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Detail analysis of puncture site complications in neuro-endovascular therapy: A single-center analysis

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ABSTRACT

Objective: Puncture site complications in neuro-endovascular therapy, which represent a significant cause of morbidity, are often difficult to treat. Vascular closure devices have evolved in endovascular therapy. We analyzed risk factors for puncture site complications and examined the efficacy of hemostasis methods in neuro-endovascular therapy.

Methods: This retrospective, observational, single-center study was conducted from January 2021 to January 2023. We enrolled 202 puncture sites of patients who underwent neuro-endovascular therapy at Kawaguchi Municipal Medical Center and analyzed the complications requiring additional intervention.

Results: There were 12 (5.94 %) puncture site complications. No patient had permanent puncture-related complications. Univariate analyses revealed that a higher risk of puncture site complications was significantly associated with multiple antiplatelet agents ($p = 0.03$), hypertension ($p = 0.03$), scheduled treatment ($p < 0.01$), higher activated clotting time (ACT) immediately before sheath removal (≥310 s, $p < 0.01$), and the non-use of Perclose (manual compression or Angio-seal, $p < 0.01$). Multivariate analyses revealed that puncture site complications were significantly higher in patients with an ACT immediately before sheath removal ≥ 310 s (HR: 10.4, 95 % CI: 2.45–44.15, $p < 0.01$), scheduled treatment (HR: 10.16, 95 % CI: 1.81–56.95, $p < 0.01$), and the non-use of Perclose (HR: 21.97, 95 % CI: 2.42–199.34, $p < 0.01$).

Conclusion: A higher ACT immediately before sheath removal was significantly associated with puncture site complications. Perclose is an efficient device, and it may reduce the risk of puncture site complications.

1. Introduction

In recent years, there have been remarkable advances in neuro-endovascular therapy, and this has expanded to various diseases for therapeutic indications. Puncture site complications in neuro-endovascular therapy are infrequent; however, it is sometimes difficult to recover from complications and lead to poor prognosis. Puncture site complications occur in 0.67 %–9.7 % of patients who underwent neuro-endovascular therapy [1–5]. The analysis of data from the Japanese Registry of Neuroendovascular Therapy (JR-NET)3 showed that the incidence of puncture site vascular complications was 0.73 %; however, 7 % of patients with puncture site complications ended up as permanent disabilities, and 2 % of the patients died [2].

Vascular closure devices (VCDs) have also evolved. VCDs that can be used in Japan include Perclose ProGlide™ and ProStyle™ (PP; Abbot Vascular), Angio-Seal™ (AS; St Jude Medical), and Exoseal™ (ES, Cordis Corporation). VCDs are helpful for shorter hemostasis time, shorter time until patients walking is allowed, shorter hospital stays, and leading patient satisfaction [4,6–8]. However, it is unclear whether VSDs reduce the rate of puncture site complications [9,10], and these complications sometimes make postoperative management difficult and remain associated with a poor prognosis. In this retrospective study, we conducted an in-depth investigation of the risk factors for puncture site complications.

2. Material and methods

Between January 2021 and January 2023, 180 patients underwent neuro-endovascular therapy via *trans*-femoral puncture at Kawaguchi Municipal Medical Center. Ten out of 180 patients had punctured both

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femoral arteries for a single treatment, and 12 underwent neuroendovascular treatment two times during this period. We analyzed a total of 202 puncture sites. The median case age was 73 years (range: 26–101 years). There were 103 males and 99 females. One hundred and twenty-five cases were treated for hypertension, 53 patients were treated for hyperlipidemia and 40 for diabetes mellitus. Sixteen patients received anticoagulants, 126 received antiplatelet agents (83 of them took multiple antiplatelet agents). Eighty-six patients received emergency treatment, while 116 others received scheduled treatment. The treatment types were as follows: coil embolization (82 patients), flow diverter use (6 patients), carotid artery stenting (23 patients), mechanical thrombectomy (66 patients), and others (25 patients). The median activated clotting time (ACT) immediately before sheath removal was 248 s (range: 112–446 s). One hundred and eighty-three patients were punctured at the right femoral artery, while 19 were punctured at the left femoral artery. In 112 patients, Perclose was used as the hemostatic method, Angio-seal was used in 73, and MC was used in 17. We mainly used Angio-seal before September 2021 and Perclose after October 2021. This retrospective study was approved by the institutional review board of KKMC (IRB 2023–15).

