Neuroform Atlas Stent for Treatment of Middle Cerebral Artery Aneurysms: 1-Year Outcomes From Neuroform Atlas Stent Pivotal Trial

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BACKGROUND: Heterogeneous effect of endovascular aneurysm therapy has been observed across different anatomic locations. There is a paucity of data for stent-assisted coiling of middle cerebral artery (MCA) aneurysms.

OBJECTIVE: To present the results of the MCA aneurysm group from the Neuroform Atlas (Stryker Neurovascular) investigational device exemption (IDE) trial.

METHODS: The Atlas IDE trial is a prospective, multicenter, single-arm, open-label study of wide-neck aneurysms (neck $\geq$ 4 mm or dome-to-neck ratio $<$ 2) in the anterior circulation treated with the Neuroform Atlas Stent and approved coils. Follow-up was obtained immediately postprocedure and 2, 6, and 12 mo postoperatively. We herein describe safety and efficacy outcomes, and functional independence of the subjects with aneurysms from all segments of MCA.

RESULTS: A total of 35 patients were included (27 MCA bifurcation, 5 M1, 3 M2). The mean aneurysm size was 6.0 $\pm$ 1.8 mm, and the mean neck was 4.4 $\pm$ 1.2 mm. Technical procedural success was achieved in all patients. A total of 26 patients had follow-up digital subtraction angiography available at 12 mo, with 80.8% (21/26) having complete aneurysm occlusion. Twelve-month safety data were collected for 91.4% (32/35), 8.5% (3/35) had primary safety endpoint, all 3 major ischemic strokes. Mortality occurred in 2 patients beyond 30 d unrelated to procedure (1 gallbladder cancer and 1 fentanyl intoxication). At 1 yr, modified Rankin Score was 0 to 2 in 84.4% (27/32), 3 in 9.4%, and 3 patients were missing. Approximately 5.7% (2/35) of patients were retreated at 12 mo.

CONCLUSION: Stent-assisted coiling with the Neuroform Atlas Stent is a viable alternative to clipping for selected MCA aneurysms. Complete aneurysm occlusion rates have improved compared to historical data. Proper case selection can lead to acceptable endovascular results.

KEY WORDS: Aneurysms, Angiography, Endovascular treatment, Embolization, Middle cerebral artery, Stent

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With the continued evolution and refinement of endovascular techniques and devices, more aneurysms are being treated with endovascular treatment than surgical clipping.[1] Although stent-assisted coil embolization of wide-necked bifurcation aneurysms is a widely accepted treatment approach, many still regard middle cerebral artery (MCA) aneurysms to be more favorable for open surgical approaches because of their superficial location, ease of exposure, and ability to reconstruct complex neck anatomy with clips. Conversely, endovascular treatment remains historically challenging because of higher complication rates added to the difficulty of sealing the neck of a wide-neck bifurcation aneurysm, which has led to lower rates of stable occlusion.[2]

The Neuroform Atlas Stent (Stryker Neurovascular, Fremont, California) is a low-profile laser-cut microstent, which allows delivery through a 0.0165-inch microcatheter

ABBREVIATIONS: IDE, investigational device exemption; **ISAT,** International Subarachnoid Aneurysm Trial; **NIHSS,** National Institute of Health Stroke Scale; **RRS,** Raymond-Roy Scale

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to facilitate navigability and placement, particularly into smaller distal vessels such as the MCA branches. This new iteration relies on the original Neuroform's open cell design, but with more struts and crowns that both reduces the size of the interstices and improves wall apposition, neck coverage, and conformability. This can further inhibit coil protrusion at the neck.

However, there is sparse prospective independently adjudicated data regarding the safety and efficacy of stent-assisted coiling of MCA aneurysms and in particular regarding the use of the Neuroform Atlas Stent. Here, we present the clinical outcomes of the MCA aneurysm subgroup from the Neuroform Atlas pivotal trial with independent core lab adjudicated occlusion results.

