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Special Theme Topic: Japanese Surveillance of Neuroendovascular Therapy in JR-NET/JR-NET2—Part I

Recent Trends in Neuroendovascular Therapy in Japan: Analysis of a Nationwide Survey—Japanese Registry of Neuroendovascular Therapy (JR-NET) 1 and 2

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Abstract

The present study retrospectively analyzed the database of the Japanese Registry of Neuroendovascular Therapy 1 and 2 (JR-NET1&2) to determine annual trends, including adverse events and clinical outcomes at 30 days after undergoing neuroendovascular therapy. JR-NET1&2 are surveys that targeted all patients in Japan who underwent neuroendovascular therapy delivered by physicians certified by the Japanese Society of Neuroendovascular Therapy (JSNET) between 2005 and 2009. Medical information about the patients was anonymized and retrospectively registered via a website. Data from 32,608 patients were analyzed. The number of treated patients constantly increased from 5,040 in 2005 to 7,406 in 2009 and the rate of octogenarians increased from 7.0% in 2005 to 10.4% in 2009. The proportion of procedures remained relatively constant, but ratios of angioplasty slightly increased from 32.8% in 2005 to 33.7% in 2009. Procedural complications were associated more frequently with acute stroke (9.6%), ruptured aneurysms (7.4%), intracranial artery disease (ICAD) (5.4%), and arteriovenous malformation (AVM, 5.2%). The number of patients requiring neuroendovascular treatment in Japan is increasing and the outcomes of such therapy are clinically acceptable. Details of each type of treatment will be investigated in sub-analyses of the database.

Key words: nationwide survey, endovascular treatment, cerebral aneurysm, angioplasty, clinical outcome

Introduction

Neuroendovascular therapy is a less invasive method of treating various cerebrovascular diseases such as cerebral aneurysm, supra-aortic artery stenosis/occlusion, arteriovenous shunts, and acute stroke[1–8] that has become increasingly popular. However, the current status of this therapy including numbers of procedures, clinical outcomes, and adverse events remain unknown.[9,10]

The Japanese Society of Neuroendovascular Therapy (JSNET) established a board certification system in 2000 that certified physicians with ≥ 200 primary operator experiences, ≥ 10 presentations at medical meetings, and ≥ 3 publications as primary author as senior trainers and specialists through a board examination. The JSNET produced an expert consensus document in 2009 when a systematic review revealed a scarcity of high-quality clinical evidence in this field, especially in Japan. Thus, the society implemented retrospective studies (Japanese Registry of Neuroendovascular Therapy 1 and 2; JR-NET1&2) to clarify the general status of neuroendovascular therapy delivered by JSNET-certified physicians. Clinical and procedural data were retrospectively collected from January 2005 through December 2007 (JR-NET1) and from January 2008 through December 2009 (JR-NET2).

These studies aimed to determine annual changes in neuroendovascular treatment modalities and in major adverse events within 30 days thereafter.

Methods

I. Study design

JR-NET1 (2005–2006): This was the first nationwide survey of neuroendovascular treatments in Japan. The registry targeted all patients treated by JSNET board-certified physicians between January 2005 and December 2006, except for those whom their physicians judged unsuitable for this registry. Medical information about the patients was anonymized and retrospectively registered via a website (https://jr-net.tri-kobe.net/jr-net/).

JR-NET2 (2007–2009): This second nationwide survey of neuroendovascular treatment in Japan targeted all patients treated by JSNET board-certified physicians between January 2007 and December 2009. Medical information of the patients was anonymized and registered as described above.

Data were collected at the Translational Research Informatics Center (TRI, http://www.tri-kobe.org/). The study protocol, which is summarized briefly here, is available on line with the full text of this article (https://jr-net.tri-kobe.net/jr-net/). All members of the writing committee assumed responsibility for the accuracy and completeness of the data and for the fidelity of the study with regard to the protocol.

II. Patients

All patients treated by neuroendovascular treatment at participating centers during the study period were basically enrolled in the study. The local institutional review boards at each institution approved the study protocol before the investigators proceeded with the study.

