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Original research

Comparative analysis of long term effectiveness of Neuroform Atlas stent versus low profile visualized intraluminal stent/Woven EndoBridge devices in treatment of wide necked intracranial aneurysms

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ABSTRACT

Background We compared the outcomes of wide necked aneurysms (WNA) treated with the Neuroform Atlas with those treated with the low profile visualized intraluminal stent (LVIS) or the Woven EndoBridge (WEB).

Methods Objective, prospectively collected, core laboratory adjudicated data from published trials for the Neuroform Atlas, LVIS, and WEB devices were reviewed. ATLAS (Safety and Effectiveness of the Treatment of Wide Neck, Saccular Intracranial Aneurysms With the Neuroform Atlas Stent System) study patients were included if they met other studies' inclusion criteria. Outcomes included (1) primary effectiveness (complete aneurysmal occlusion without retreatment/>50% parent vessel stenosis), (2) primary safety, (3) complete aneurysmal occlusion, and (4) retreatment rates (outcomes evaluated at the 12 month follow-up). Matching adjusted indirect comparison analysis was used to compare outcomes.

Results Analytical samples included 141 ATLAS subjects meeting WEB-IT (Woven EndoBridge Intrasaccular Therapy Study) criteria (ATLAS/WEB-IT) and 241 meeting LVIS (Pivotal Study of the Low Profile Visualized Intraluminal Support) criteria (ATLAS/LVIS). ATLAS/WEB-IT exhibited significantly higher rates of primary effectiveness and complete occlusion versus WEB (86.6% vs 53.9 %, P<0.0001, and 90.3% vs 53.9%, P<0.0001, respectively). For LVIS, there was no significant differences in primary effectiveness rates between ATLAS and LVIS (84.2% vs 77.7%, respectively, P=0.12). However, ATLAS/LVIS had a significantly higher proportion of patients achieving complete occlusion than LVIS (88.1 vs 79.1, P=0.03). Retreatment rates and primary safety outcomes were not significantly different (P>0.05) for the Atlas versus other devices except for a lower retreatment rate for ATLAS/WEB-IT versus WEB-IT (2.4% vs 9.8%, P=0.01).

Conclusion The Neuroform Atlas provided higher occlusion rates and similar retreatment rates in comparable datasets compared with LVIS and WEB devices when treating WNA.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Wide neck intracranial aneurysms (WNA) continue to pose unique therapeutic challenges to endovascular treatment modalities.
⇒ We provide a comparative analysis of the three recently introduced devices to the US market (Neuroform Atlas stent, Woven Endobridge (WEB) embolization, and low profile visualized intraluminal stent (LVIS)), using prospective trial data which have not been reported before.

WHAT THIS STUDY ADDS

⇒ We found that the Atlas device provided higher occlusion rates and similar retreatment rates in comparable datasets compared with the LVIS and WEB devices when treating WNA.
⇒ Safety events rates were not significantly different between ATLAS/LVIS, and between ATLAS/WEB-IT, with a trend for lower rates in the WEB-IT cohort.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

⇒ This study represents the first comparative analysis of these devices using prospective central core laboratory adjudicated data.
⇒ Future dedicated randomized trials to compare these devices are warranted.

INTRODUCTION

Unruptured, intracranial aneurysms affect approximately 2–4% of the general population.[1 2] Since the introduction of detachable platinum coils almost three decades ago, the need for open surgical clipping of aneurysms has been substantially decreased due to the use of endovascular coil embolization. Up to 22 000 aneurysms are treated via endovascular therapy annually.[3] Wide necked aneurysms (WNA), defined as a neck diameter ≥4.0 mm or dome-to-neck ratio <2.0, present a unique therapeutic challenge and often require an adjunctive device.

