

Hiroo Yamaga,^{1,2,†} Yusuke Tsuboko,^{3,4,†} Tomoaki Terada,² and Kiyotaka Iwasaki^{1,3,4,5,6}

Objective: To facilitate understanding for the safe use of the Wingspan stent, a comprehensive literature analysis was conducted, and incidence rates of 30-day stroke or death before and after the Stenting versus Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) trial were compared. We also investigated the associations between 30-day stroke or death rate and four lesion vessels, the internal carotid artery (ICA), middle cerebral artery (MCA), basilar artery (BA), and vertebral artery (VA).

Methods: We searched MEDLINE, Embase, Web of Science, and Cochrane Library databases. The incidence rates of 30-day stroke or death in pre- and post-SAMMPRIS were compared using forest plots and funnel plots.

Results: Thirty studies (15 before and 15 after the SAMMPRIS) were identified, comprising 2071 patients. Post-SAMMPRIS studies showed lower incidence rates of 30-day stroke or death compared to the pre-SAMMPRIS studies (8.5% vs. 5.6\%, p = 0.014). The odds ratio of 30-day stroke or death of the post-SAMMPRIS group compared to that of the pre-SAMMPRIS group was 0.64 (95% confidence interval: 0.45–0.92, p = 0.014). The average 30-day stroke or death rates of overall, pre-, and post-SAMMPIS studies were 1.1%, 1.1%, and 1.1% for ICA; 6.2%, 8.8%, and 5.3% for MCA; 0.9%, 6.0%, and 2.7% for VA; and 13.5%, 15.1%, and 12.5% for BA, respectively. The post-SAMMPRIS group did (p = 0.003 and p = 0.006, respectively). The incidence rates of ischemic and hemorrhagic stroke were 3.5% and 2.0%, respectively.

Conclusion: This systematic surveillance study indicated that the modification of the indications for use based on the results of the SAMMPRIS trial for the Wingspan stent was effective in reducing 30-day stroke or death.

Keywords > percutaneous transluminal angioplasty, intracranial stent, cerebral infarction, stroke, Wingspan stent system

Introduction

The Wingspan stent system (Stryker, Kalamazoo, MI, USA) is a self-expandable stent used for intracranial atherosclerotic stenosis in the US, EU, and Japan. The Wingspan stent was approved in 2005 in the US based on

the clinical trial data of Humanitarian Device Exemption¹⁾ and obtained CE marking certification in the EU in 2005. The US and EU studies^{1–4)} reported the efficacy for intracranial atherosclerotic stenosis. However, the Stenting versus Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis

¹Cooperative Major in Advanced Biomedical Sciences, Joint Graduate School of Tokyo Women's Medical University and Waseda University, Waseda University, Tokyo, Japan

²Department of Neurosurgery, Showa University Northern Yokohama Hospital, Yokohama, Kanagawa, Japan

³Waseda Research Institute for Science and Engineering, Waseda University, Tokyo, Japan

⁴Institute for Medical Regulatory Science, Comprehensive Research Organization, Waseda University, Tokyo, Japan

⁵Department of Integrative Bioscience and Biomedical Engineering, Graduate School of Advanced Science and Engineering, Waseda University, Tokyo, Japan

⁶Department of Modern Mechanical Engineering, School of

Creative Science and Engineering, Waseda University, Tokyo, Japan

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Corresponding author: Kiyotaka Iwasaki. Cooperative Major in Advanced Biomedical Sciences, Joint Graduate School of Tokyo Women's Medical University and Waseda University, Waseda University, 2-2, Wakamatsucho, Shinjuku-ku, Tokyo 162-8480, Japan Email: iwasaki@waseda.jp

[†]These two authors equally contributed to this work.



