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Analysis of Puncture Site-related Complications in Japanese Registry of Neuroendovascular Therapy (JR-NET)3

Masayuki SATO,[1] Yuji MATSUMARU,[1] Nobuyuki SAKAI,[2] and on behalf of JR-NET study group affiliations

[1]*Department of Neurosurgery, Faculty of Medicine, University of Tsukuba, Tsukuba, Ibaraki, Japan;*
[2]*Department of Neurosurgery and Comprehensive Stroke Center, Kobe City Medical Center General Hospital, Kobe, Hyogo, Japan*

Abstract

A subgroup analysis of puncture site-related complications listed in the Japanese Registry of NeuroEndovascular Therapy 3, based on retrospective studies, was performed. Puncture site-related complications occurred in 315 (0.73%, average age: 65.2) of 36,708 patients out of all 43,303 registered cases. Carotid artery stenting (CAS, 95 patients, 1.1%, *P* <0.01) and extracranial percutaneous transluminal angioplasty (PTA, 21 patients, 1.4%, *P* <0.01) were associated with significantly higher incidence of puncture site-related complications. The incidence of complications correlated with the number of antiplatelet drugs (*P* <0.001). Although 40% of the puncture complications were treated conservatively, 13% were treated endovascularly and 5% underwent open surgery.

Key words: puncture-site related complication, endovascular treatment, nationwide survey

Introduction

Puncture site-related vascular complications occur in 3.1–9.7% of patients who underwent neuroendovascular therapy.[1)] Our previous data analysis from the Japanese Registry of Neuroendovascular Therapy (JR-NET)1 & 2 showed that access site complications occurred in 0.63% of all procedures.[2)] Retroperitoneal hematoma may result in death due to the massive bleeding. In recent years, hemostatic devices have been developed and improved, and showed efficacy in numerous meta-analyses, but retroperitoneal hematoma still requires much caution.[1,3–5)] In Japan, a prospective study on the access-site hemostatic device Angio-Seal (Terumo, Tokyo, Japan) proved its efficacy in neurondovascular therapy.[6)] JR-NET3 includes retrospectively registered studies on neuroendovascular therapy conducted by the Japanese Society for Neuroendovascular Therapy from January 2010 to December 2013. The registration parameters included disease-specific and cross-sectional parameters common in all diseases. In this article, puncture site-related vascular complications in JR-NET3 (a cross-sectional parameter) are analyzed.

Materials and Methods

Data of 36,708 patients out of all 43,303 cases registered in JR-NET3 were included in the evaluation. Puncture site-related complications included hemorrhagic complications, ischemic complications, and infections. If the hemostatic method was not described, it was not assessed. The presence or absence of an access site complication, age, sex, treatment facility (main hospital or satellite hospital), timing of surgery (scheduled or emergency), investigator (supervisor/specialist, or non-specialist), treatment (cerebral aneurysm embolization, arteriovenous malformation embolization, spinal lesion, dural arteriovenous fistula, intracranial tumor, carotid artery stenting (CAS), extracranial percutaneous transluminal angioplasty (PTA), intracranial PTA, acute recanalization therapy, spasm treatment, or other), outcome of complications (asymptomatic, transiently symptomatic, moderate disability, severe disability, or death), and the effect of complications on the treatment outcome were assessed. For puncture-related complications, we also examined how they were treated (conservative treatment, additional endovascular therapy, open

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surgery). Out of all patients who received treatment (cerebral aneurysm embolization, carotid artery stenting, extracranial PTA, and intracranial PTA), 25,348 cases with available data regarding antiplatelet therapy were included in the assessment of preoperative use of antiplatelet drugs. These variables were analyzed using Chi-square test for categorical variables and *t*-test for continuous variables, with a significance level of $P < 0.05$ (SPSS Ver. 22, IBM, Armonk, NY, USA) used in statistical analysis.

