Characteristics and Outcomes of the Real-World Cohort of Patients with Non-Cardioembolic Ischemic Stroke or Transient Ischemic Attack Compatible With the OCEANIC-STROKE Clinical Trial Population in Japan

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Teruyuki Hirano,[1] Ryu Matsuo,[2] Suguru Okami,[3] Coralie Lecomte,[4] Daniela Yucuma,[5] Makiko Takeichi,[3] Tsubasa Tajima,[3] Luke Bamber,[6] Jason Xeni,[7] Kristina Karlsdotter,[8] Mukul Sharma,[9]

[1]Department of Stroke and Cerebrovascular Medicine, Kyorin University School of Medicine, Mitaka, Japan; [2]Department of Health Care Administration and Management, Graduate School of Medical Science, Kyushu University, Fukuoka, Japan; [3]Medical Affairs & Pharmacovigilance, Bayer Yakuhin, Ltd., Osaka, Japan; [4]Science, Aetion, a Datavant Company, New York, New York, USA; [5]Science, Aetion, a Datavant Company, Barcelona, Spain; [6]Health Economics and Outcomes Research, Bayer AG, Wuppertal, Germany; [7]Global Medical and Evidence, Bayer Inc., Mississauga, Ontario, Canada; [8]Global Medical and Evidence, Bayer Hispania, S.L.U., Barcelona, Spain; [9]Department of Medicine, McMaster University, Population Health Research Institute, Hamilton Health Sciences, Hamilton, Ontario, Canada.

Introduction

- Stroke is the second-leading cause of death in Japan[1]; however, data on the risk of secondary stroke have not been fully established in contemporary clinical settings in Japan.[2]
- Despite the use of guideline-recommended antiplatelet therapy (APT), 1-year recurrence rates are ~10% following an initial ischemic stroke (IS), with ~20% of stroke survivors experiencing a secondary stroke within 5 years.[3]
- In the OCEANIC-STROKE study, asundexian (an inhibitor of activated Factor XI) combined with standard APT reduced the risk of IS without increasing International Society on Thrombosis and Haemostasis major bleeding rate compared with placebo plus APT following a non-cardioembolic IS or transient ischemic attack (TIA).[4,5]
- Using data from the ASTRIS Japan study, we aimed to describe the characteristics and outcomes of patients hospitalized for a first-ever non-cardioembolic IS or TIA in real-world settings in Japan who are compatible with the OCEANIC-STROKE study population.

Methods

- ASTRIS Japan is a non-interventional, retrospective cohort study that included adult patients (≥18 years of age) from ≥200 hospitals using a Japanese nationwide hospital database (Real-World Data, Co. Ltd; **Figure 1**).
- By emulating the OCEANIC-STROKE eligibility criteria, a subset of patients were identified who were compatible with the OCEANIC-STROKE study population.
  - Patients using APT after the index event without a prescription record were excluded from the OCEANIC-STROKE-compatible cohort.
- Clinical events were assessed after discharge of the index non-cardioembolic IS or TIA hospitalization. Events that occurred during the hospitalization for index stroke were not considered.

Statistical Analysis

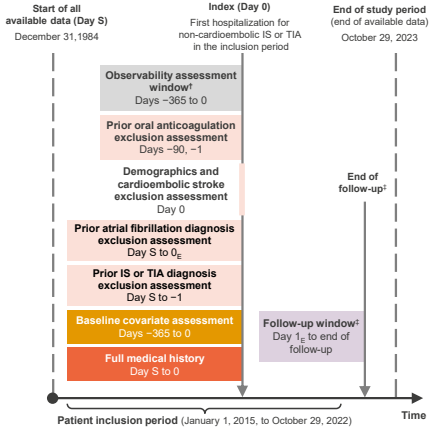
- Descriptive analyses were conducted using summary statistics for continuous and categorical data.

Results

Participants

- In total, 18,719 patients with non-cardioembolic IS or TIA were identified.
  - Of these, 5778 (30.9%) were included in the OCEANIC-STROKE-compatible cohort (**Figure 2**).
- The median (quartile 1, quartile 3) length of follow-up was 520 (66.0, 1245.0) days for the overall cohort and 715 (170.8, 1355.3) days for the OCEANIC-STROKE-compatible cohort.
- Baseline characteristics of the OCEANIC-STROKE-compatible cohort and the OCEANIC-STROKE study population are shown in **Table 1**.

Figure 1. ASTRIS Japan study design



†An observability lookback period of at least 365 days (spanning Days −365 to 0) was assessed before evaluating patient baseline characteristics. ‡Patients were followed until the earliest occurrence of death, end of observability, or end of the study period. All event rates were censored upon the earliest occurrence of IS or death, end of the data collection period (October 29, 2023), or end of the study period. Follow-up time does not consider IS recurrence as a censoring criterion. Additional censoring criteria were applied based on specific analyses.
Day 0_E, discharge from index hospitalization; Day 1_E, 1 day after Day 0_E; Day S, start date of all available data; IS, ischemic stroke; TIA, transient ischemic attack.