III. Primary and secondary endpoints

The primary endpoint was activities of daily life (ADL) determined according to modified Rankin scale (mRS) scores. The secondary endpoints comprised the technical success of procedures and major adverse events (MAEs) that occurred within and at 30 days after procedures.

A score of 0 on the mRS indicates no disability, whereas scores of 1 or 2 indicate slight disability (some help required with ADL but basically independent), scores of 3 to 5 indicate moderate disability (some help required with ADL) to severe disability (bedridden or constant specific care required), and a score of 6 indicates death.

Adverse events were classified as minor and major when mRS scores deteriorated by 1 and ≥2 points, respectively.

IV. Statistical analysis

Data were statistically analyzed using JMP 7 software (SAS Institute, Cary, North Carolina, USA). The statistical significance of intergroup differences was assessed using the *t*-test for quantitative scales, Pearson's χ^2 test; $p < 0.05$ was considered significant.

Results

I. Backgrounds and characteristics of patients

A total of 32,068 patients (mean age, 63.5 ± 13.9

Table 1 Annual trends of JR-NET data

	2005	2006	2007	2008	2009	Total
Total number	n = 5,040	n = 6,174	n = 6,690	n = 6,758	n = 7,406	n = 32,068
Age	64.0+/−13.8	63.4+/−12.9	64.1+/−13.7	64.6+/−13.3	64.4+/−13.8	63.5+/−13.9
Female	2,341 (46.4%)	2,921 (47.3%)	3,109 (46.5%)	3,131 (46.3%)	3,495 (47.2%)	14,997 (46.8%)
mRS before treatment	0.7	0.7	0.7	0.6	0.6	0.7
Procedures	n = 4,500	n = 5,457	n = 6,466	n = 6,503	n = 7,232	n = 30,158
Aneurysm treatment	1,777 (39.5%)	2,396 (43.9%)	2,725 (42.1%)	2,668 (41.0%)	3,112 (43.0%)	12,678 (40.5%)
Dome embolization, ruptured	751 (16.7%)	963 (17.7%)	1,073 (16.6%)	1,091 (16.8%)	1,254 (17.3%)	5,132 (17.0%)
Dome embolization, unruptured	883 (19.6%)	1,105 (20.3%)	1,373 (21.2%)	1,302 (20.0%)	1,597 (22.1%)	6,260 (20.8%)
Dissection/parent artery occlusion	143 (3.2%)	328 (6.0%)	279 (4.3%)	275 (4.2%)	261 (3.6%)	1,439 (4.8%)
Angioplasty/stenting	1,476 (32.8%)	1,734 (31.2%)	2,275 (35.2%)	2,363 (36.3%)	2,438 (33.7%)	10,286 (34.1%)
Carotid artery	1,042 (23.2%)	1,281 (23.5%)	1,717 (26.6%)	1,855 (28.5%)	1,926 (26.6%)	7,821 (25.9%)
Vertebral/subclavian artery	203 (4.5%)	230 (4.2%)	281 (4.4%)	282 (4.3%)	254 (3.5%)	1,250 (4.1%)
Intracranial artery	231 (5.1%)	223 (4.1%)	277 (4.3%)	226 (3.5%)	258 (3.6%)	1,215 (4.0%)
Brain & spinal AVM embolization	217 (4.8%)	281 (5.1%)	204 (3.2%)	213 (3.3%)	259 (3.6%)	1,174 (3.9%)
DAVF embolization	317 (7.0%)	424 (7.8%)	468 (7.2%)	464 (7.1%)	525 (7.3%)	2,198 (7.3%)
Tumor embolization	347 (7.7%)	373 (6.8%)	317 (4.9%)	319 (4.9%)	382 (5.3%)	1,738 (5.8%)
Acute stroke treatment	366 (8.1%)	249 (4.6%)	277 (4.3%)	266 (4.1%)	281 (3.9%)	1,439 (4.8%)
Physicians in charge	n = 4,935	n = 5,988	n = 6,690	n = 6,758	n = 7,406	n = 31,777
Senior trainer, board certified	3,139 (63.6%)	3,573 (59.7%)	3,097 (46.3%)	3,277 (48.5%)	3,624 (48.9%)	16,710 (52.6%)
Specialist, board certified	1,355 (27.5%)	1,801 (30.1%)	3,103 (46.4%)	3,044 (45.0%)	3,358 (45.3%)	12,661 (39.8%)
Non-specialist	438 (8.9%)	617 (10.3%)	462 (6.9%)	375 (5.5%)	405 (5.5%)	2,297 (7.2%)