The well established stent assisted coiling technique, in which intracranial stents reconstruct the aneurysm neck to facilitate coil packing, has improved the outcome of WNA treatment over standalone coiling.[4 5] The new generation of stents include the eNeuroform Atlas stent system (Stryker Neurovascular) and the low profile visualized intraluminal stent (LVIS) and LVIS Jr devices (Microvention Terumo). Another device specifically designed

Table 1 Baseline patient characteristics

Characteristics	ATLAS subjects who met comparator trial inclusion/exclusion criteria		Comparator trial
	Crude	MAIC weighted	
LVIS			
No of patients	241	184	153
Age (years) (mean (SD))	59.0 (10.3)	58.2 (10.9)	58.3 (10.5)
Aneurysm location (n (%))			
Internal carotid artery	67 (27.8)	52 (28.1)	43 (28.1)
Anterior cerebral artery	49 (20.3)	69 (37.3)	57 (37.3)
Middle cerebral artery	29 (12.0)	20 (11.1)	17 (11.1)
Posterior cerebral artery	2 (0.8)	7 (3.9)	6 (3.9)
Basilar artery	81 (33.6)	32 (17.6)	27 (17.6)
Superior cerebellar artery	3 (1.2)	1 (0.7)	1 (0.7)
Vertebral artery	10 (4.2)	2 (1.3)	2 (1.3)
Index aneurysm prior rupture (n (%))	28 (11.6)	27 (14.4)	22 (14.4)
Neck width (mm) (mean (SD))	4.5 (1.4)	4.2 (1.4)	4.2 (1.4)
Dome height (mm) (mean (SD))	5.9 (2.3)	5.9 (2.4)	6.0 (2.2)
Dome width (mm) (mean (SD))	5.8 (2.2)	5.6 (2.0)	5.5 (2.3)
Index aneurysm dome-to-neck ratio (mean (SD))	1.2 (0.3)	1.3 (0.4)	1.3 (0.4)
WEB-IT			
No of patients	141	109	150
Age (mean (SD))	59.7 (10.4)	59 (10.3)	59.0 (10.2)
Aneurysm location (n (%))			
Anterior communicating artery	47 (33.3)	29/109 (26.7)	40 (26.7)
Basilar apex	67 (47.5)	43/109 (39.3)	59 (39.3)
Internal carotid artery bifurcation/terminus	6 (4.3)	4/109 (4.0)	6 (4.0)
Middle cerebral artery bifurcation	21 (14.9)	33/109 (30.0)	45 (30.0)
Index aneurysm prior rupture (n (%))	17 (12.1)	7/109 (6.0)	9 (6.0)
Index aneurysm size (mm) (mean (SD))	6.0 (1.6)	6.4 (1.6)	6.4 (1.6)
Index aneurysm dome-to-neck ratio (mean (SD))	1.2 (0.3)	1.3 (0.3)	1.3 (0.2)

ATLAS, Safety and Effectiveness of the Treatment of Wide Neck, Saccular Intracranial Aneurysms With the Neuroform Atlas Stent System; LVIS, Pivotal Study of the Low Profile Visualized Intraluminal Support; MAIC, matching adjusted indirect comparison method; WEB-IT, Woven EndoBridge Intrasaccular Therapy Study.

for WNAs is the Woven EndoBridge (WEB) Aneurysm Embolization System (Microvention Terumo), an intrasaccular flow diverter.

Few studies have compared treatment of aneurysms with different devices due to the heterogeneity of trial design, patient selection, and device limitations.[6 7] We present a comparative analysis between the Neuroform Atlas, LVIS, and WEB devices to assess for differences in primary effectiveness, safety, and retreatment rates.

