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Treatment Outcome of Intracranial Tumor Embolization in Japan: Japanese Registry of NeuroEndovascular Therapy 3 (JR-NET3)

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Abstract

Embolization for intracranial tumor is performed as a standard endovascular treatment. A retrospective, multicenter, observational study was conducted to clarify the nature, frequency, and risk factors of complications in intracranial tumor embolization. Patients were derived from the Japanese Registry of NeuroEndovascular Therapy (JR-NET3) using data taken from January 2010 through December 2014 in Japan. A total of 40,169 patients were enrolled in JR-NET3, of which, 1,545 patients (3.85%) with intracranial tumors underwent embolization. The primary end point was the proportion of patients with a modified Rankin scale (mRS) score of 0–2 (independency) at 30 days after embolization. The secondary end point was the occurrence of complications related to the procedures. The risk factors of the development of complications were analyzed. The proportion of patients with mRS scores ≤2 at 30 days after procedure was 89.5%. Complications occurred in 57 of the 1544 patients (3.7%). Multivariate analysis showed that target vessels other than external carotid artery (ECA) (OR, 3.56; 95% CI, 2.03–6.25; *P* <0.001) and use of liquid material (OR, 2.65; 95% CI, 1.50–4.68; *P* <0.001) were significantly associated with the development of complications. In JR-NET3, the primary end point was 89.5%, and the procedure-related complication rate was 3.7%. Embolization from other than ECA was significant risk factor of the complications. In addition, increasing usage of liquid embolic material worsened the risk of complications.

Key words: complication, intracranial tumor, embolization, liquid embolic material, Japanese registry

Introduction

Embolization for intracranial tumor, especially for meningioma, has been established as one of standard procedure in neuroendovascular treatment.[1–6] Recent rapid development of interventional neuroradiology allowed us more stable results with lower complication rate in intracranial tumor embolization.[5–7]

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The multicenter Japanese Registry of NeuroEndovascular Therapy (JR-NET) Study Group was formed in 2005 to clarify the factors that affect the results of neuroendovascular treatment.[8] Previous JR-NET2 study clearly demonstrated the real-world date of intracranial tumor embolization in Japan using large number of the patients' data. In JR-NET2, complication occurred in 15 of the 1,012 patients (1.5%) received intracranial tumor embolization. In addition, multivariate analysis showed that embolization for tumors other than meningioma was significantly associated with the development of complications.[7] Similar to JR-NET2, JR-NET3 was conducted to identify the nature, frequency, and risk factors of

complications of intracranial tumor embolization in Japan using more recent data.

Patients and Methods

Patients were derived from JR-NET3, which was a retrospective, observational study using data taken from January 2010 through December 2014 in 122 neurosurgical centers in Japan. The Japanese Society of NeuroEndovascular Therapy has a specialist qualification system through which it certifies two classes of specialists: Specialists and consulting specialists.[9] A consulting specialist is a senior specialist who must already be qualified as a specialist. In this observational study, a specialist or consulting specialist had to participate in each patient's neuroendovascular treatment. A total of 40,169 patients were enrolled in JR-NET3; of these, 1,545 patients (3.85%) with intracranial tumors underwent embolization. The primary end point was the proportion of patients with a modified Rankin scale (mRS) score of 0–2 (independency) at 30 days after embolization. The secondary end point was the occurrence of complications related to the procedures.

Age, gender, and preoperative mRS were recorded as the patients' backgrounds. Whether the main operator was a specialist, consulting specialist, or non-specialist was also recorded. Types of tumors, target vessels for embolization, embolic materials used, and results of embolization were evaluated. The target vessels were categorized as the feeders from the internal carotid artery (ICA), those from the external carotid artery (ECA), and those from the vertebrobasilar artery (VBA). The types of embolic materials used were coils, liquid materials such as *n*-butyl cyanoacrylate (NBCA), particle materials such as polyvinyl alcohol, and combinations of these. The results of each embolization were indicated by the degree of devascularization seen in each tumor, which was graded as total, subtotal, partial, and unchanged.