AVM: arteriovenous malformation, DAVF: dural arteriovenous fistula, mRS: modified Rankin Scale.

years; female, 46.8%) were registered in this study (Table 1), which involved 200 and 256 board-certified physicians at 122 and 150 centers in JR-NET[11] and in JR-NET2, respectively (Appendix). Figure 1 shows the proportions of treated patients within various age groups. Although patients aged between 40 years and 70 years were the main recipients of treatment, the rate of octogenarians increased annually from 7.0% in 2005 to 10.4% in 2009 ($p < 0.001$). In contrast, the ratio of younger patients (< 40 years) remained constant ($p = 0.361$; Fig. 1).

II. Procedures

Among a total of 32,068 neuroendovascular procedures implemented between 2005 and 2009, angioplasty and treatment for aneurysms accounted for 34.1% and 40.5%, respectively. Embolization of brain and spinal arteriovenous malformations (AVMs), dural arteriovenous fistulae (dAVF), tumors, and treatment for acute stroke accounted for 3.9%, 7.3%, 5.8%, and 4.8% of procedures, respectively. Carotid artery stenting (CAS) accounted for 25.9% of all procedures (Table 1). The proportions of treatments remained relatively constant, except for CAS, which slightly increased from 23.2% in 2005 to 26.6% in 2009 ($p < 0.001$; Fig. 2).

Elective or emergency procedures: The total numbers of elective and emergency procedures increased annually, but the rate of emergency treatment remained relatively constant between 28% and 30% throughout the study period (Fig. 3).

Physicians in charge: Senior trainers certified by JSNET were in charge of 63.6% and 48.9% of procedures during 2005 and in 2009 (Table 1), respectively. The total number of treatment procedures with JSNET senior trainers and specialists in charge increased annually, but the rate of procedures supervised by JSNET senior trainers gradually decreased, although the difference did not reach significance. However, treatment delivered with JSNET non-specialist in charge decreased from 8.9% in 2005 to 5.5% in 2009 ($p = 0.029$).

mRS scores before and after treatment: Figure 4A and 4B shows the overall proportions of mRS scores before and after treatment. Before treatment, ≥90% of patients were in relatively good condition, with mRS scores of 0–2 (Fig. 4A). At 30 days after undergoing procedures, >80% of patients maintained mRS scores of 0–2 (Fig. 4B).

mRS scores after each type of procedure: Figure 5 shows the outcomes of each type of treatment

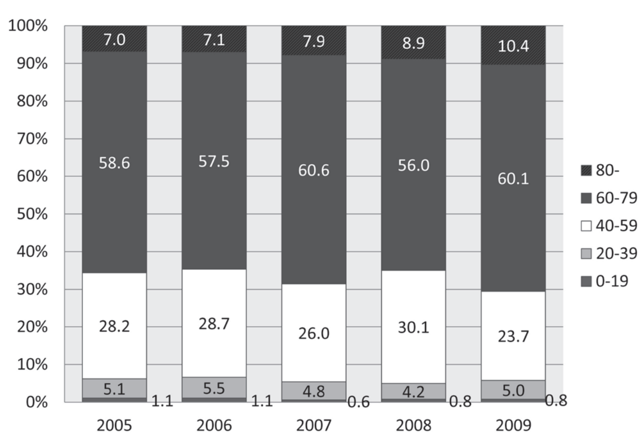

Fig. 1 Annual changes in patients' age during JR-NET1&2. Rates of octogenarians increased annually from 7.0% in 2005 to 10.4% in 2009 ($p < 0.001$), whereas the ratio of younger patients (< 40 years) remained constant ($p = 0.361$). JR-NET1&2: Japanese Registry of Neuroendovascular Therapy 1 and 2.