We defined puncture site complications as situations requiring at least one of the following additional interventions: surgery for occlusion, pseudoaneurysm, or arteriovenous fistula, blood transfusion for puncture-related bleeding, antibiotic treatment for local infection around the puncture site, and additional compression. Additional compression was defined the compression of a subcutaneous hematoma in a patient with hemodynamic instability (systolic blood pressure below 90 mmHg and heart rate above 100 /min) after the initial hemostatic procedure or compression for delayed bleeding after the release of bed rest at the puncture site. The effects of the following clinical variables were studied: age, sex, past medical history (hypertension, hyperlipidemia, diabetes mellitus), anticoagulant use, number of antiplatelet agents received (>2 vs. 0 or 1), BMI, preoperative blood examination (hemoglobin, platelet count, prothrombin time, and activated partial thromboplastin time), type of surgery (scheduled vs. emergency), treatment type (coil embolization or FD vs. others), ACT immediately before sheath removal, side of the femoral artery, femoral artery diameter, puncture appropriateness, sheath type (guiding sheath vs. standard sheath), sheath size, and hemostatic methods (PP, AS, or MC). The appropriate puncture was defined as the puncture of the femoral artery between the bifurcation of the superficial and deep femoral artery and the distal portion of the inferior abdominal wall artery and deep iliac artery (Table 1).

Table 1
Characteristics of 180 patients with 202 puncture sites.

Characteristics	Value
Median age (years, range)	73 (26–101)
Sex (No., %)	
Male	99 (49%)
Female	103 (51%)
Past medical history (No., %)	
Hypertension	125 (62%)
Hyperlipidemia	53 (26%)
Diabetes Miletus	40 (20%)
Preoperative medication (No., %)	
Anticoagulated agent	16 (8%)
No. of antiplatelet agent	
≥2	83 (41%)
1	43 (21%)
0	76 (38%)
Median body mass index (range)	23.1 (15.6–33.7)
Preoperative blood examination (median, range)	
Hemoglobin (g/dl)	13.4 (7.7–18.5)
Platlet count Platlet count (10^4/dl)	22.2 (9–65.2)
Prothrombin time (seconds)	1.0 (0.84–3.10)
Activated partical thromboplastin time (seconds)	27.7 (19.3–47.8)
Treatment timing (No., %)	
Scheduled	86 (43%)
Emergency	116 (57%)
Treatment type (No., %)	
Coil embolization for aneurysm without stent assist	56 (28%)
Coil embolization for aneurysm with stent assist	26 (13%)
Flow divertor	6 (3%)
Carotid artery stenting	23 (11%)
Mechanical thrombectomy	66 (33%)
Others	25 (12%)
Median ACT immediately before sheath removal (range)	248 (112–446)
Side of femoral artery	
Right	183 (91%)
Left	19 (9%)
Median femoral artery diameter (range)	10.2 (6.4–14.7)
Appropriate puncture	169* (90%)
Sheath type	
Standard sheath	117 (58%)
Guiding sheath	85 (42%)
Sheath size (Fr, %)	
4–6 Fr	95 (47%)
7–9 Fr	107 (53%)
Hemostatic method	
Manual compression	17 (8%)
Angio-seal	73 (36%)
Perclose	112 (55%)

ACT: activated whole blood clotting time. *14 sites' data were not available.

All statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R (The R Fondation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of R commander designed to add statistical functions frequently used in biostatistics [11]. The suggested cutoff value for continuous variables (Age, BMI, ACT, PLT, PT, APTT, Hb, and femoral artery diameter) was determined by the Youden index based on receiver operating characteristic (ROC) curve analyses. Categorical variables were analyzed using the Fisher exact test for categorical variables with a significance level of $P < 0.05$. To control for confounding factors, multivariate logistic regression (including factors that had $P \leq 0.05$ in the univariate analysis) was performed.