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(SAMMPRIS) trial in 2011 indicated that percutaneous transluminal angioplasty and stenting (PTAS) treatment with the device was inferior to aggressive medical treatment.⁵⁻⁸⁾ Based on this post-marketing clinical research and outcome, the safety information and indications for use (IFU) were drastically modified in August 2012 in the US and EU. In Japan, the clinical trial of the Wingspan stent commenced in 2009, and the device was approved in 2013.^{9,10)}

The SAMMPRIS trial denied the efficacy of PTAS compared to aggressive medical therapy. However, few treatment options, including percutaneous transluminal angioplasty (PTA) and cerebral artery bypass surgery, are available in cases of recurrent cerebral infarction with symptomatic drug-resistant stenosis. Since PTA is associated with dissection, recoil, and restenosis risks, and the outcome of bypass surgery depends on the lesion location, there is a pressing need for the intracranial stent. Considering that Asian people have a higher prevalence of intracranial atherosclerotic stenosis than Western people,^{11–13)} and concerning the poor clinical outcomes of treatmentresistant lesions,^{14–18)} there are unmet needs for the intracranial stent. Besides, a recent post-market surveillance study of the Wingspan stent system (WEAVE trial) showed that stenting of intracranial artery stenosis is considered effective when used by experienced surgeons with strict adherence to the indications.19)

To facilitate the safe and proper use of the intracranial stent, a comprehensive literature analysis of the Wingspan stent was conducted, and incidence rates of 30-day stroke or death before and after the SAMMPRIS trial were compared. Moreover, we investigated the associations between 30-day stroke or death rate and four target vessels, the internal carotid artery (ICA), middle cerebral artery (MCA), basilar artery (BA), and vertebral artery (VA).

Materials and Methods

Literature search and study selection

The literature search was performed for English articles published before March 2021 using PubMed (MEDLINE), Web of Science, Embase, and Cochrane Library. Two individuals performed the search. The search keywords were "Wingspan," "intracranial stent," "stenosis," and "stenotic" in article titles and abstracts. After removing duplicate records, all the abstracts were screened. The inclusion criteria were studies of the Wingspan stent treating intracranial artery stenosis and reporting a 30-day stroke or death rate. Studies without reporting the number of treatments and 30-day stroke or deaths for each target vessel, studies without a focus on treatments, and those including transient ischemic attack patients were excluded. Case studies with fewer than five subjects, conference abstracts, reviews, meta-analyses, and systematic reviews were excluded. The studies selected were independently assessed, and any disagreement was resolved by consensus. This study used information on the treatment outcomes of intracranial stenting from previously published articles, and no ethics approval by the institutional review board was required.

The incidence rate of overall 30-day stroke or death was defined as a primary assessment parameter. The 30-day stroke or death rate for each ICA, MCA, BA, and VA, and the type of stroke (ischemic or hemorrhagic) were defined as secondary parameters.

Forest plots and funnel plots

The incidence rates of a 30-day stroke or death of the Wingspan stents were compared using forest plots and funnel plots.^{20–22)} Using funnel plots, it becomes possible to compare the events observed among different studies and different sample sizes. Based on the rate of Wingspan stent use and 30-day stroke or death rate in each study, event rates were calculated.

Statistical analysis

All data were processed using statistical software R (Version 3.5.2; The R Foundation, Indianapolis, IN, USA), and Microsoft Excel was used to generate funnel and forest plots. The 95% limit lines were derived from the means and standard deviations of the data. Event rates above the control limits for risk were deemed to be outliers. The chi-squared test was used to compare the pre- and post-SAMMPRIS event rates. For one-sided tests, a p-value less than 0.05 was regarded as significant.

Results

Data included for the quantitative analysis

The schematic diagram of the screening process is shown in **Fig. 1**. After screening, 30 studies^{S1–8,S10–12,S14–17,S21,S24–28,S31–35, S38–42,S44–49} comprising 2071 patients were included from the initial 4219 studies. **Table 1** provides the studies included in this analysis, and **Supplementary List 1** provides detailed information of the 30 studies included. The



Fig. 1 Literature search and study selection process in the systematic analysis

breakdown of 30 studies was as follows: 15 studies comprising 661 patients published before the SAMMPRIS trial and 15 studies comprising 1410 patients published after the SAMMPRIS trial. The number and percentage for target vessels were 182 (8.8%) for ICA, 1,148 (55.4%) for MCA, 343 (16.6%) for VA, and 396 (19.1%) for BA. After the SAMMPRIS trial, the papers from the EU and the US decreased, and those from Asian countries increased.