METHODS

The Atlas investigational device exemption (IDE) trial is a prospective, multicenter, single-arm, open-label study of wide-neck unruptured intracranial aneurysms treated with the Neuroform Atlas Stent and FDA-approved coils. The study was approved by the Institutional Review Board at each participating site, and patients provided written informed consent before participation in the trial. The original study design, protocol, device description, procedure description, and initial results have been published previously.[3] In summary, inclusion criteria encompassed 18 to 80 yr of age, wide-necked intracranial aneurysm (neck $\geq$ 4 mm or dome-to-neck ratio $<$ 2), and parent vessel diameter of 2.0 to 4.5 mm. Among other previously reported specific criteria, main reasons for patient exclusion comprised the presence of any of the following: multiple untreated intracranial aneurysms, prior treatment with stent-assisted coiling, acutely ruptured within 14 d of enrollment, underlying atherosclerosis in the parent artery, and a presenting Hunt and Hess scale $\geq$ 3 or baseline modified Rankin Scale (mRS) of $\geq$ 4. The dual antiplatelet protocol in the Atlas IDE trial required oral aspirin (81-325 mg) and clopidogrel (75 mg) administration for at least 5 d before the procedure. Assessment of platelet activity occurred according to the standard of care in the enrolling site, and it was not obligatory per the protocol. Intraprocedure anticoagulation using intravenous heparin with monitoring was recommended, aiming to maintain activated clotting time between 250 and 300 s.

Consecutive patients who met the inclusion-exclusion criteria were enrolled from 25 hospitals across the United States. Clinical follow-up data were reported immediately postprocedure and at 2 $\pm$ 1, 6 $\pm$ 1, and 12 $\pm$ 1 mo postoperatively. The following assessments were collected: neurological evaluation, National Institute of Health Stroke Scale (NIHSS), mRS, antiplatelet regimen compliance, adverse events, and quality of life assessment. Evaluation of aneurysm occlusion rates was obtained by obtaining digital subtraction angiography (DSA) at 12 $\pm$ 2 mo using Raymond-Roy scale (RRS).

The primary safety endpoint was the rate of major ipsilateral stroke (defined as an increase of 4 points or greater on the NIHSS lasting for >24 h) or neurological death within 12 mo following the procedure. Secondary outcomes included technical success in deploying the stent at the desired location, incidence of postprocedural major ipsilateral stroke, incidence of device-related serious adverse events, functional outcome as defined by mRS, all-cause mortality, aneurysm retreatment rate, aneurysm occlusion or recanalization rate (based on the 12-mo follow-up angiogram), stent migration, and parent artery patency. We performed a subgroup analysis of the original study to isolate patients with aneurysms arising from the MCA bifurcation or the M1 or M2 segments of the MCA.

Statistical Analysis

Means and standard deviations are presented for continuous variables, medians, and interquartile range for ordinal, and frequency is presented for categorical and binary variables. One-sided Fisher's exact test was used for the evaluation of the primary endpoints with a significance level of $\alpha = 0.025$. The performance goals used for the comparison were determined a priori as previously discussed.[3] Multiple imputation method was performed to fill missing data. A logistic regression model was performed, having probability of success as the dependent variable and age, gender, and race as independent variables. All analyses were performed using SAS (Cary, North Carolina, version 9.4).

RESULTS

Of a total of 201 patients with anterior circulation aneurysms enrolled between June 2015 and October 2016 in the Atlas IDE trial, 35 patients underwent treatment of MCA aneurysms and were included in our subgroup analysis (Figure 1). Of these, 27 patients presented with MCA bifurcation aneurysms, 5 patients with M1 segment aneurysms, and 3 patients with M2 segment aneurysms. The mean aneurysm size was 6.0 $\pm$ 1.8 mm, the mean neck width was 4.4 $\pm$ 1.2 mm, and the mean dome-to-neck ratio was 1.1 $\pm$ 0.3. Five patients (14.3%) had a history of previous rupture. A single stent was used in 27 cases (case illustration, Figure 2), whereas a Y-stent configuration was used in 8 cases (case illustration, Figure 3). Technical procedural success was achieved in all patients. Results are summarized in Tables 1 and 2.