Conclusions

- **In this real-world setting, patients from Japan who were compatible with the OCEANIC-STROKE study population had a high risk of IS recurrence following hospital discharge, similar to the overall cohort.**
- **These findings contribute to the growing body of evidence underscoring the need for improved treatment strategies in secondary stroke prevention following non-cardioembolic IS or TIA.**

Figure 2. Flowchart of patients who met emulated OCEANIC-STROKE eligibility criteria

Patients with non-cardioembolic IS or TIA meeting overall cohort criteria	(N=18,719)
Patients with SSI† ≤13.439 per protocol or high-risk TIA	(N=14,845)
Patients with atherosclerosis or non-lacunar infarct	(N=12,525)
Patients on APT after index event and during index hospitalization	(N=9134)
Patients without stroke due to procedure or other causes	(N=8936)
Patients without mRS 4–5 at discharge, known vascular malformation of the brain, or active nontrivial bleeding	(N=6702)
Patients without liver disease, end-stage renal disease, or major surgery	(N=5778)
OCEANIC-STROKE-compatible cohort	**(N=5778)**

Inclusion criteria; Exclusion criteria

†SSI was used as an alternative to the NIHSS.
APT, antiplatelet therapy; IS, ischemic stroke; mRS, modified Rankin scale; NIHSS, National Institutes of Health Stroke Scale; SSI, Stroke Severity Index; TIA, transient ischemic attack.

Table 1. Baseline characteristics of the overall, OCEANIC-STROKE-compatible, and OCEANIC-STROKE study cohorts

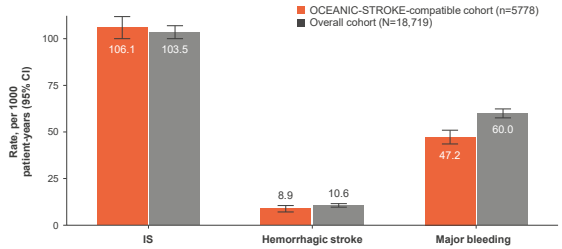
	Overall cohort N=18,719	OCEANIC-STROKE-compatible cohort n=5778	OCEANIC-STROKE study[2] N=12,327†
Demographics			
Age, years			
Mean (SD)	74.6 (12.4)	73.1 (11.9)	67.6 (10.8)
Median (Q1, Q3)	77 (68, 84)	75 (67, 82)	–
Female, n (%)	8307 (44.4)	2181 (37.7)	4111 (33.3)
Current smoker, n (%)	4678 (25.0)	2012 (34.8)	3309 (26.8)
Comorbidities, n (%)			
Hypertension	12,750 (68.1)	4305 (74.5)	9780 (79.3)
Chronic kidney disease	5815 (31.1)	1653 (28.6)	729 (5.9)
Diabetes	5137 (27.4)	1768 (30.6)	4238 (34.4)
Coronary artery disease	4192 (22.4)	1231 (21.3)	1945 (15.8)
Carotid stenosis or previous carotid revascularization	1282 (6.8)	515 (8.9)	–
Dementia	2616 (14.0)	579 (10.0)	–
Dysphagia	2247 (12.0)	541 (9.4)	–
Pre-medication, n (%)			
Antihypertensives	6385 (34.1)	1843 (31.9)	–
Lipid-lowering drugs	3708 (19.8)	1404 (24.3)	–
Statins	3308 (17.7)	1278 (22.1)	–
Anti-diabetic medications	2563 (13.7)	795 (13.8)	–
Index event management, n (%)			
APT initiation within 2 days of admission	8928 (47.7)	4067 (70.4)	–
Argatroban	3420 (18.3)	1664 (28.8)	–
Mechanical thrombectomy	153 (0.8)	41 (0.7)	3199 (27.4)[§]
rt-PA	437 (2.3)	175 (3.0)	–
Intra-artery revascularization	217 (1.2)	52 (0.9)	–
Rehabilitation therapy	9546 (51.0)	4134 (71.5)	–
APT during the index hospitalization, n (%)			
Single APT‡	11,477 (61.3)	4830 (83.6)	4613 (37.4)
Dual APT‡	4428 (23.7)	1991 (34.5)	7714 (62.6)
Triple APT‡	195 (1.0)	82 (1.4)	–

†Includes patients enrolled January 2023–February 2025. Any patients enrolled after this initial cut-off date were not captured in this analysis. ‡Not mutually exclusive. APT includes aspirin, clopidogrel, prasugrel, and cilostazol. §IV thrombolysis and/or endovascular therapy (index IS only).
APT, antiplatelet therapy; IS, ischemic stroke; IV, intravenous; Q, quartile; rt-PA, recombinant tissue-type plasminogen activator; SD, standard deviation.

Clinical Events

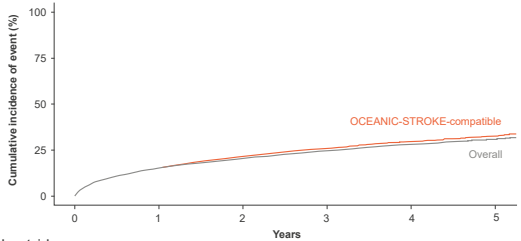
- Compared with the overall cohort, a similar rate of IS and a numerically lower rate of major bleeding were observed in the OCEANIC-STROKE-compatible cohort up to 5 years (**Figure 3**).
- The cumulative incidence of IS was similar between the OCEANIC-STROKE-compatible cohort and the overall cohort over 5 years (**Figure 4**).

Figure 3. Rates of IS, hemorrhagic stroke, and major bleeding events in the overall and OCEANIC-STROKE-compatible cohorts during the follow-up period



CI, confidence interval; IS, ischemic stroke.

Figure 4. Cumulative incidence of IS in the overall and OCEANIC-STROKE-compatible cohorts during the follow-up period



Number at risk						
Overall cohort	18,719	9242	6532	4301	2752	1643
OCEANIC-STROKE-compatible cohort	5778	3228	2318	1508	929	551

IS, ischemic stroke.

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Conflicts of Interest/Disclosures

TH and RM have received honoraria from Bayer. SO, MT, TT, LB, JX, and KK are employees of Bayer and may own shares in the company. CL and DY are employees of Aetion and may own shares in the company. MS has received research funding from, and has consulted for, Bayer.

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