METHODS

Study design

The study was designed to compare objective, prospectively collected, core laboratory adjudicated data in subjects undergoing treatment for WNA with the Neuroform Atlas stent, LVIS, and WEB. The study selection criteria were trials that reported on the primary effectiveness rate of complete (ie, 100%) aneurysmal occlusion without significant (>50%) parent artery stenosis, with central core laboratory adjudicated outcomes, at

Table 2 One year post-procedure outcomes

Comparator trial	Outcome	ATLAS subjects who met comparator trial inclusion/exclusion criteria		Comparator trial	P value
		Crude	MAIC weighted		
LVIS	Primary safety	11/241 (4.6)	7/184 (3.6)	8/153 (5.2)	0.43
	Primary effectiveness	166/207 (80.2)	132/157 (84.2)	108/139 (77.7)	0.12
	Complete occlusion	172/201 (85.6)	136/154 (88.2)	110/139 (79.1)	0.02
	Retreatment	10/241 (4.2)	4/184 (2.4)	2/153 (1.3)	0.44
WEB-IT	Primary safety	5/141 (3.6)	4/109 (3.7)	1/148 (0.7)	0.06
	Primary effectiveness	107/124 (86.3)	79/91 (86.6)	77/143 (53.9)	<0.0001
	Complete occlusion	111/122 (91.0)	81/90 (90.3)	77/143 (53.9)	<0.0001
	Retreatment	5/141 (3.6)	3/109 (2.4)	14/143 (9.8)	0.01

ATLAS, Safety and Effectiveness of the Treatment of Wide Neck, Saccular Intracranial Aneurysms With the Neuroform Atlas Stent System; LVIS, Pivotal Study of the Low Profile Visualized Intraluminal Support; MAIC, matching adjusted indirect comparison method; WEB-IT, Woven EndoBridge Intrasaccular Therapy Study.

the 12 month follow-up using DSA. The comparative analysis aimed to assess differences across the following endpoints: (1) primary effectiveness (defined as complete aneurysmal occlusion without retreatment/>50% parent vessel stenosis), (2) primary safety (exact definitions varied between the studies), (3) complete aneurysmal occlusion (angiographic obliteration (ie, Raymond class I),[8] and (4) retreatment rates of target WNA (outcomes evaluated at the 12 month follow-up). Matching adjusted indirect comparison (MAIC) analysis was used to compare outcomes.

Data collection and classification

Device instruction for use and published clinical trial results were reviewed for extraction of objective, prospectively collected, core laboratory adjudicated data. Patient demographics, aneurysm morphology, and data corresponding to primary effectiveness (complete occlusion without retreatment or >50% parent vessel stenosis), safety, complete occlusion (Raymond Class I), and retreatment rates were obtained from: (1) the ATLAS (Safety and Effectiveness of the Treatment of Wide Neck, Saccular Intracranial Aneurysms With the Neuroform Atlas Stent System) study publications[9 10] for the Neuroform Atlas, and the FDA summary of safety and effectiveness data and study publications for LVIS (Pivotal Study of the Low Profile Visualized Intraluminal Support)[11] and WEB-IT (Woven EndoBridge Intrasaccular Therapy Study).[12]

We classified data for ATLAS study patients according to the inclusion/exclusion criteria of each comparator device, and only compared data from ATLAS study patients that met the inclusion/exclusion criteria of studies of the specified study. All subjects harbored wide necked aneurysms as defined by a neck width of ≥4 mm or dome-to-neck ratio <2. ATLAS subjects who met the following criteria were included in the ATLAS/LVIS subgroup: (1) aneurysm size of 4–20 mm and (2) patients aged 18–75 years. ATLAS subjects who met the following criteria were included in the ATLAS/WEB-IT subgroup: (1) target WNA location was middle cerebral artery bifurcation, anterior communicating artery, internal carotid artery bifurcation/terminus, or basilar apex; (2) aneurysm size 3–10 mm; (3) patients aged 18–75 years; and (4) modified Rankin Scale score of 0 or 1.