Efficacy Results

Follow-up catheter-based angiography at 12 mo was available on 27 patients (77.1%). One of these underwent retreatment before the 12-mo angiogram, so it is excluded from following analysis. Of the 26 patients with available follow-up DSA and no retreatment, 21 patients (80.8%) had complete aneurysm occlusion (RRS 1), 15.4% had RRS 2, and 3.8% RRS 3. Of 26 patients, 24 (92.3%) had occlusion rate the same or better at follow-up angiography. Two patients (5.7%) were retreated at 12 mo, and both retreated with uncomplicated redo coiling. Eight

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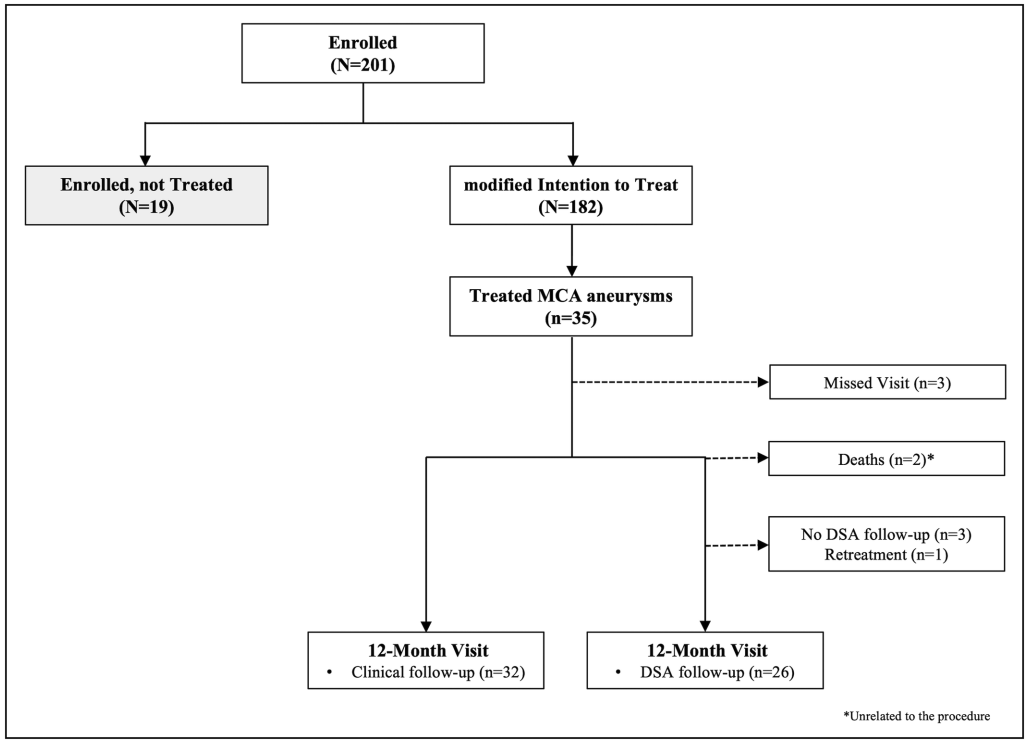


FIGURE 1. *Patient flow diagram of MCA aneurysms in the ATLAS trial (Safety and Effectiveness of the Treatment of Wide Neck, Saccular Intracranial Aneurysms With the Neuroform Atlas Stent System).*

patients did not have 12-mo follow-up DSA, 2 had died, 3 refused follow-up DSA and had MRA done instead, and 3 were lost to follow-up.