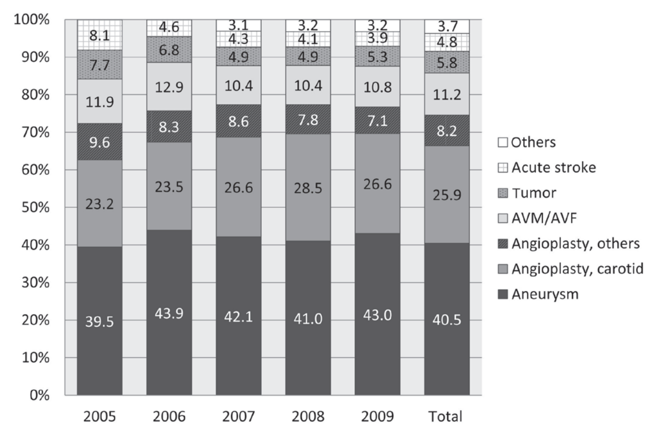

Fig. 2 Annual changes in the types of procedures. The proportion of treatments remained relatively constant, but carotid artery stenting (CAS) slightly increased from 23.2% in 2005 to 26.6% in 2009 ($p < 0.001$).

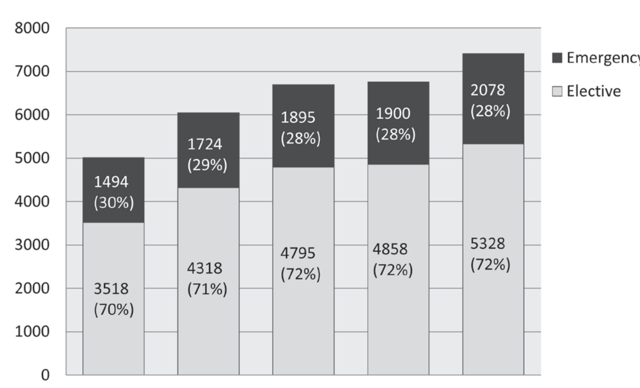

Fig. 3 Number of elective and emergency procedures. The total numbers of elective and emergency procedures increased annually, although the overall rate of emergency treatment remained between 28% and 30% throughout the period.

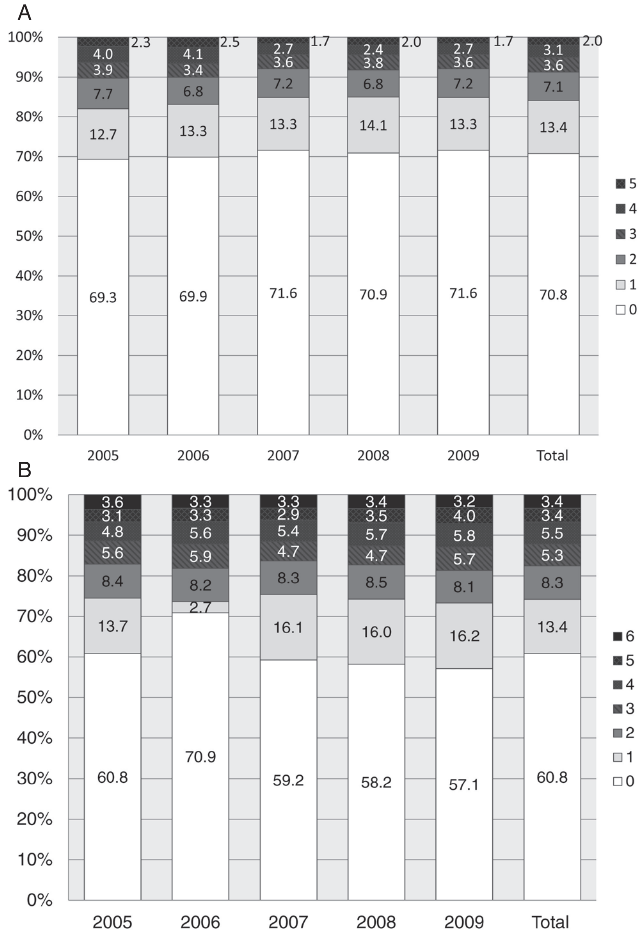

Fig. 4 Proportions of modified Rankin scale (mRS) scores before and after procedures. Ratio of patients with mRS 0–2 was ≥90% before therapeutic procedures (A), decreased at 30 days thereafter (B), but remained >80%.