Table 3 Primary safety event definitions in the three trials

Study	Primary safety event definitions
ATLAS	Any major ipsilateral stroke or neurological death within 12 months following the procedure. An ipsilateral stroke was defined as an acute episode of focal or global neurological dysfunction due to brain or retinal infarction or due to an intracranial hemorrhage inclusive of subarachnoid, intraventricular, or intraparenchymal hemorrhage, occurring in the same hemisphere as the target aneurysm. A major ipsilateral stroke was defined as an ipsilateral stroke with an increase of ≥4 points on the National Institutes of Health Stroke Scale assessment at 24 hours after symptoms onset
WEB-IT	Proportion of subjects with death of any non-accidental cause or any major stroke (an ischemic or hemorrhagic stroke resulting in an increase of 4 points or more on the National Institutes of Health Stroke Scale as of day 7 post onset) within the first 30 days after treatment or major ipsilateral stroke or death due to neurologic cause from day 31 to 365 after treatment. A major stroke is a stroke which increased the National Institutes of Health Stroke Scale score by ≥4, at the time of assessment and which remained present after 7 days
LVIS	Primary safety composite rate (disabling stroke with modified Rankin Scale score ≥3 within 12 months at any time point between 90 days and last available follow-up or neurological death)

ATLAS, Safety and Effectiveness of the Treatment of Wide Neck, Saccular Intracranial Aneurysms With the Neuroform Atlas Stent System; LVIS, Pivotal Study of the Low Profile Visualized Intraluminal Support; WEB-IT, Woven EndoBridge Intrasaccular Therapy Study.

Statistical analysis

As described previously, inclusion/exclusion criteria used by each comparator study were applied to ATLAS data to create two subgroups, one for LVIS and another for WEB. Crude (unadjusted) estimates were described for the ATLAS/LVIS and ATLAS/WEB-IT subgroups. The MAIC method[13] was used to compare patient level outcomes from the ATLAS study with the aggregate outcomes reported in the literature for the LVIS and WEB studies. First, this method weights the individual patients in the ATLAS/LVIS subgroup to match the LVIS study on patient age and aneurysm characteristics (ie, location, dome height/width, neck measurements, and dome-to-neck ratio) to generate balanced trial cohorts. Second, the outcomes were compared between the ATLAS/LVIS subgroup and the LVIS study by applying the weights to the ATLAS/LVIS subgroup. Both crude (unadjusted) and weighted values are presented in the tables. This same process was followed to compare ATLAS/WEB versus WEB-IT. Crude descriptive analyses were calculated using SAS 9.4 (SAS Institute, Cary, North Carolina, USA). The MAIC analyses were performed using the maic package in R (R Statistical Software, V4.1.3; R Core Team 2021). P values <0.05 were considered statistically significant.

RESULTS

Demographic and target aneurysm characteristics

Patient baseline characteristics for each analysis are presented in table 1. Imaging consisted of DSA in >95% of patients. The analytical samples included 241 ATLAS subjects who met the inclusion criteria for the LVIS study (n=153) criteria, and 141 ATLAS subjects who met the inclusion criteria for the WEB-IT study (n=150) criteria. The discrepancies in distribution of aneurysms locations in the crude cohort were adjusted for in the MAIC analysis. Demographic data and aneurysm characteristics are presented in table 1.

Long term post-procedure aneurysm outcomes

Table 2 shows primary effectiveness, safety, complete occlusion, and retreatment outcomes at the 12 month follow-up

ATLAS versus LVIS

There were no significant differences in primary effectiveness for ATLAS/LVIS and LVIS (84.2% vs 77.7% respectively, P=0.0.13). Similarly, retreatment rates (2.4% vs 1.3%; P=0.44) and primary safety endpoint (3.6% vs 5.2%; P=0.43) were not significantly different between the matched cohorts. However, complete occlusion rates were significantly higher in the ATLAS cohort (88.1% vs 79.1%; P=0.03).

ATLAS versus WEB-IT

The primary effectiveness rates were significantly higher in the ATLAS group compared with the WEB-IT group (86.6% vs 53.9%; P<0.0001). Similarly, complete occlusion rates were significantly higher in the ATLAS cohort (90.3% vs 53.9%; P<0.0001). The retreatment rates were significantly lower in the ATLAS cohort (2.4% vs 9.8%; P=0.01), while there were no significant differences in primary safety rates between ATLAS and WEB-IT (3.7% vs 0.7%; P=0.06).