Safety and Clinical Outcome Results

Clinical follow-up at the desired endpoints was available from 32 patients (91%). The other 3 did not return for 12-mo clinical follow-up. Three patients (8.5%) had primary endpoint safety events, all with major ipsilateral ischemic strokes. The first event occurred during a procedure that was complicated by a significant blood loss of 2 L with resultant profound anemia and hypotension. The patient suffered a right MCA stroke with left facial droop, spatial, and sensory neglect. The NIHSS at discharge was 5, and mRS at 12-mo follow-up was 3 compared to the baseline mRS of 0. The second event occurred during a procedure in which a coil became stuck on the stent after coil manipulation. The patient suffered a left MCA stroke with aphasia, with an NIHSS of 5 at discharge that improved with mRS of 0 at 12-mo follow-up. The third event occurred 5 mo after the procedure, when the patient with intrinsic left MCA stenosis suffered a left corona radiata stroke after stopping Plavix (RxList), with an NIHSS of 14. This patient also had a poor baseline mRS of 3 and NIHSS of 7 from prior subarachnoid hemorrhage. All 3 of these patients had a single stent placed.

Two additional patients experienced subarachnoid hemorrhage. The first suffered an intraoperative aneurysm rupture with definite contrast extravasation. The second developed worsening aphasia and alertness and was found to have mild subarachnoid hemorrhage on MRI that later worsened, also adjudicated as periprocedural. Both of these patients had good functional outcome (mRS 0-1) with symptoms resolved without any residual effect.

There were 2 cases of mortality beyond 30 d unrelated to the procedure or aneurysm, with one due to gallbladder cancer and another due to acute fentanyl intoxication. Twenty-seven patients (84%) had an mRS of 0 to 2 at 12 mo, with 3 (9%) patients having an mRS of 3. There were no additional secondary safety endpoints beyond the 30-d period at 12-mo follow-up.

DISCUSSION

Aneurysms arising from the MCA territory account for approximately 20% of all intracranial aneurysms,[4] and the rate of favorable outcomes between endovascular coiling and surgical clipping has been previously demonstrated to be comparable based on results from the International Study of Unruptured Intracranial Aneurysms.[5] However, surgical clipping of MCA aneurysms is generally still preferred because of their higher rate