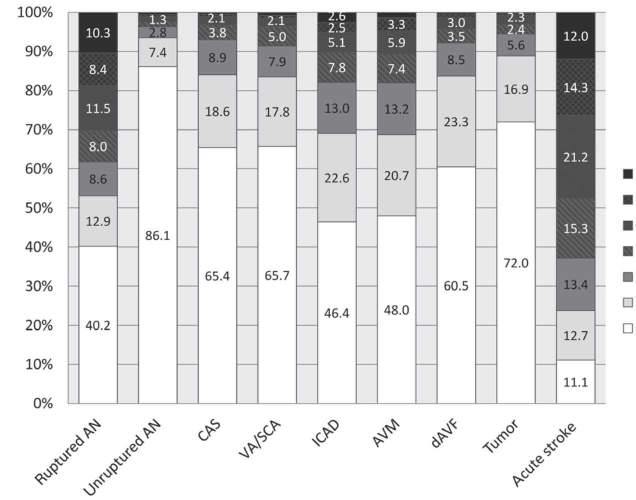

Fig. 5 Proportions of modified Rankin scale (mRS) scores at 30 days after various procedures. Outcomes were favorable (mRS 0–2) for 61.7% and 96.3% of patients with ruptured and unruptured aneurysms respectively. Ratios of favorable outcomes of carotid artery stenting (CAS), vertebral artery (VA)/SCA (subclavian artery), dural arteriovenous fistula (dAVF), and tumor embolization were >90%. On the other hand, the ratios of favorable outcomes were 82.0%, 81.9%, and only 37.2% in intracranial artery disease (ICAD), arteriovenous malformation (AVM) and acute stroke, respectively.

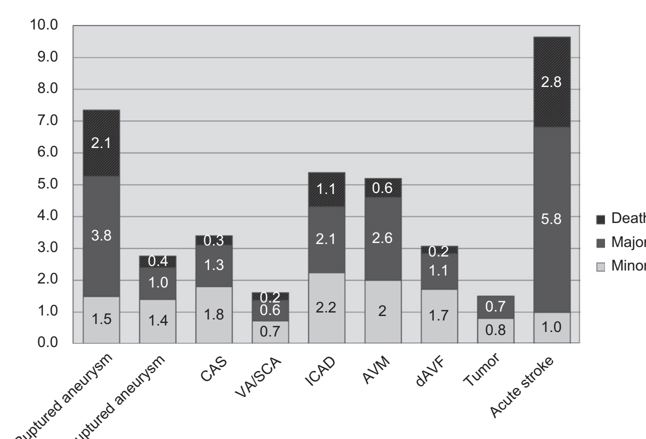

Fig. 6 Complications associated with each procedure. Complication rates were higher after procedures for ruptured aneurysm (7.4%) and acute stroke (9.5%), but less frequent for those that treated unruptured aneurysms (2.8%), VA/SCA (1.5%), and tumor embolization (1.5%).

according to mRS scores. Outcomes were favorable for 61.7% and 96.3% of patients with ruptured and unruptured aneurysms, respectively, (mRS 0–2) and for ≥90% those after CAS, VA/SCA, dAVF, and tumors. On the other hand, 82.0%, 81.9%, and 37.2% of those treated for intracranial artery disease (ICAD), in AVM, and acute stroke had favorable outcomes.

