Management of post-puncture bleeding after neurointerventional procedures performed with a large-bore sheath introducer

Iori Ozono, Shigeyuki Sakamoto, Takahito Okazaki, Jumpei Oshita, Daizo Ishii and Kaoru Kurisu

Affiliations:

1) Department of Neurosurgery, Graduate School of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan

Corresponding author's name and complete mailing address:

Shigeyuki Sakamoto
Department of Neurosurgery
Graduate School of Biomedical and Health Sciences
Hiroshima University
1-2-3 Kasumi, Minamiku, 734 8551 Hiroshima, Japan

Phone: +81 82 257 5227
Fax: +81 82 257 5229
E-mail address: sakamoto@hiroshima-u.ac.jp

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Abstract

Various adjunctive techniques for neurointerventional procedures require a large-bore sheath introducer, but there is concern that this could result in more puncture site hemorrhagic complications despite using a vascular closure device. The purpose of this study was to assess the relationship between use of large-bore sheath introducer and post-procedural complications. Between January 2016 and April 2018, 126 neurointerventional procedures were performed in our hospital using 8 or 9 Fr sheath introducer in size and the Angio-seal STS PLUS (St. Jude Medical, Minnetonka, USA). Hemorrhagic complications were defined as obvious swelling or bleeding at the puncture site or as extravascular bleeding detected by ultrasonography or contrast-enhanced computed tomography. The procedures were divided into a group with post-puncture bleeding (group B, n = 21) and a group without bleeding (group N, n = 105). Risk factors were compared between the groups according to the incidence of post-puncture bleeding. In addition, we assessed the outcome and approach to hemostasis in the procedures with bleeding. In result, hemorrhagic complications occurred in 21 procedures (17%), and pseudoaneurysm was detected in 4 procedures (3.2%). In 20 of group B (16%), manual compression was performed for an average of 36.4 minutes. One patient (0.79%) required surgical angioplasty. Risk factors for bleeding were not significantly different between the two groups. None of the patients with bleeding showed a decrease on the modified Rankin Scale. In conclusion, use of a large-bore sheath introducer may increase the incidence of post-

puncture bleeding, but the outcome of this complication is acceptable.

Key Word

Angio-Seal; hemorrhagic complication; neurointervention

Introduction

Recently, various adjunctive techniques for neurointerventional procedures require the use of a large-bore sheath introducer. A vascular closure device can achieve hemostasis easily and safely, as well as decreasing the length of hospital stay and improving patient satisfaction [1]. The Angio-Seal device (St. Jude Medical, Minnetonka, MN, USA) can prevent complications and it achieves hemostasis with a higher success rate than manual compression [2] [3] [4]. However, whether using a large-bore sheath introducer increases the incidence of complications remains controversial.

Puncture-related complications associated with the Angio-Seal include vascular stenosis or occlusion, as well as and hemorrhagic complications such as pseudoaneurysm [5]. Iatrogenic pseudoaneurysms can rupture or can cause thromboembolism, compression of neurovascular structures, or necrosis of overlying skin and subcutaneous tissue, and sometimes require surgical repair [6]. Previous studies have shown that risk factors correlated with hemorrhagic complications after use of the Angio-Seal device include female sex, low body mass index, femoral artery depth at the puncture site, use of antiplatelet agents, and a history of peripheral vascular disease in female patients [2, 7-10]. However, the average sheath size was relatively small in these studies, and no study has assessed the relationship between use of a large-bore sheath introducer for neurointerventional procedures and hemorrhagic complications or outcomes obtained with the Angio-Seal device. Therefore, this study was performed to evaluate

risk factors associated with post-puncture bleeding and its outcome after use of a large-bore sheath introducer.