3. Results

A total of 202 puncture sites were studied, and puncture site complications requiring intervention occurred in 12 sites (5.94 %) of 11 patients. One case required open surgery for femoral artery occlusion. In this patient, AS was used for puncture site hemostasis. Blood clots had grown around the intravascular anchor, and it was removed (Fig. 1). Five cases required blood transfusion: one retroperitoneal bleeding, two subcutaneous bleeding with anemia, and two anemia without subcutaneous bleeding of unknown etiology (Table 3; Cases 1 and 2 involve the same person). Six cases required additional compression: three cases of subcutaneous bleeding with hemodynamic instability without anemia and three cases of delayed bleeding after the release of bed rest at the puncture site. There were no cases of arteriovenous fistula, distal embolization, and infection. The details of the complications we encountered are presented in Table 3.

In our univariate analysis, HT ($p = 0.032$), the use of multiple antiplatelet agents ($p = 0.030$), scheduled treatment ($p = 0.005$), a higher ACT immediately before sheath removal (≥310, $p = 0.001$), and the non-use of Perclose ($p = 0.001$) were significantly associated with a higher risk of puncture site complications, whereas none of the following factors were significantly associated with it: age, sex, operator, surgery type, past medical history (HL, DM), BMI, preoperative blood examination (PT, APTT, PLT, Hb), femoral artery diameter, the side of the femoral artery, puncture appropriateness, sheath type, and sheath size. In the multivariate analysis, scheduled treatment ($p = 0.008$, HR: 10.16, 95 % CI: 1.81–56.95), a higher ACT immediately before sheath removal (≥310, $p = 0.001$, HR: 10.4, 95 % CI: 2.45–44.15), and the non-use of Perclose ($p = 0.006$, HR: 21.97, 95 % CI: 2.42–199.34) were significantly associated with a higher risk of puncture site complications (Table 2).

Fig. 1. A 63-year-old man underwent carotid artery stenting via right femoral puncture, and Angio-Seal was used for puncture site hemostasis. The day after CAS, the patient complained of pain in his right leg, and his right dorsalis pedis artery was no longer palpable. Ultrasonography revealed the occlusion of his right femoral artery, and the patient underwent surgery to remove the thrombus the around anchor. This is the thrombus with the anchor.

Table 2
Univariate and multivariate statical analyses of puncture site complication risk.

Variable	Univariate p value	Multivariate analysis		
		p value	HR	95 % CI
Age (<65 vs. ≥65)	0.537	NA	NA	NA
Sex	0.374	NA	NA	NA
Hypertension	0.032	0.080	NA	NA
Hyperlipidemia	0.307	NA	NA	NA
Diabetes Miletus	1.000	NA	NA	NA
Anticoagulated agent (≥1 vs. 0)	0.604	NA	NA	NA
Multiple antiplatelet agent (≥2 vs. <2)	0.030	0.893	NA	NA
BMI (≥21.5 vs. <21.5)	0.101	NA	NA	NA
Hb (<14 vs. ≥14)	0.060	NA	NA	NA
Platelet (<19 vs. ≥19)	0.096	NA	NA	NA
PT (<1.0 vs. ≥1.0)	1.000	NA	NA	NA
APTT (<27.0 vs. ≥27.0)	0.238	NA	NA	NA
Timing (Scheduled vs. Emergency)	0.005	0.008	10.16	1.81–56.95
Treatment type (Coiling or FD vs. others)	0.371	NA	NA	NA
ACT (≥310 vs. <310)	0.001	0.001	10.4	2.45–44.15
Puncture side (Left vs. Right)	0.090	NA	NA	NA
Femoral artery diameter (<9.4 vs. ≥9.4)	0.062	NA	NA	NA
Appropriate puncture	1.000	NA	NA	NA
Sheath type (Guiding sheath vs. Standard sheath)	0.129	NA	NA	NA
Sheath size (4–6 Fr vs. 7–9 Fr)	0.071	NA	NA	NA
Hemostatic method (MC or AS vs. Perclose)	0.001	0.006	21.97	2.42–199.34

BMI: body mass index, Hb: hemoglobin, PT: prothrombin time, APTT: activated partial thromboplastin time, ACT: activated whole blood clotting time, FD: flow diverter, MC: manual compression, AS: Angio-seal.