Procedural complications of each treatment: Figure 6 shows the frequency of procedural complications after each type of treatment. Death, major and minor procedural complications occurred in 7.4% and 2.8% of patients treated for ruptured and unruptured aneurysms, respectively. Among angioplasties, procedural complications occurred in 3.4%, 1.5%, and 5.4% in the carotid artery, the VA/SCA and in ICAD, respectively. Among arteriovenous shunt diseases, complications developed in 5.2% and 3.0% of those treated for AVM and dAVF, respectively. The rate of complications of tumor embolization was 1.5%, and none of the patients died of procedure-related complications. On the other hand, complications developed at a rate of 9.6% in patients treated for acute stroke, including 2.8% who died.

Discussion

The present study investigated recent trends in neuroendovascular therapy through analyses of 32,608 patients registered in the nationwide JR-NET1&2 surveys. The number of procedures constantly increased from 5,040 in 2005 to 7,406 in 2009, and the rate of octogenarians increased annually from 7.0% in 2005 to 10.4% in 2009. The proportion of treatments remained relatively constant, but angioplasty/stenting for carotid diseases slightly increased from 23.2% in 2005 to 26.6% in 2009. More procedural complications were associated with acute stroke (9.5%), ruptured aneurysm (7.4%), ICAD (5.4%), and AVM (5.2%).

The number of annual neuroendovascular procedures increased by 46.9% (from 5,040 to 7,406). The annual numbers of procedures required to treat intracranial aneurysms and angioplasty/stenting for atherosclerotic disease between 2005 and 2009 increased by 75.1% (from 1,777 to 3,112) and 65.2% (1,476 to 2,438), respectively. The mRS scores after procedures remained favorable in >80% of the patients each year. Clinical outcomes and complication rates significantly differed among procedures. Rates of favorable outcomes of procedures to treat ruptured aneurysms and acute stroke were around 60% and < 40%, respectively, and more procedural complications were also associated with these conditions. However, whether complications were major or minor was sometimes difficult to judge in emergency patients under general anesthesia or sedation, and in patients with poor neurological status. Thus, procedural complications in these two groups might have been over- or underestimated.

Several reports have described nationwide trends in neuroendovascular therapies.[12–19] Some of them are analyses of a national healthcare database in the United States.[12–15,17,20] For example, Huang et al. reported trends in the management of unruptured cerebral aneurysms in the United States.[15] They analyzed the length of hospital stay, in-hospital mortality rates, the number of hospitalizations, and total national charges related to inpatient treatment. Their findings provide valuable information regarding trends, but obtaining clinical data about neurological status, neuroendovascular procedures, and follow-up results might be difficult. Detailed evaluations and analyses could be achieved if areas or centers were selected. Higashida et al. described endovascular treatment for unruptured intracranial aneurysms in 18 of 47 states in the United Staes during 2007.[21] Qureshi et al. described how class I evidence (ISAT) from a nationwide impact survey impacted clinical practice. Their database was derived from stratified sampling at 20% of US hospitals.[20] In that regard, data from the nationwide JR-NET1&2 surveys are valuable because the study collected precise information regarding not only patient's characteristics, but also neurological status, types of treatment, devices, complications, and follow-up at 30 days after procedures.

This study has some limitations. Although JR-NET 1&2 provided a robust amount of patient information including clinical details, particularly information related to neuroendovascular therapies, it covered only about 35% of all procedures performed in Japan, which was calculated according to annual reports of training facilities of the Japan neurosurgical society (unpublished). This was a significant drawback in terms of avoiding selection bias. This shortcoming might be improved in a new nationwide survey (JR-NET 3), which is collecting information between 2010 and 2013 in a similar setting to that of JR-NET 1&2.

Conclusion

Data from this study suggest an increasing trend towards neuroendovascular treatment in Japan. The rate of neuroendovascular intervention is increasing annually and clinical outcomes seem acceptable. Details about each treatment or disease will be assessed in sub-analyses of this database.

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Conflicts of Interest Disclosure

All authors who are members of The Japan Neurosurgical Society (JNS) have registered self-reported COI disclosure statements through the website for JNS members.

This manuscript has not been published or presented elsewhere in part or in entirety, and is not under consideration by another journal.

Appendix

Participants, their hospitals, and the number of registered patients in JR-NET2 are listed when >100 patients were registered; names of investigators are listed when < 100 patients were registered. This information has already been reported for JR-NET1.[11]

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