Forest plot and funnel plot

The 30-day stroke or death rate before and after the SAMMPRIS trial was compared. Based on the relation between the rate of Wingspan use and the 30-day stroke or death rate, the 30-day stroke or death rate of 30 studies was calculated and shown by forest and funnel plots (**Figs. 2** and **3**). Each point on the funnel plots represents one of the studies. The x-axis represents the number of Wingspan stents used, and the y-axis denotes the calculated 30-day stroke or death rate. Two pre-SAMMPRIS studies^{S6,S14} and one post-SAMMPRIS study^{S28} exceeded the 95% control limits. Post-SAMMPRIS studies showed lower event rates despite the high frequency of Wingspan use.

We assessed the 30-day stroke or death rate for four target vessels. **Table 2** shows the total and each vessel's 30-day stroke or death rates. The average 30-day stroke or death rates of overall, pre-, and post-SAMMPIS studies were 1.1%, 1.1%, and 1.1% for ICA; 6.2%, 8.8%, and 5.3% for MCA; 0.9%, 6.0%, and 2.7% for VA; and 13.5%, 15.1%, and 12.5% for BA (**Table 3**). The post-SAMMPRIS study group showed significantly lower event rates for the treatment of MCA and VA than the pre-SAMMPRIS group did. (p = 0.003 and p = 0.006, respectively).

Figure 4 shows the 30-day stroke or death rates for each target vessel. All post-SAMMPRIS studies were distributed within the 95% limit, whereas three studies that targeted MCA in pre-SAMMPRIS were outliers.

Stroke type

Table 4 indicates the stroke type within 30 days of Wingspan placement in 30 studies comprising 2071 patients. The ischemic and hemorrhagic stroke rates were 3.5% and 2.0%, respectively.

Comparison of 30 days stroke or death rates among the SAMMPRIS, before and after SAMMPRIS studies

In the SAMMPRIS trial (224 cases in total), the complications and severe complications in the stent group were summarized as follows: 40 (17.9%) cases of ischemic cerebral infarction and 12 (5.4%) cases of hemorrhagic infarction were documented as complications, and 11 (4.9%) cases of ischemia and 8 (3.6%) cases of bleeding were documented as severe complications.⁶) Compared with the pre-SAMMPRIS studies, the incidence rates of