4. Discussion

There were puncture site complications at 12 puncture sites (5.94 %). A systematic review by Das R et al. reported that puncture site complications in neuro-endovascular therapy occurred in 3.1 %–9.7 % [1], which was similar to the rate we found in our study. Data analyses of JR-NET3 showed that access site complications in neuro-endovascular therapy occurred in 0.73 % of all procedures [2]. This rate is lower than what we found in our study, possibly due to the ambiguous definition of puncture site complications and the presence of unreported mild cases.

The Perclose system is designed to deliver a single monofilament polypropylene suture to close femoral artery puncture sites. In the multivariate analysis, Perclose had significantly fewer puncture site complications; thus, we may reduce the risk of puncture site complications in neuro-endovascular therapy. There was one complication in the Perclose group requiring blood transfusion with anemia and no subcutaneous bleeding. (Cases 1 and 2 in Table 3). The etiology is unknown because a search for the cause has not been conducted; however, retroperitoneal hemorrhage cannot be ruled out. Even with the use of Perclose, retroperitoneal bleeding cannot be prevented; thus, caution is required in high and posterior wall punctures. Perclose use is associated with a complicated procedure, and device failure occurs in 2.38 % of cases [12]. Most of them were due to suture breakage during plunger withdrawal or the knot could not be formed over the femoral artery. Moreover, after 40 procedures, the success of Perclose utilization significantly increased, and the complications of the procedure significantly decreased [13]. In this study, when we failed to use Perclose, we used MC as a hemostatic method. All Perclose procedure failures were counted by MC, and the failure rate could not be analyzed. There were no puncture site complications when we failed to use Perclose in this study. The failure rate increases in cases with calcified lesions in the punctured vessel because the needle does not penetrate. We must preoperatively evaluate calcified lesions in advance with computed tomography or echocardiographic, and in the case of the femoral artery with calcified lesions, we must modify the hemostatic method.

Angio-seal is a hemostatic device that anchor abuts the vessel wall and a collagen plug is deployed over the arteriotomy. The plug expands when it enters the subcutaneous tissue and accelerates the clotting cascade, and the anchor and plug are resorbed over time. Three cases required additional compression due to delayed bleeding after the release of bed rest at the puncture site in the Angio-seal group (Table 3, Cases 8, 9, and 10). Delayed bleeding occurred while sitting on the toilet. It is thought that the collagen sponge detached from the vessel wall when patients sit on the toilet, resulting in delayed puncture site bleeding. This may have been because the collagen sponge was not adequately adhered to the vessel wall when we used Angio-seal. One case required surgery due to femoral artery occlusion (Table 3, Case 12). A thrombus adhered to an anchor, resulting in femoral artery occlusion, and this thrombus was surgically removed (Fig. 1). Several previous kinds of literature reported femoral artery occlusion, and to prevent puncture site complications [14], Angio-seal should be used for limited indications, such as in patients with relatively good femoral artery characteristics and patients who can maintain bed rest for a long time [5]. If Angio-seal is deemed unsuitable for use, hemostasis methods should be changed.

Heparinization also had a significantly higher incidence of puncture site complications [3], and patients who had the ACT immediately before sheath removal ≥ 300 s were associated with puncture site complications in neuro-endovascular therapy [15]. In this study, the ACT immediately before sheath removal was also used to analyze the relationship between the ACT and puncture site complications. The ACT was associated with puncture site complications. We calculated the ACT and ROC curves for puncture site complications using the Youden index. We found a cutoff value at an ACT of 310 s. There were significantly more puncture site complications in the group with the ACT more significant than 310 s ($p = 0.001$, Table 2).

Scheduled surgical procedures resulted in a higher incidence of puncture site complications. This is the opposite of the results reported for cardiac catheterization using VCDs [16]. JR-NET and JR-NET2 also had a statistically significant number of puncture site complications in scheduled surgery, and they concluded that this might be due to the high proportion of patients receiving preoperative multiple antiplatelet agents, and CAS and PTA (which have a higher risk of puncture site

Table 3
Summary of patients with puncture site complications.