Methods

Patients

This study was approved by the local university institutional review board. A total of 139 consecutive patients (151 procedures) who underwent neurointerventional procedures at our hospital between January 2016 and April 2018 were enrolled retrospectively. The procedures using < 8Fr sheath introducers were excluded, leaving 116 patients (126 procedures) for investigation. The age of the patients ranged from 33 to 86 years (mean age: 68 years) and 67 were men. Coil embolization of intracranial aneurysms (CE) was performed in 69 procedures (55%), while revascularization was done in 57 procedures (45%) for carotid artery stenosis or acute ischemic stroke.

Procedure

All procedures using the Angio-Seal involved femoral artery puncture and the puncture site was located over the lower half of the femoral head. The femoral artery diameter and puncture site were confirmed to be suitable for using the Angio-Seal. After the procedure, the patient rested in bed for more than 15 hours with the affected leg fixed. Then the femoral artery

puncture site was assessed by ultrasonography (US) on the next morning.

Definition and Management of Hemorrhagic Complications

Hemorrhagic complications were defined as obvious swelling or bleeding at the puncture site, or as bleeding detected by US or contrast-enhanced computed tomography (CT). These complications were treated with US-guided manual compression and successful hemostasis was confirmed by US or contrast-enhanced CT.

Statistical analysis

Statistical analysis was performed using JMP Pro version 14 (SAS Institute, Cary, NC). Results are presented as the mean ± standard deviation. Categorical variables were compared with the Fisher exact probability test. Continuous variables with a normal distribution were analyzed by the Student t-test, and those without a normal distribution were analyzed by the Mann–Whitney U-test. The procedures were divided into a group with post-puncture bleeding (group B, n = 21) and a group without bleeding (group N, n = 105). Potential risk factors such as the procedure, sex, age, body mass index, past history, activated clotting time, procedure time, sheath size, and presence/absence of puncture site calcification on CT were compared between these groups and sorted by the incidence of post-puncture bleeding. Significance was defined as $P < 0.05$. In addition, the method and outcome of hemostasis were evaluated in group B.

Results

Clinical outcome

All neurointerventional procedures were performed successfully. Post-puncture bleeding was observed in 21 procedures (17%), and a pseudoaneurysm was detected in 4 (3.2%). Risk factors are displayed in Table 1 for the two procedural groups. In 20 procedures with post-puncture bleeding from group B (16%), manual compression was performed for an average of 36.4 minutes. However, one patient (0.79%) needed repair by surgical angioplasty. Potential risk factors for bleeding were not significantly different between the two groups. None of the patients with post-puncture bleeding showed a decrease of the modified Rankin Scale.

Representative case

An 84-year-old man with asymptomatic severe internal carotid artery stenosis was treated by carotid artery stenting under local anesthesia. Hemostasis was performed with the Angio-Seal device. The next day, there was no obvious puncture site swelling, but US detected a pseudoaneurysm with blood flow at the puncture site in the right femoral artery (Figure 1A). After manual compression for 30 minutes, cessation of extravascular bleeding was shown by US (Figure 1B). The patient was discharged from hospital after one week with no adverse effects.

Discussion

In recent years, various new techniques and devices have emerged with significant advantages for neurointerventional procedures[11]. Application of these devices may require a large-diameter sheath, especially when more than one device is simultaneously introduced into the target lesion. This study was the first to investigate hemorrhagic complications after use of a large-bore sheath introducer and Angio-Seal device in neurointerventional procedures.

Major hemorrhagic complications have been reported after use of the Angio-Seal. Previous studies have revealed that female sex, body mass index (BMI) < 21, and a shallow femoral artery depth (< 11.1 mm) at the puncture site were significantly associated with hemorrhagic complications [2] [7]. Furthermore, a recent retrospective cohort study of percutaneous coronary intervention showed that BMI ≤ 26 was an independent predictor of the overall risk of complications associated with use of the Angio-Seal or Perclose or manual compression after the procedure [12]. However, the sheath size was relatively small (6.0 – 6.4 F) in these previous studies and none of the patients were managed with a large-bore sheath-introducer (8 or 9 Fr) [2] [9] [10] [13]. Therefore, it has been unclear whether or not using a large-bore sheath introducer results in more hemorrhagic complications.