-			č		Total Wingspan	Wing	span placemen	ts per target ve	essel
Number	Autnor, year	Hegion	study type	larget vessel	placements	ICA	MCA	VA	BA
S1	Henkes et al., 2005	Germany	Prospective	ICA, MCA, VA, BA	15	3 (20.0%)	3 (20.0%)	4 (26.7%)	5 (33.3%)
S2	Fiorella et al., 2007	SU	Prospective	ICA, MCA, VA, BA	82	32 (41.0%)	22 (28.2%)	14 (17.9%)	14 (17.9%)
S3	Leung et al., 2009	China	Prospective	MCA	24	I	24 (100%)	ı	ı
S4	Zhao et al., 2009	China	Retrospective	MCA, VBA	27	2 (7.4%)	10 (37.0%)	ı	15 (55.6%)
S5	Wolfe et al., 2009	SN	Prospective	ICA, MCA, VA, BA	51	14 (27.5%)	9 (17.6%)	18 (35.3%)	8 (15.7%)
S6	Lanfranconi et al., 2010	Italy	Prospective/Retrospective	ICA, MCA, BA	16	6 (37.5%)	3 (18.8%)	ı	7 (43.8%)
S7	Costalat et al., 2010	France	Retrospective	ICA, MCA, VA, BA	19	2 (10.5%)	7 (36.8%)	3 (15.8%)	7 (36.8%)
S8	Jiang et al., 2010	China	Prospective	VA, BA	43	ı	ı	23 (53.5%)	20 (46.5%)
S9	Yue et al., 2011	China	Retrospective	MCA	28	ı	28 (100%)	ı	ı
S10	Li et al., 2011	China	Prospective	MCA	47	ı	47 (100%)	ı	ı
S11	Guo et al., 2011	China	Retrospective	MCA	52	ı	52 (100%)	ı	ı
S12	Costalat et al., 2011	France	Retrospective	ICA, MCA, VA, BA	52	9 (17.3%)	13 (25.0%)	12 (23.1%)	18 (34.6%)
S13	AI-Ali et al., 2011	SN	Prospective/Retrospective	ICA, MCA, VA, BA	73	11 (15.1%)	35 (47.9%)	8 (11.0%)	19 (26.0%)
S14	Jiang et al., 2011	China	Prospective	ICA, MCA, VA, BA	105	16 (15.2%)	44 (41.9%)	26 (24.8%)	19 (18.1%)
S15	Li et al., 2012	China	Prospective	VA, BA	31	ı	ı	17 (56.7%)	14 (45.2%)
S16	Castaño et al., 2012	Spanish	Retrospective	ICA, MCA, VA, BA	7	1 (14.3%)	3 (42.9%)	2 (28.6%)	1 (14.3%)
S17	Dorn et al., 2012	Germany	Retrospective	ICA, MCA, VA, BA	15	7 (46.7%)	1 (6.7%)	2 (13.3%)	5 (33.3%)
S18	Zhang et al., 2012	China	Retrospective	ICA, MCA, VBA	53	2 (3.8%)	43 (81.1%)	ı	8 (15.1%)
S19	Qureshi et al., 2013	SN	Prospective	ICA, MCA, VA, BA	ω	2 (25.0%)	3 (37.5%)	1 (12.5%)	2 (25.0%)
S20	Gandini et al., 2013	Italy	Prospective	MCA, VA	21	ı	19 (90.5%)	·	2 (9.5%)
S21	Park et al., 2013	Korea	Retrospective	MCA, VA, BA	21	ı	17 (80.1%)	3 (14.3%)	1 (4.8%)
S22	Zhang et al., 2013	China	Retrospective	ICA, MCA, VBA	60	ı	60 (100%)	ı	ı
S23	Zaidat et al., 2014	SN	Retrospective	MCA	5	I	1 (20.0%)	ı	I
S24	Wang et al., 2015	China	Prospective	VA	88	ı	ı	88 (100%)	ı
S25	Li et al., 2015	China	Prospective	ICA, MCA, VA, BA	433	58 (18.4%)	196 (45.3%)	88 (20.3%)	91 (21.0%)
S26	Liu et al., 2016	China	Prospective	VA, BA	38	I	ı	16 (42.1%)	22 (57.9%)
S27	Bai et al., 2016	China	Prospective	BA	91	I	ı	ı	91 (100%)
S28	Gao et al., 2016	China	Prospective	ICA, MCA, VA, BA	100	17 (17.0%)	38 (38.0%)	18 (18.0%)	27 (27.0%)
S29	Wang et al., 2016	China	Retrospective	MCA	192	I	192 (100%)	I	I
S30	Zhao et al., 2016	China	Prospective	MCA	278	ı	278 (100%)	ı	ı
BA: basilar art	ery; ICA: internal carotid artery	; MCA: middle o	arebral artery; VA: vertebral artery						



Fig. 2 Forest plots showing the 30-day stroke or death rates of 30 studies using Wingspan stents. PTAS: percutaneous transluminal angioplasty and stenting; SAMMPRIS: Stenting versus Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis



Fig. 3 Funnel plots showing the 30-day stroke or death rates of 30 studies using Wingspan stents. CI: confidence interval; PTAS: percutaneous transluminal angioplasty and stenting; SAMMPRIS: Stenting versus Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis

30-day stroke or death decreased after the SAMMPRIS trial (8.5% vs. 5.6%, p = 0.014). In **Fig. 5**, the odds ratio of 30-day stroke or death of the post-SAMMPRIS group compared to that of the pre-SAMMPRIS group was 0.64 (95% confidence interval: 0.45–0.92, p = 0.014).

Discussion

Our results elucidated that the post-SAMMPRIS studies showed lower incidence rates of 30-day stroke or death compared to the pre-SAMMPRIS studies. The