Results

Puncture site-related complications occurred in 315 (0.73%) of all 43,303 cases (Table 1). Incidence of puncture site-related complications was not affected

Table 1 Characteristics of puncture site-related complications

	Total	Complications (%)	Puncture site complication (%)	% In access site complication	Data unavailable	*P*-value
Patients	36708					
Cases	43303	3922 (10.7%)	315 (0.7)		0	
Age ± SD	65.2 ± 14.2				748	
Male	18,626 (50.7%)				710	
Facility						
Main	34403	3350 (9.7)	269 (0.8)	85.4	52	0.57
Satellite	2253	572 (25.4)	20 (0.9)	6.3		
Timing						
Schedule	24551	2396 (9.8)	193 (0.8)	61.3	40	0.84
Emergency	12117	526 (4.3)	96 (0.8)	30.5		
Operator						
Supervisor/Specialist	34026	2023 (5.9)	301 (0.9)	95.6	718	0.43
Non-specialist	1964	171 (8.7)	14 (0.7)	4.4		
Treatment					0	
Aneurysm embolization	17348	1803 (10.4)	140 (0.8)	7.8		NS
Aneurysm parent artery occlusion	1315	260 (19.8)	8 (0.5)	3.1		<0.01
Arteriovenous malformation	1456	128 (8.8)	1 (0.1)	0.8		<0.01
Spinal lesion	275	22 (8.0)	0	0.0		NS
Dural AVF	2776	129 (4.6)	4 (0.1)	3.1		NS
Tumour	1657	61 (3.7)	4 (0.1)	6.6		NS
Carotid artery stent	8889	674 (7.6)	95 (1.1)	14.1		<0.01
Extracranial PTA	1491	97 (6.5)	21 (1.4)	21.6		<0.01
Intracranial PTA	1268	134 (10.6)	6 (0.5)	4.5		NS
Acute recanalization therapy	3974	508 (12.8)	22 (0.6)	4.3		<0.01
Apasm	1804	42 (2.3)	0	0.0		NS
Other	1050	64 (6.1)	10 (1.0)	15.6		(–)
Outcome					2	
Asymptomatic			78	24.8		
Transient symptom			207	65.7		
Moderate disability			12	3.8		
Severe disability			10	3.2		
Dead			6	1.9		

by the facility where operation was done, timing of operation, and the operator. Regarding the treatment, CAS (95 patients, 1.1%, P <0.01) and extracranial PTA (21 patients, 1.4%, P <0.01) were associated with a significantly higher incidence of complications, while parent artery aneurysm occlusion (one patient, 0.06%, P <0.05), arteriovenous malformation (one patient, 0.1%, P <0.01), and acute recanalization therapy (22 patient, 0.6%, P <0.01) were associated with a significantly lower incidence. The treatment for puncture site-related complications was conservative in 125 patients (40.0%), endovascular in 42 patients (13.3%), and open surgery in 16 patients (5.1%). The treatment outcome was asymptomatic or transiently symptomatic in 90.5% of patients, permanent disability in 22 patients (0.05%), and fatal in six patients (0.01%). The incidence of puncture site-related complications according to the use of antiplatelet drugs is shown in Figure 1. It was significantly different between the patients without therapy for complications (17 patients, 0.32%), those who received 1 or 2 drugs (202 patients, 1.16%), and those who received 3 or more drugs (28 patients, 1.47%). At the time of acute revascularization, combination of treatment with tissue plasminogen activator (tPA) had no effect on puncture site-related complications (0.6% with tPA vs 0.6% without tPA, P-value = 0.96; Table 2). In the carotid stent group, there was no difference in the incidence of puncture complications in the use of sheath equal or larger than 8 Fr. (19 cases, 1.2%) and the sheath smaller than 8 Fr. (75 cases, 1.1%). Regarding the age, there was no difference in the frequency of complications between those aged 75 or older (68 cases, 0.7%) and those younger than 75 (190 cases, 0.7%). Although 40% of the puncture complications were treated conservatively, 13% were treated endovascularly and 5% underwent direct surgery.

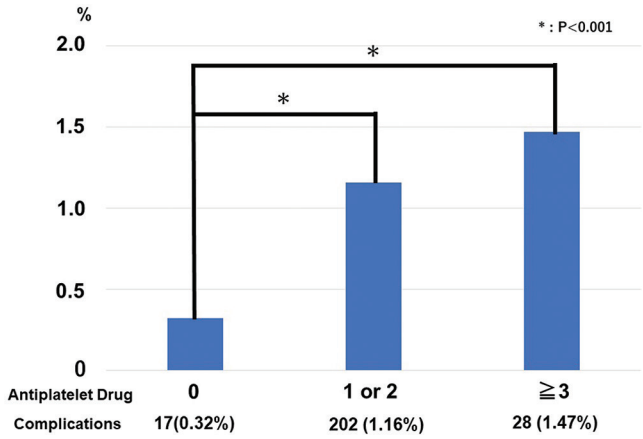

Fig. 1 Univariate analysis of the antiplatelet agent status. The incidence of puncture site-related complications was significantly different between the patients receiving no medications or 1 or 2 drugs, and no medications or 3 drugs.