The Angio-Seal device achieves hemostasis by sealing the arteriotomy site between a polymer anchor and collagen sponge with the assistance of a self-tightening suture, after which these components of the device are absorbed within 90 days. A previous investigation of the

causes of hemorrhagic complications after use of the Angio-Seal indicated that puncture site calcification could prevent proper coverage of the arteriotomy site by the intravascular polymer anchor and extravascular collagen sponge [14]. In another study, a low BMI (< 19) and shallow femoral artery were risk factors for post-puncture bleeding, presumably due to insufficient adhesion between the Angio-Seal components and the punctured artery [2]. Considering the mechanism by which the Angio-Seal device achieves hemostasis, using a larger sheath might make the arteriotomy hole less stable and it is therefore possible that a larger sheath could increase hemorrhagic complications.

The frequency of puncture sites complications after using the Angio-Seal device was 2.6 - 9.2% in previous reports, while it was higher in the present study (17%) [2] [9] [10] [13]. The definition of post-puncture complications in varied previous studies, such as events requiring additional treatment and further hospitalization, an unplanned increase in the level of care, or transfusion, or events resulting in permanent sequelae or death. On the other hand, study employed a stricter definition, which was obvious swelling/bleeding at the puncture site or bleeding detected by US or contrast-enhanced CT. Thus, we included patients without any symptom in whom bleeding was only found by US, and routinely performing US assessment contributed to the high rate of post-puncture complications. Well known post-puncture complications include hematoma, pseudoaneurysm, arteriovenous fistula, femoral artery dissection, and arterial thrombus/occlusion, all of which can be detected by US [15]. In

particular, pseudoaneurysm often becomes problematic and may need surgical repair [3]. Serial follow-up using a noninvasive modality like US is not only useful to detect complications, but also to monitor patients with these problems. Our strict definition could have led to the relatively high incidence of complications in this study.

Use of a large-bore sheath might increase the frequency of post-puncture bleeding complications. However, the high rate in the present study may have resulted from differences in the definition of post-puncture bleeding and routine performance of follow-up US at the puncture site. In present study, none of the patients who had post-puncture bleeding complications developed permanent neurologic deficits with a decrease on the modified Rankin Scale. Accordingly, use of a large-bore sheath introducer to allow application of various techniques for neurointerventional procedures seems to be warranted.

Conclusion

Using a large-bore sheath introducer might increase the incidence of post-puncture bleeding, even if the Angio-Seal is employed for hemostasis. However, post-puncture bleeding complications could be controlled by prompt and appropriate treatment, and the outcome was acceptable.