Complications were defined as any neurological deficit or death that occurred during or after embolization. Radiographical abnormalities after embolization, such as ischemic or hemorrhagic changes, were also classified as complications even if the patients were asymptomatic. In patients with complications, the type of complication, the timing and duration of its occurrence, the treatments used, and the final outcomes of the complication were recorded. To identify the risk factors of complications, the following factors in patients with complications were compared with those in patients without: Age, gender, anesthesia, preoperative mRS, schedule of treatment, main operator, target vessels, embolic materials, and result of embolization.

Statistical analysis

A univariate analysis was performed using Fisher's exact probability test for nominal variables, and the Mann–Whitney U test for continuous variables. A multivariate analysis for factors related to the development of complications was performed using a logistic regression model. Variables with a probability value of less than 0.05 on a univariate analysis were selected for a multivariate analysis. All statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). *P*-values less than 0.05 were considered to be statistically significant.

Results

As the record for one patient did not have sufficient information for evaluation in a total of 1545 patients registered with intracranial tumor embolization in JR-NET3, 1544 patients [937 female, median age 63 years (interquartile range (IQR) 52–70 years)] were analyzed.

Table 1 shows the patient characteristics in this investigation. The primary end point (mRS score 0–2 at 30 days after procedure) was observed in 1382 patients (89.5%). About 57 of the 1544 patients (3.7%) suffered from procedural complications which was set as the secondary end point.

Aggravation of mRS was observed in 231 patients (15.0%). Among them, there were 192 out of 1337 patients with meningioma (14.4%) and 17 out of 72 patients with hemangioblastoma (23.6%).

Types and outcomes of complications

Of the 57 complications, 7 (12.3%) were hemorrhagic, 32 (56.1%) were ischemic, 4 (7.0%) were puncture site, 1 (1.8%) was systemic, and the remaining 13 (22.8%) were other complications. As a result of complications, 18 (31.6%) were asymptomatic, 20 (35.1%) developed temporary symptoms, and 17 (29.8%) developed permanent symptoms. Of these 17, the mRS score at 30 days declined by 1 point in 13 (22.8%), and by more than 2 points in 4 (7.0%). Data was not acquired in 2 (3.5%).

Risk factors for the occurrence of complications

The results of the univariate analysis for factors of the development of complications are shown in Table 2. In patients undergoing tumor embolization,

Table 1 Patient characteristics

	Patients (N = 1544)
Age, year (median, IQR)	63 (52–70)
Female sex	937 (60.7)
Preoperative mRS	
0	1034 (67.0)
1	271 (17.5)
2	137 (8.9)
3	58 (3.7)
4	34 (2.2)
5	6 (0.4)
Data not acquired	4 (0.3)
Type of tumors	
Meningioma	1337 (86.6)
Hemangioblastoma	72 (4.7)
Glioma	10 (0.6)
Others	121 (7.8)
Data not acquired	4 (0.3)
Anesthesia	
General	203 (13.1)
Local	1338 (86.7)
Data not acquired	3 (0.2)
Scheduled intervention	
Yes	1520 (98.4)
No	21 (1.4)
Data not acquired	3 (0.2)
Main operator	
Consulting specialist	648 (42.0)
Specialist	772 (50.0)
Non-specialist	122 (7.9)
Data not acquired	2 (0.1)
Target vessels	
ECA	1294 (83.8)
ICA	78 (5.0)
VBA	86 (5.6)
ECA + ICA	52 (3.4)
ECA + VBA	16 (1.0)
ECA + ICA + VBA	1 (0.1)
Others	2 (0.1)
Data not acquired	15 (1.0)
Embolic materials	
Coil	827 (53.6)
Particle materials	632 (40.9)
Liquid materials	627 (40.6)
Data not acquired	23 (1.5)
Results of embolization	
Total	385 (24.9)
Subtotal	627 (40.6)
Partial	492 (31.9)
Unchanged	16 (1.0)
Data not acquired	24 (1.6)

Age is presented as the median and interquartile range (IQR): other values are presented as the raw numbers with percentages in parentheses. ECA: external carotid artery, ICA: internal carotid artery, mRS: modified Rankin scale, VBA: vertebrobasilar artery.