DISCUSSION

This study constituted the first comparative analysis between the three most used FDA approved endovascular devices to aid in the treatment of WNA using prospective independently adjudicated data. Following the application of our inclusion criteria, three trials were found eligible for inclusion (other prospective trials, eg, CLinical Assessment of WEB device in Ruptured aneurYSms (CLARYS) and WEB Clinical Assessment of Intrasaccular Aneurysm Therapy (WEBCAST) were excluded; table 3). Our data showed that the Neuroform Atlas provided statistically significant improvement in complete occlusion rates compared with the WEB and LVIS, improvement in the primary efficacy endpoint compared to the WEB-IT, and a lower retreatment rate for ATLAS compared with the WEB-IT cohort. Safety events

Table 4 Summary of main endpoints in the three included trials versus other trials

Trial	Follow-up duration	Occlusion metric	Parent vessel stenosis	Retreatment	Imaging modality	Core laboratory	100% occlusion rate (%)
ATLAS, WEB-IT, LVIS	1 year	100% occlusion	>50 stenosis	Evaluated	DSA	Yes	
WEBCAST	6 months	100% occlusion or stable neck remnant	Not evaluated	Evaluated	DSA	Yes	56
WEBCAST 2	1 year	Not specified	Not evaluated	Evaluated	DSA 78%	Expert independently evaluated	54
CLARYS	1 year	RR 1	Not evaluated	Evaluated	65% DSA	Yes	41

ATLAS, Safety and Effectiveness of the Treatment of Wide Neck, Saccular Intracranial Aneurysms With the Neuroform Atlas Stent System; CLARYS, CLinical Assessment of WEB device in Ruptured aneurYSms; LVIS, Pivotal Study of the Low Profile Visualized Intraluminal Support; WEBCAST, WEB Clinical Assessment of Intrasaccular Aneurysm Therapy; WEB-IT, Woven EndoBridge Intrasaccular Therapy Study.

rates were not significantly different between ATLAS/LVIS, and between ATLAS/WEB-IT, with a trend for lower rates in the WEB-IT cohort.

WNA are known to pose unique therapeutic challenges but their exact definitions varied considerably between the three included trials. While the WEB-IT trial was exclusive to bifurcation aneurysms,[12] both the ATLAS and LVIS trials included side wall aneurysms (about 41.4% of aneurysms in the LVIS[11] trial were sidewall aneurysms,[11] vs 45.1% and 24.1% of aneurysms in the ATLAS anterior[9] and posterior circulation[10] cohorts, respectively). To account for this, we compared ATLAS patients who would have met the inclusion criteria of each corresponding device trial to the original trial cohort. When comparing ATLAS with WEB-IT, we excluded side wall aneurysms from the analysis. As the LVIS trial allowed side wall aneurysms, a similar distribution of side wall aneurysms was included in the adjusted ATLAS comparison cohort (table 2). Nonetheless, the high rates of complete aneurysm occlusion among subjects treated with the Neuroform Atlas at 12 months in this study (87.5%) are in line with three recent retrospective studies that reported complete occlusion rates at~12 month follow-up of 85.7% at 6–12 months[14], 82%,[15] and 92%.[6] In contrast, the retreatment rates were relatively higher (3.8–6.9%) compared with the no retreatment outcome reported in two studies using the Neuroform Atlas to treat wide necked aneurysm at 12 months.[6 15] The higher retreatment rates of this study are likely influenced by the prospective and rigorous follow-up in the humanitarian device exemption/pre-market approval trials compared with the inherent bias of uncontrolled low-quality retrospective studies.