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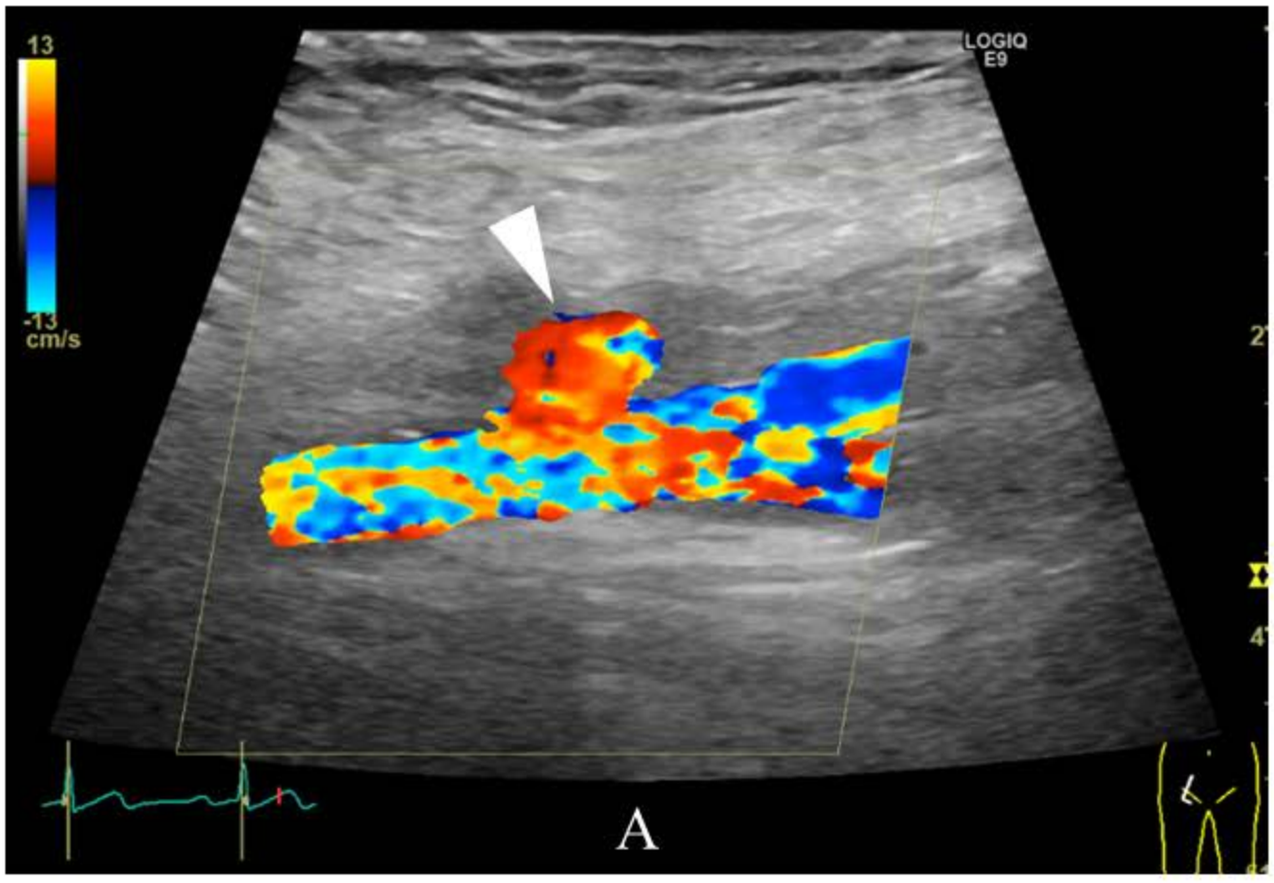
Figure 1 Representative case

Ultrasonography reveals a pseudoaneurysm with blood flow at the puncture site in the right femoral artery (A) (white arrowhead). After manual compression, the pseudoaneurysm is no longer detected (B).

Table 1. Baseline characteristics of the study patients.

Risk factor		Bleeding (Group: B, n=21)	No bleeding (Group: N, n=105)	P value
Sex	Male	13 (62 %)	54 (51 %)	0.38
	Female	8 (38 %)	51 (49 %)	
	Age	66.4 ± 11.5	68.3 ± 10.9	0.44
	BMI	23.6 ± 2.56	23.3 ± 3.12	0.66
Procedure	CE	9 (43 %)	60 (57 %)	0.23
	Revascularization	12 (57 %)	45 (43 %)	
	ACT	302 ± 31.1	304 ± 48.3	0.91
	Heparin dose	5452 ± 1522	5070 ± 1141	0.12
	Procedure time	115 ± 56.4	116 ± 56.5	0.96
	Sheath-size	8.81 ± 0.39	8.83 ± 0.38	0.76
	Calcification FA	5 (25 %)	37 (41 %)	0.18
Past history	HT	13 (62 %)	70 (67 %)	0.67
	DL	12 (57 %)	44 (42 %)	0.2
	DM	7 (33 %)	24 (23 %)	0.31
	MI	3 (14 %)	16 (15 %)	0.91
	PAD	1 (5 %)	5 (5 %)	1
	CKD	3 (14 %)	16 (15 %)	0.91
	Stroke	4 (19 %)	20 (19 %)	1
	Smoking	10 (48 %)	56 (53 %)	0.63