	Age/Sex	Treatment	APA	PMH	Timing	ACT	Hemostasis	Sheath type & size (Fr)	Complication	Outcome
1	81/F	SACE	DAPT	HT, HL	Schedule	366	MC	Guiding sheath (4)	Anemia	Blood Transfusion
2	81/F	SACE	DAPT	HT, HL	Schedule	366	PP	Guiding sheath (6)	Anemia	Blood Transfusion
3	84/F	SACE	DAPT	HT	Schedule	255	MC	Guiding sheath (4)	Subcutaneous bleeding	Compression
4	59/F	CAE	DAPT	HT, HL	Schedule	334	MC	Guiding sheath (4)	Subcutaneous bleeding	Blood Transfusion
5	55/M	CAS	TAPT	HT, DM	Schedule	149	AS	Standard sheath (8)	Subcutaneous bleeding	Compression
6	79/F	CAE	DAPT	HT	Schedule	256	AS	Standard sheath (6)	Subcutaneous bleeding	Compression
7	86/F	Tumor	None	HT	Schedule	267	AS	Guiding sheath (5)	Subcutaneous bleeding	Blood Transfusion
8	44/F	FD	DAPT	None	Schedule	334	AS	Guiding sheath (6)	Delayed bleeding	Compression
9	50/M	PAO	SAPT	HT	Emergency	392	AS	Guiding sheath (5)	Delayed bleeding	Compression
10	65/M	MT	SAPT	HT, HL	Emergency	360	AS	Standard sheath (8)	Delayed bleeding	Compression
11	73/F	FD	TAPT	HT	Schedule	314	AS	Guiding sheath (6)	Retroperitoneal bleeding	Blood Transfusion
12	63/M	CAS	DAPT	HT, HL, DM	Schedule	269	AS	Standard sheath (8)	Femoral artery occlusion	Vascular Surgery

SACE: stent assisted coil embolization, CAE: cerebral aneurysm embolization, CAS: carotid artery stenting, FD: flow diverter, PAO: parent artery occlusion, MT: mechanical thrombectomy, APA: antiplatelet agent, SAPT: single antiplatelet therapy, DAPT: dual antiplatelet therapy, TAPT: triple antiplatelet therapy, PMH: past medical history, HT: hypertension, HL: hyperlipidemia, DM: diabetes mellitus, MC: manual compression, AS: AngioSeal™, PP: Perclose ProGlide™ or ProStyle™.

vascular complications) were essentially performed as scheduled surgery [3]. In this study, a comparison of the ACT immediately before sheath removal between scheduled surgery and emergency surgery showed that the ACT was significantly higher in scheduled surgery ($p < 0.01$). MT was performed in 55.9 % of emergency surgeries. Intraoperative heparinization for MT has been controversial (especially after intravenous tissue-type plasminogen activator (t-PA) therapy) because of safety concerns. Intravenous t-PA was initiated preoperatively in 41 % of MT, and inadequate heparinization leads to lower ACT in emergency surgical procedures. The high ACT immediately before sheath removal may have increased puncture site complications in scheduled surgical procedures.

The ACT immediately before sheath removal was significantly associated with puncture site complications, and Perclose may reduce the risk of puncture site complications.

However, this study has a few limitations, including the fact that it is a single-center retrospective study that does not follow standardized protocols. Puncture site complications are rare complications, and several cases would have statistical validity as a result.

5. Conclusion

The incidence of puncture site complications requiring intervention in this study was 5.94 %. The higher ACT immediately before sheath removal was significantly associated with puncture site complications in neuro-endovascular therapy. Perclose may reduce the risk of puncture site complications.

Author contributions

Conception and design: Takeuchi, Ogino. Acquisition of data: Takeuchi. Analysis and interpretation of data: Takeuchi, Ogino. Drafting the article: Takeuchi. Critically revising the article: Ogino. Reviewed submitted version of manuscript: Kano, Furuichi, Yoshino. Study supervision: Furuichi, Yoshino.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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