The WEB device is deployed within the aneurysmal sac, similar to coils, and ideally obviating the need for parent artery treatment. A cumulative analysis of the cohort from three prospective multicenter studies, the French Observatory,[16] the WEB Clinical Assessment of Intrasaccular Aneurysm Therapy (WEBCAST),[17] and the WEBCAST-2,[18] showed a complete aneurysm occlusion rate of 52.9% at 12 months.[19] This occlusion rate was similar to the results of safety and effectiveness data,[20] the WEB-IT trial.[12] The retreatment rate for the WEB pooled cohort was 7.2% between the index procedure and the 12 month follow-up,[21] which was close to the rate of the WEB-IT study, thus validating the data we used for comparison between devices.

Long term data with both the WEB/Atlas are currently pending given the recency of both devices. Moreover, while the differences between WEB embolization and coil embolization of aneurysms remain to be elucidated, the current best data stem from previous literature (eg, CARAT study[22] on aneurysms coiling). While most neck residuals are likely benign,[23] a higher risk of aneurysm rerupture is associated with neck residuals,[22 24] therefore underscoring the importance of achieving complete angiographic occlusion which would favor the Atlas with higher occlusion rates. Nonetheless, the 5 year results of the WEB-IT trial, recently published, reported complete occlusion and adequate occlusion rates of 58.1% and 87.2% of patients, respectively.[25] No rebleeding events from the index aneurysms were encountered throughout the study follow-up, regardless of occlusion status or initial rupture status, pointing towards a benign natural history of neck remnants with the WEB device which is further in line with the 5 year follow-up of the WEBCAST/WEBCAST-2 combined data.[26] Furthermore, 76.8%[25] of the aneurysms' occlusion grade in the 5 year WEB-IT remained stable or improved, again in line with the French data (87.1%).[26]

In this study, the primary focus of the paper was to compare efficacy across the devices given the significant heterogeneity in the definitions of safety endpoints across the trials. Regardless, despite lower primary effectiveness rates, the WEB-IT trial trended towards having a comparatively lower reported safety events rate compared with the ATLAS trial, although this did not reach statistical significance in the analysis (table 2). This could be attributed, partially at least, to the different safety endpoint definitions, with lower thresholds for inclusion of transient adverse events as safety events in the ATLAS trial compared with the WEB-IT and LVIS trials (table 4; definitions obtained from the summary of safety and effectiveness data of each trial).

Limitations

As with many prospectively collected data analyses and comparative studies, bias may result from the lack of a direct comparator for the same study. Despite opting to compare the ATLAS results using only aneurysms that would meet the inclusion criteria for that trial and using the MAIC analysis to minimize bias, some heterogeneity remains difficult to account for, including the potential differences between the central core laboratory adjudications of each trial. The strict inclusion criteria for our analysis resulted in excluding other prospective trials which might potentially limit the generalizability of the results.

Conclusion

This study demonstrated that wide necked intracranial aneurysms treated with the Neuroform Atlas had higher occlusion rates and similar or reduced retreatment rates than patients treated with the LVIS or WEB. Comparison of prospectively collected, core laboratory adjudicated data can provide meaningful comparisons between studies and devices. The onus is on the clinicians to determine if this translates into clinically measurable benefits for the patient.

Correction notice Since this paper first published, it has been resupplied as open access in October 2024.

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Contributors All authors contributed to the paper, satisfying the ICMJE guidelines for authorship. MMS, BJ, and LLP were involved in the design of the study, acquisition and analysis of the data, and drafting and revising the manuscript. JKB and OOZ contributed to drafting and revising the manuscript for intellectual content. All authors agree to be accountable for all aspects of the current work, including its accuracy and integrity, and sound investigative methodology. BTJ is the guarantor of the study and accepts full responsibility for the work

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Competing interests BJ and OOZ are national co-PIs of the ATLAS trial. LLP is a senior clinical statistician at Stryker Neurovascular.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the lead center: University of Pennsylvania (IRB No 822253). This post hoc analysis of the ATLAS trial (Safety and Effectiveness of the Treatment of Wide Neck, Saccular Intracranial Aneurysms With the Neuroform Atlas Stent System) did not require informed consent.

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