ACT, activated clotting time; BMI, body mass index; CE, coil embolization; CKD, chronic kidney disease; DL, dyslipidemia; DM, diabetes mellitus; FA, femoral artery; HT, hypertension; MI, myocardial infarction; PAD, peripheral artery disease



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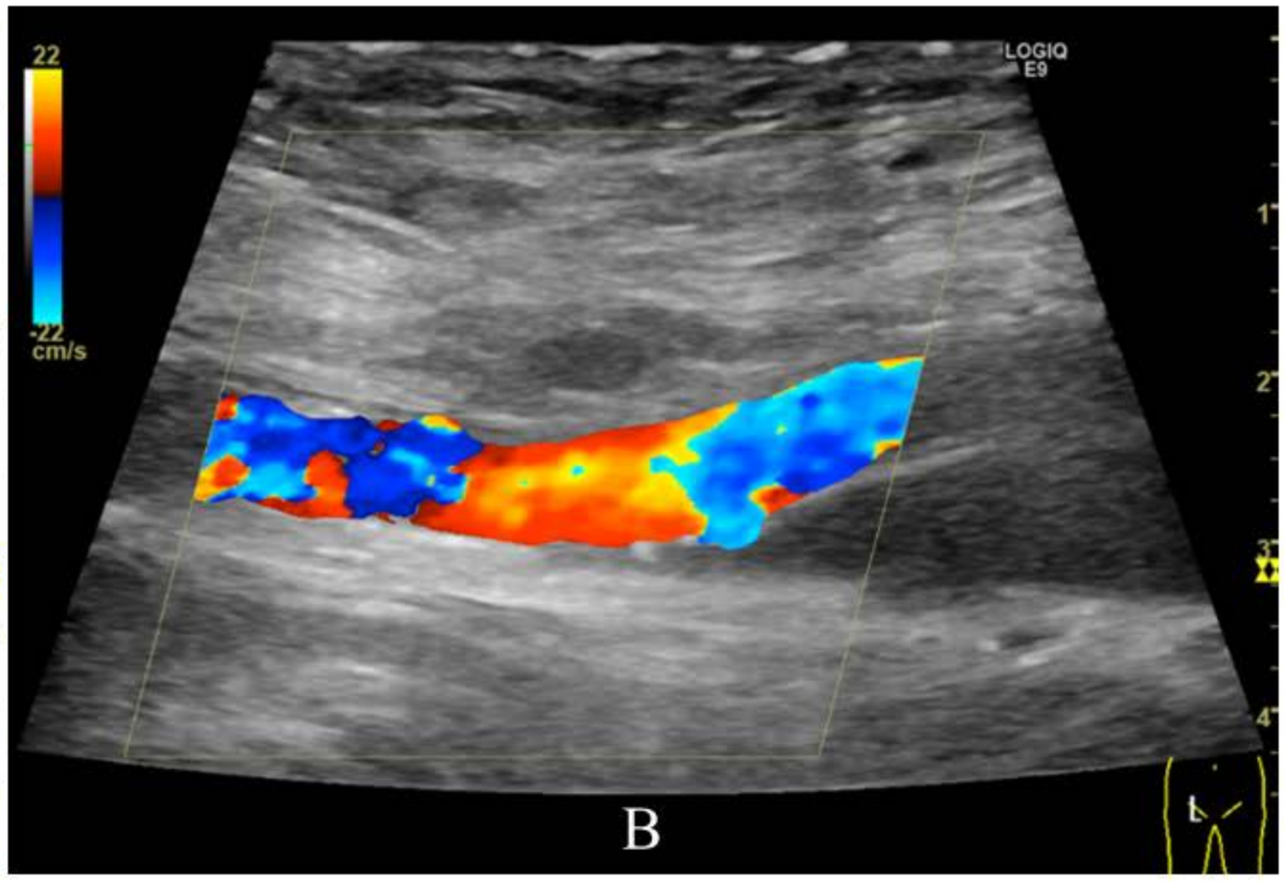

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