Number	Author, vear	Total 30-day stroke or death	30-day stroke or death for each vessel (rate %)			
T Carrison	, lation, your	(rate %)	ICA	MCA	VA	BA
S1	Henkes et al., 2005	0/15 (0%)	0/3 (0%)	0/3 (0%)	0/4 (0%)	0/5 (0%)
S2	Fiorella et al., 2007	5/78 (6.4%)	0/32 (0%)	2/22 (9.1%)	0/14 (0%)	3/14 (21.4%)
S3	Leung et al., 2009	0/24 (0%)	-	0/24 (0%)	-	-
S4	Zhao et al., 2009	0/27 (0%)	0/2 (0%)	0/10 (0%)	-	0/15 (0%)
S5	Wolfe et al., 2009	4/51 (7.8%)	0/14 (0%)	1/9 (11.1%)	0/10 (0%)	3/8 (37.5%)
S6	Lanfranconi et al., 2010	3/16 (18.8%)	0/6 (0%)	2/3 (66.7%)	-	1/7 (14.3%)
S7	Costalat et al., 2010	4/19 (21.1%)	0/2 (0%)	2/7 (28.6%)	0/3 (0%)	2/7 (28.6%)
S8	Jiang et al., 2010	3/43 (7.0%).	-	-	1/23 (4.3%)	2/20 (0.1%)
S9	Yue et al., 2011	2/28 (7.1%)	-	2/28 (7.1%)	-	-
S10	Li et al., 2011	3/47 (6.4%)	-	3/47 (6.4%)	-	-
S11	Guo et al., 2011	2/52 (3.8%)	-	2/52 (3.8%)	-	-
S12	Costalat et al., 2011	4/52 (7.7%)	0/9 (0%)	1/13 (7.7%)	1/12 (8.3%)	2/18 (11.1%)
S13	Al-Ali et al., 2011	18/73 (24.7%)	1/11 (9.1%)	10/35 (28.6%)	2/8 (25.0%)	5/19 (26.3%)
S14	Jiang et al., 2011	5/105 (4.8%)	0/16 (0%)	1/44 (2.3%)	2/26 (7.7%)	2/19 (10.5%)
S15	Li et al., 2012	3/31 (9.7%)	-	-	1/17 (5.9%)	2/14 (14.3%)
S16	Castaño et al., 2012	0/7 (0%)	0/1 (0%)	0/3 (0%)	0/2 (0%)	0/1 (0%)
S17	Dorn et al., 2012	2/15 (13.3%)	0/7 (0%)	1/1 (100%)	0/2 (0%)	1/5 (20.0%)
S18	Zhang et al., 2012	0/60 (0%)	0/2 (0%)	0/43 (0%)	-	0/8 (0%)
S19	Qureshi et al., 2013	0/8 (0%)	0/2 (0%)	0/3 (0%)	0/1 (0%)	0/2 (0%)
S20	Gandini et al., 2013	0/21 (0%)	-	0/19 (0%)	0/2 (0%)	-
S21	Park et al., 2013	1/21 (4.8%)	-	1/17 (5.89%)	0/3 (0%)	0/1 (0%)
S22	Zhang et al., 2013	3/60 (5.0%)	-	3/60 (5.0%)	-	-
S23	Zaidat et al., 2014	0/5 (0%)	-	0/1 (0%)	-	-
S24	Wang et al., 2015	1/88 (1.1%)	-	-	1/88 (1.1%)	-
S25	Li et al., 2015	29/433 (6.7%)	1/58 (17.2%)	14/196 (7.1%)	1/88 (1.1%)	13/91 (14.3%)
S26	Liu et al., 2016	2/38 (5.3%)	-	-	0/16 (0%)	2/22 (9.1%)
S27	Bai et al., 2016	13/91 (14.3%)	-	-	-	13/91 (14.3%)
S28	Gao et al., 2016	2/100 (2.0%)	0/17 (0%)	0/38 (0%)	0/18 (0%)	2/27 (7.4%)
S29	Wang et al., 2016	14/192 (7.3%)	-	14/192 (7.3%)	-	-
S30	Zhao et al., 2016	12/278 (4.3%)	-	12/278 (4.3%)	-	-

Table 2 Total and each vessel's 30-day stroke or death

BA: basilar artery; ICA: internal carotid artery; MCA: middle cerebral artery; VA: vertebral artery

Table 3 Average pre-, post-SAMMPRIS, and overall 30-day stroke or death rates

	Pre-SAMMPRIS group (15 studies)	Post-SAMMPRIS group (15 studies)	p-value (Pre vs. Post)
Total 30-day stroke or death (rate %)	56/661 (8.5%)	79/1410 (5.6%)	0.014
30-day stroke or death for each	n vessel (rate %)		
ICA	1/95 (1.1%)	1/87 (1.1%)	0.950
MCA	26/297 (8.8%)	45/851 (5.3%)	0.003
VA	7/117 (6.0%)	2/220 (0.9%)	0.006
BA	22/146 (15.1%)	31/248 (12.5%)	0.502