Table 2 Univariate analysis of factors related to the development of complications in tumor embolization

Factors	Occurrence of complications		P-value
	Yes	No	
Numbers of patients	57	1487	
Age (median, IQR)	62 (50–68)	63 (52–70)	0.272
Female sex	26 (45.6)	911 (61.3)	0.025
Preoperative mRS 3–5	7 (12.3)	91 (6.1)	0.112
Other than meningioma	12 (21.4)	191 (12.9)	0.097
Non-specialist	4 (7)	118 (7.9)	0.996
Scheduled procedure	55 (98.2)	1465 (98.7)	1
General anesthesia	11 (19.3)	192 (12.9)	0.233
Other than ECA	23 (40.4)	210 (14.3)	<0.001
Coil	22 (38.6)	805 (55)	0.021
Particle material	13 (22.8)	619 (42.3)	0.005
Liquid material	38 (66.7)	589 (40.2)	<0.001
Complete embolization	9 (15.8)	376 (25.6)	0.13

female sex, target vessels other than ECA, and use of liquid material were significantly associated with the development of complications. The odds ratios for these variables on the multivariate analysis were shown in Table 3. The multivariate analysis showed that target vessels other than ECA (OR, 3.56; 95% CI, 2.03–6.25; P <0.001) and use of liquid material (OR, 2.65; 95% CI, 1.50–4.68; P <0.001) were significantly associated with the development of complications.

Table 3 Logistic regression analysis for factors related to the development of complications

Variables	Complications		OR	95% CI	*P*-value
	Yes	No			
Female sex	26 (45.6)	911 (61.3)	0.64	0.37–1.09	0.1
Other than ECA	23 (40.4)	210 (14.3)	3.56	2.03–6.25	<0.001
Liquid material	38 (66.7)	589 (40.2)	2.65	1.50–4.68	<0.001

Discussion

Usefulness of preoperative embolization for intracranial embolization

Although many reports have suggested usefulness of preoperative embolization for intracranial tumors focusing on reducing intraoperative blood loss,[1–6,10,11] a certain number of procedure-related complications has also been reported in the literatures.[10–12] There is a critical paper which has demonstrated that preoperative meningioma embolization did not result in better clinical outcome or significant reduction of blood loss.[12] Raper et al.[13] also reported that preoperative embolization did not alter the operative duration, complication, or degree of resection from their analysis of 224 patients with meningioma. Latchaw[14] advocated technical considerations affecting the risk-to-benefit ratio of preoperative intracranial meningioma embolization. The degree of surgical blood loss may be dependent upon several factors such as type of tumor, its inherent degree of vascularity, the surgical skill, and location of the tumor. So objective data about easiness of surgery is difficult to obtain. In general, preoperative embolization may play an important role including the following: (1) Meningioma of the skull base, (2) a large meningioma with abundant edema, (3) tumorous involvement of persistently patent dural sinus, (4) tumorous involvement of the scalp and calvarium, (5) predominant vascular supply from the external carotid artery, (6) tumors in eloquent area.[13,14] From the standpoint of risk-to-benefit, the procedure related complication rate should set as low as possible.

Incidence of complications in tumor embolization in Japan

This study incorporated data from most of the major neurosurgical institutes in Japan, and data is considered to reflect the current situation of neuroendovascular treatment in Japan using largest number of cases. In JR-NET3, 3.7% of the 1544 patients who underwent intracranial tumor embolization experienced procedure related complications. Many previous studies on the embolization of meningiomas have reported that a range of incidents of complications from 3 to 9%.[10–13,15] In a recent systematic review, the overall complication rate of preoperative embolization for intracranial meningiomas was 4.6% and, of these, 14.3% were major or fetal complications.[16] The prevalence of complication in JR-NET3 was equal to or lower than other reports. One of the reasons for low frequency of complications may be that the procedures were conducted by specialists or consulting specialists certified by the Japanese Society of NeuroEndovascular Therapy in 92%. Although the procedures by non-specialists did not increase the occurrence of complications in this study, it would be safer to be performed under observation of well-trained operators.