Discussion

In this study, the incidence of puncture site-related complications was 0.73%, which is substantially lower than previously reported 3.1–9.7%.[1,2,4,7,8] Compared with our previous study based on JR-NET1 & 2 data, puncture site-related complications had also very low incidence of 0.63%.[6] As a result of strict management of puncture complications in Japanese endovascular treatment facilities, low incidence of puncture site-related complications is estimated. CAS and extracranial PTA are associated with higher incidence of complications mainly due to intraoperative heparinization, the use of multiple antiplatelet agents, larger diameter sheaths, and peripheral atherosclerosis. There was no difference in puncture complications related with alteplase administration in acute revascularization therapy.

In case of acute revascularization, a 9-Fr guiding catheter with a balloon is often used in Japan. Since a puncture site hemostatic device is applicable only for catheters up to 8 Fr, it was estimated that

Table 2 Sub-analysis of puncture site-related complications frequency

		Cases	Puncture site complications (%)	Data unavailable	P-value
Acute recanalization therapy	tPA (+)	1396	8 (0.6)	0	0.96
	tPA (–)	2492	14 (0.6)		
Carotid artery stent sheath size	<8 Fr	1597	19 (1.2)	667	0.85
	≥8 Fr	6625	75 (1.1)		
Age	<75 y/o	26027	190 (0.7)	57	0.64
	≥75 y/o	9947	68 (0.7)		

using catheters over 8 Fr would lead to puncture site complications, but it turned to be similar to other groups.

There is concern about an increase in complications at the puncture site due to the intravenous administration of alteplase prior to endovascular treatment. In this study, the use of tPA did not lead to the increase in puncture site complications. The results were in line with those in the recent publication.[9]

Recent reports have shown that hemostasis can be achieved using various hemostatic devices without increasing complication rate.[9,10]

In the carotid stent group, there was no difference in the incidence of puncture site complications between 8 and 6 Fr sheath use, presuming that the hemostatic device was effectively used. In our previous study on the effectiveness of Angio-Seal, it was shown that the occurrence frequency of the puncture site complications is not related to the sheath size.[6]

It was estimated that the progression of arteriosclerosis increasing with age may cause an increase in puncture-related complications, but this study did not show any increase in complications depending on age.

The treatment outcome was asymptomatic or transiently symptomatic in 90.5%, but caused disability in 7.0%. Death-related access site complications occurred in six patients (0.016%), but those patients had not only access site, but also other (ischemic and/or hemorrhagic) complications. In this study, it cannot be definitively concluded whether the treatment outcome was affected by puncture site-related complications or not, because some patients had not only puncture site-related, but also other complications. Most puncture site complications resolved after conservative therapy, but in a few cases additional endovascular treatment or open surgery were necessary.

Looking at the annual trends of retrospectively registered studies in JR-NET1–3, conducted from 2005 to 2012, the same trend was found in occurrence frequency, severity, and cause with the respect to puncture complications.[2] Although there are no innovations and advances in development of hemostasis devices, vascular puncture-related complications have been strictly managed in Japanese endovascular treatment facilities, and thus a low puncture complication rate has been maintained.

Regarding the limitations, it was a retrospective study based on the registry data, and no description whether the hemostasis was done by the main operator or the assistant was provided. The evaluation criteria for puncture site complications in particular are ambiguous and may be underestimated due to oversight. There was no distinction between using a hemostatic device or manual compression to achieve hemostasis. Regarding puncture site complications, some data may be missing, which may affect statistical analysis.

Conclusion

The incidence of puncture site vascular complications was 0.73%. These complications resulted in permanent disability in 22 patients (0.06%) and death in six patients (0.017%). CAS, extracranial PTA, and use of antiplatelet drugs were associated with higher incidence of complications. Compared with JR-NET1–3 data were comparable in terms of puncture site complications.

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Conflicts of Interest Disclosure

We declare no conflicts of interest. All authors who are members of The Japan Neurosurgical Society (JNS) have registered self-reported COI disclosure statement forms online through the website for JNS members.

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Address reprint requests to: Yuji Matsumaru, MD, PhD, Department of neurosurgery, Faculty of Medicine, University of Tsukuba, 2-1-1 Amakubo, Tsukuba, Ibaraki 305-8576, Japan.
e-mail: yujimatsumaru@md.tsukuba.ac.jp