BA: basilar artery; ICA: internal carotid artery; MCA: middle cerebral artery; SAMMPRIS: Stenting versus Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis; VA: vertebral artery

post-SAMMPRIS study group showed significantly lower event rates for the treatment of MCA and VA than the pre-SAMMPRIS group did. Event rates were low for ICA and VA and high for BA. The incidence rate of ischemic stroke was relatively high compared to that of hemorrhagic stroke (3.5% vs. 2.0%). This study showed that two pre-SAMMPRIS studies and one post-SAMMPRIS study exceeded the 95% control limits. The outlier studies included patients with >50% stenosis or a minimum preoperative antiplatelet duration of 3–5 days. After the SAMMPRIS trial, the indication in the US was revised to patients with a stenosis rate of 70–99%, and patients within





Table 4 Type of stroke among 30 studies

		No. (%)		
	Overall	Pre-SAMMPRIS group	Post-SAMMPRIS group	p-Value (pre vs. post)
Total Wingspan placements	2071	661	1410	-
30-day stroke	115 (5.6%)	36 (5.4%)	79 (5.6%)	0.88
Ischemic stroke	73 (3.5%)	21 (3.2%)	52 (3.7%)	0.55
Hemorrhagic stroke	42 (2.0%)	15 (2.3%)	27 (1.9%)	0.59
30-day death	14 (0.7%)	6 (0.1%)	8 (0.6%)	0.38

SAMMPRIS: Stenting versus Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis





seven days of a current symptomatic stroke were excluded from the indication. It was speculated that dual antiplatelet therapy for more than seven days might have improved the outcomes. As to the vessels treated, three studies that targeted MCA before SAMMPRIS showed higher incidence rates of 30-day stroke or death exceeding the 95% limit. However, no outlier was identified after SAMMPRIS, and the incidence rates of 30-day stroke or death decreased with a larger number of patients. Although the SAMMPRIS did not describe the results by target vessel, the 2-year post-SAMMPRIS study described the incidences by target vessel. For the stent group, the incidences were 29% in ICA, 14.2% in MCA, 21.1% in VA, and 24.5% in BA, and for the medical therapy group, the incidences were 23.2% in ICA, 12.8% in MCA, 9.5% in VA, and 9.9 in BA.7) This study showed that the incidence rates of 30-day stroke or death in MCA lesions decreased in post-SAMMPRIS studies with larger patients in comparison with the SAMMPRIS trial (Table 3). The incidence rates of 30-day stroke or death were numerically comparable between the aggressive medical treatment arm in the SAMMPRIS study and the post-SAMMPRIS group (5.8%⁶⁾ vs. 5.6%). Few studies reported the outcome of the Wingspan stent in ICA lesions. It was speculated that ICA was excluded from the treatment with the Wingspan stent because ICA has a large perfusion area, and complications due to stent implantation are likely to occur. From our study, the average 30-day stroke or death rate for each vessel was 1.1% for ICA, 6.2% for MCA, 2.7% for VA, and 13.5% for BA. Event rates were low for ICA and VA and high for BA. The higher event rate in BA was considered because of the presence of many perforating branches to the pyramidal tract and its relatively small vessel diameter. These findings may contribute to the safe and effective treatment of intracranial atherosclerotic stenosis with the Wingspan stent.

Limitations

First, the influences of device size and lesion morphology on the adverse events could not be investigated because of the lack of information. Second, similar to other statistical methods, funnel plots strongly depend on the assumption of the underlying risk. Assuming the heterogeneity of potential risks due to institutional treatment policy, operator expertise, and patient disease progression may reflect more deviations from control limits than when only treatment outcomes were considered. Preparation of a wellorganized registry may help to analyze the influences of target vessel morphology and device size on the better outcomes of the intracranial stents.

Conclusion

This systematic surveillance study indicated that the modification of the IFU based on the results of the SAMMPRIS trial for the intracranial self-expandable stent was effective in reducing 30-day stroke or death. Moreover, our analysis showed that the incidence rates of 30-day stroke or death for the treatment of MCA and VA were lower in the post-SAMMPRIS study group than in the pre-SAMMPRIS group. Further clinical trials, as well as the development of new dedicated intracranial stents, are warranted to better treatments for patients with intracranial atherosclerotic stenosis.

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Disclosure Statement

The authors have no conflicts of interest for this article.

Supplementary Information

A supplementary file below is available online.

Supplementary List 1

Article information for the 30 included studies.

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