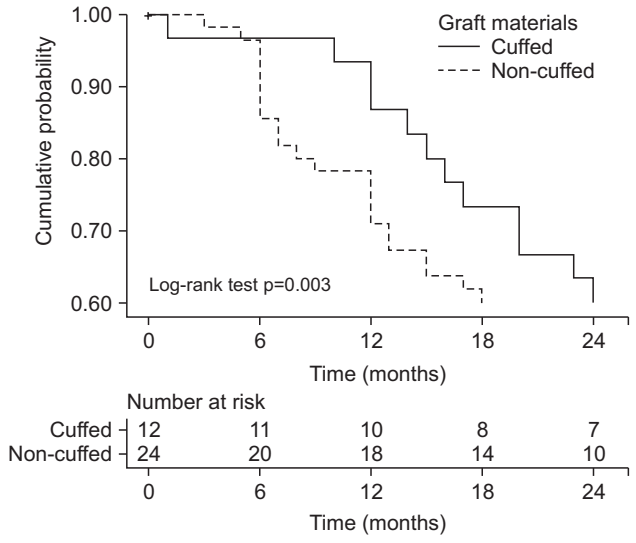

Fig. 3. Kaplan-Meier curve of re-intervention survival rate of vascular access by graft type.

Previous studies demonstrated better patency rates for cuffed than non-cuffed grafts. However, the 1-year primary patency rates reported by these studies were less than 60%, indicating a problem with the vascular access surgery technique [9-11].

2. Re-intervention patency rate

We confirmed that the primary patency rate did not differ between the two groups, but the time to re-intervention was longer for the cuffed graft. This indicates that the cuffed graft was more likely than the non-cuffed one to maintain patency after the intervention. In other words, procedures at the cuffed graft outlet, such as stenosis site ballooning, are performed more efficiently. It can be assumed that less of the re-coiling phenomenon of the corresponding part after ballooning occurs in the cuffed graft. Re-coiling is the most common cause of restenosis after the ballooning procedure. The basic mechanism of expanding the lumen diameter of the stenosis lesion using the ballooning procedure is to push the intimal hyperplasia in the direction of the graft wall using the pressure of the balloon expansion [12]. However, this balloon procedure does not remove the intimal hyperplasia layer; rather, it compresses it and pushes it in the radial direction; thus, over time, graft re-coiling occurs due to the cohesive force generated on the graft wall. According to the law of Laplace, the smaller the graft lumen diameter, the stronger the tension acts. So, the smaller the post-balloon graft lumen diameter, the more easily the re-coiling phenomenon occurs. Both prosthetic graft types had the same graft diameter of 6 mm just before the venous anastomosis, but the diameter of the outlet of the cuffed graft was larger; thus, the post-balloon diameter of the corresponding part was also larger in the cuffed graft than in the non-cuffed graft. For this reason, we hypothesized that the re-intervention patency rate would have been better for the cuffed graft, which has less post-balloon cohesion tension for re-coiling.