Factors related to the development of complications

In the present study, the multivariate analysis showed that target vessels other than ECA and use of liquid materials were independent risk factors for the development of complications related to preoperative tumor embolization. Intracranial meningiomas are mainly fed by the ECAs, which are relatively safe target of embolization. Other than ECA vessel was targeted in 15.1% of the patients in JR-NET3. More aggressive embolization targeted to other than ECA increased in JR-NET3. Intracranial hemangiomas and gliomas are usually supplied by the ICAs and VBAs, and large skull base meningiomas may have pial supplies from these vessels. In the other review on preoperative embolization for skull base meningiomas, it is described that because vascular supply to skull base meningiomas is quite complex and varied, aggressive embolization may be associated with serious complications.[17] Ischemic complications can occur if embolic materials migrate into vessels supplying the normal brain cortex when targeting the ICAs or VBAs.[13] Although several papers demonstrated relatively good results with using various techniques,[18–20] embolization for the branches of ICAs and VBAs still has higher risk of complications.

Hemangioblastoma was the second target of tumor embolization in the present study, although it accounted for only 4.7% of all cases. Because hemangioblastoma is highly vascular-rich tumor, preoperative embolization seems to be beneficial.[21–23] In the present study, tumor type other than meningiomas was not significantly associated with procedure related complications. On the other hand, Ampie et al.[24] do not recommend embolization as standard of care for intracranial hemangioblastoma, because complication rates of preoperative embolization of intracranial hemangioblastoma were 11.7%, and following consequent surgery were 20.7% in their systematic review. Kuwahara et al.[25] reported safety and effectiveness of preoperative embolization for cerebellar hemangioblastoma with NBCA on the day of surgery. Such efforts, development of devices, and accumulated experiences may improve the result of preoperative embolization for hemangioblastoma.

In JR-NET3, liquid materials, such as NBCA and Onyx (Medtronic, Minneapolis, MN, USA), were used in 40.6%. Onyx was approved for embolization of brain arterio-venous malformation in 2008. Since then, liquid embolic materials have been gradually used for intracranial embolization. Although the use of Onyx and NBCA for the purpose of intracranial tumor embolization are not covered by insurance in Japan, one of the reasons for increasing use of liquid materials is that meningiomas are relatively easier target to have experience with liquid material rather than arteriovenous malformations or fistulas. Compared to coils and particles, the use of liquid materials requires experience and expertise to handle them. Although penetration into tumor vasculature decreases intraoperative blood loss,[26] hemorrhage may be more common after glue than particle embolization, secondary to reflux or distal embolization into physiologically important draining veins.[13] From the results of the present study, use of liquid embolic materials was not recommended for the preoperative embolization routinely. Endovascular neurosurgeons should consider the balance between the risks and benefits of embolization especially when targeting vessels were other than the ECA.

Study limitations

The present study has some limitations. First, this study is limited by its retrospective registry study. Second, this study did not include data on the size and location of tumors. The location and size of tumors could be risk factors of complications of embolization. Third, the primary end point might be affected by not only embolization itself but also by surgery, especially in skull base meningioma which seemed to be surgically difficult to treat. Fourth, this study lacked more detail information about embolic material. For example, particle materials may include both polyvinyl alcohol and trisacryl gelatin microspheres. Bendszus et al.[27] reported the difference between these two types of particles. Similarly, NBCA and Onyx, which were used in the present study as liquid materials, have a different characteristic. Fifth, this study lacked information on surgical resection. The embolization of tumors is usually performed preoperatively to reduce intraoperative bleeding and operative difficulty in hypervascular tumor surgery. Unfortunately, in the present study, we could not estimate a real efficacy of preoperative embolization.

Conclusion

In JR-NET3, the primary end point (mRS score 0–2 at 30 days after procedure) was 89.5%, and the procedure-related complication rate was 3.7%. Target vessels other than ECA and use of liquid embolic material were significantly associated with the development of complications.

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Conflicts of Interest Disclosure

The authors declare that they have no conflicts of interest.

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