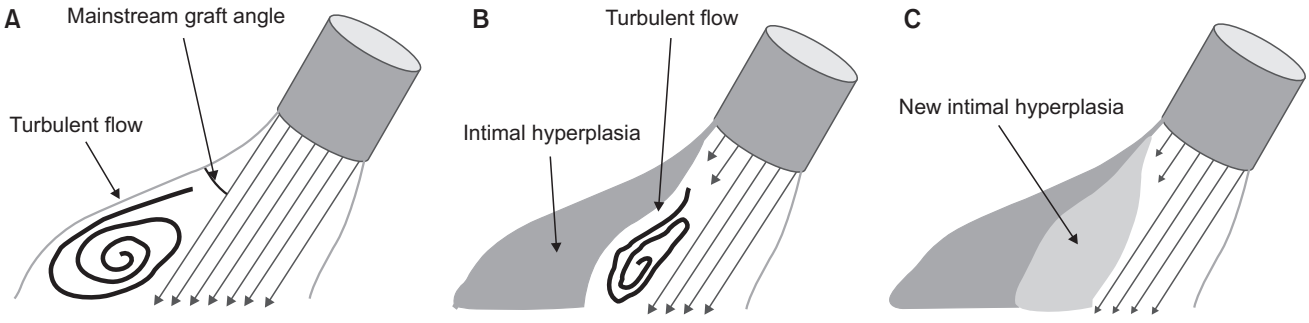

Fig. 4. Intimal hyperplasia occurs at the cuffed graft outlet over time. (A) Immediate after vein anastomosis, (B) Occurrence of intimal hyperplasia in flow separation space, (C) New intimal hyperplasia following the anastomosis lumen remodeling.

This study had several limitations. First, the follow-up periods of the two groups were significantly different. This is because of a supplying problem, non-cuffed prosthetic grafts were used first and cuffed prosthetic grafts were used later. However, due to the non-selective graft supply, this study has the advantage of reducing surgeon's graft selection bias, even though it is not a randomized controlled study. Second, it is difficult to say that clinically meaningful results were derived because of the small number of enrolled patients. Our results can be interpreted clinically meaningful, if the future studies in this subject using large numbers of patients will demonstrated the same results.

CONCLUSION

Vascular access using cuffed grafts did not differ in primary patency from non-cuffed grafts, but the re-intervention survival rate was better for cuffed graft vascular access. we suggest that using a cuffed vascular access graft can help improve graft patency.

FUNDING

This study was funded by the Korean Society for Dialysis Access (2018AN0317).

REFERENCES

1. Lok CE, Huber TS, Lee T, et al. KDOQI Clinical Practice Guideline for vascular access: 2019 update. Am J Kidney Dis, 2020; 75(4 Suppl 2): S1-164.
2. Fluck R, Kumwenda M. Renal Association Clinical Practice Guideline on vascular access for haemodialysis. Nephron Clin Pract, 2011; 118 Suppl 1: c225-40.
3. Schmidli J, Widmer MK, Basile C, et al. Editor's choice - vascular access: 2018 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS). Eur J Vasc Endovasc Surg, 2018; 55(6): 757-818.
4. Tordoir JH, Herman JM, Kwan TS, et al. Long-term follow-up of the polytetrafluoroethylene (PTFE) prosthesis as an arteriovenous fistula for haemodialysis. Eur J Vasc Surg, 1988; 2(1): 3-7.
5. Longest PW, Kleinstreuer C, Andreotti PJ. Computational analyses and design improvements of graft-to-vein anastomoses. Crit Rev Biomed Eng, 2000; 28(1-2): 141-7.
6. Heise M, Husmann I, Gruneberg AK, et al. Comparison of straight and Venaflo-type cuffed arteriovenous ePTFE grafts in an animal study. J Vasc Surg, 2011; 53(6): 1661-7.
7. Sidawy AN, Gray R, Besarab A, et al. Recommended standards for reports dealing with arteriovenous hemodialysis accesses. J Vasc Surg, 2002; 35(3): 603-10.
8. Lemson MS, Tordoir JH, Daemen MJ, et al. Intimal hyperplasia in vascular grafts. Eur J Vasc Endovasc Surg, 2000; 19(4): 336-50.
9. Liu YH, Hung YN, Hsieh HC, et al. Impact of cuffed, expanded polytetrafluoroethylene dialysis grafts on graft outlet stenosis. World J Surg, 2006; 30(12): 2290-4.
10. Tsoulfas G, Hertl M, Ko DS, et al. Long-term outcome of a cuffed expanded PTFE graft for hemodialysis vascular access. World J Surg, 2008; 32(8): 1827-31.
11. Ko PJ, Liu YH, Hung YN, et al. Patency rates of cuffed and noncuffed extended polytetrafluoroethylene grafts in dialysis access: a prospective, randomized study. World J Surg, 2009; 33(4): 846-51.
12. Gardiner GA, Jr., Bonn J, Sullivan KL. Quantification of elastic recoil after balloon angioplasty in the iliac arteries. J Vasc Interv Radiol, 2001; 12(12): 1389-93.