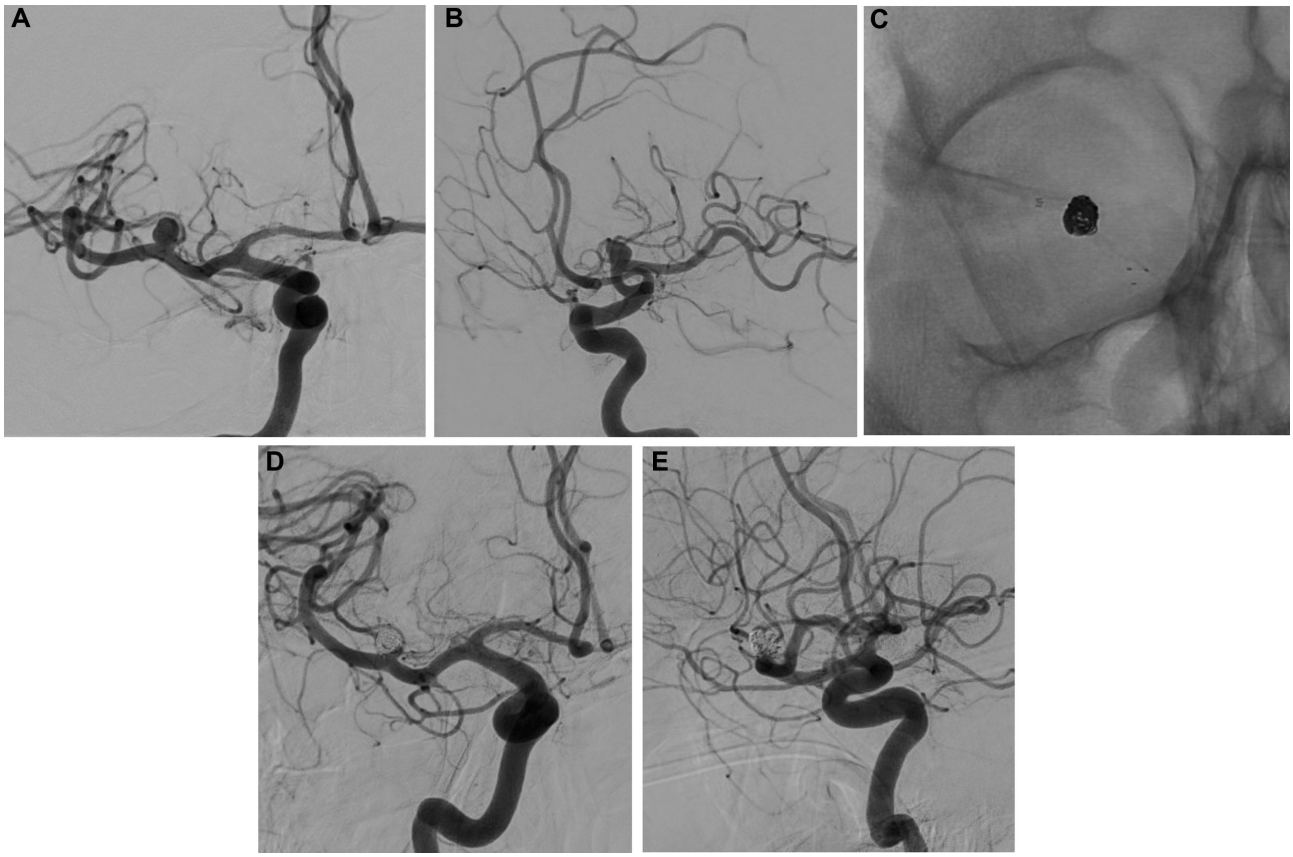


FIGURE 2. *A sexagenarian male presented with documented growth of a right MCA aneurysm. Cerebral catheter-based angiogram AP* **A** *and lateral* **B** *demonstrating a 7-mm aneurysm at MCA bifurcation with asymmetric branches and sharp angle at superior division origin. Decision made for Atlas stent-assisted coiling with stent extending from the superior division to the M1 trunk. (*C*, unsubtracted stent and coil mass in place.) Follow-up angiography at 12 mo demonstrated complete aneurysm occlusion with good preservation of branch stented with no major in-stent stenosis* **D**, *AP and* **E**, *lateral.*

of complete occlusion, lower rate of retreatment, and lower rate of postoperative complications.[6] A common challenge when coiling MCA aneurysms is their wide-necked anatomy associated with a bifurcation. This forces the operator to often choose between subtotal coiling vs compromising the parent or distal vessels. Development of stents specifically designed for stent-assisted coiling, including the ability to Y-stent and the Neuroform Atlas Stent, has largely addressed this problem. At present, there is a paucity of data regarding the safety and long-term efficacy of these devices for the treatment of MCA aneurysms warranting further investigation.

The MCA aneurysm subgroup analysis from the Atlas IDE trial demonstrates higher complete aneurysm occlusion rates (RRS 1) at 12-mo angiographic follow-up than demonstrated previously. When compared with a recent meta-analysis of 29 studies, including 464 patients with unruptured MCA aneurysms treated endovascularly using various devices (stents, flow diverters, and flow disruptors), the Atlas IDE trial demonstrated superior rates of complete aneurysm occlusion of 80.8% vs 60%.[7] This result is comparable to 2 studies that evaluated MCA aneurysms treated specifically by stent-assisted coiling with long-term complete occlusion rates of 78.9%[8] and 90.6%.[9] The retreatment rate from this study was 5.7%, which is also consistent with previously published results of 5.4%,[7] 10.5%,[8] and 4.7%.[9] As demonstrated on Table 3, rate of combined RRS1 and RRS2 was 96.2% with stable or improved RRS at 12 mo 92.2%, with only 7.7% of patients undergoing retreatment at 1 yr.

Unfortunately, there is a paucity of prospective data for clinical and angiographic results of microsurgical treatment of MCA aneurysms. The results presented here are comparable to the 82% angiographic occlusion rate of surgically clipped aneurysms in the International Subarachnoid Aneurysm Trial (ISAT).[10] However, the ISAT studied ruptured aneurysms, where only 47% of the surgical cohort had angiograms performed, and MCA aneurysms were generally underrepresented in this trial, accounting for only 13% (139/1055) of surgically treated lesions. A meta-analysis

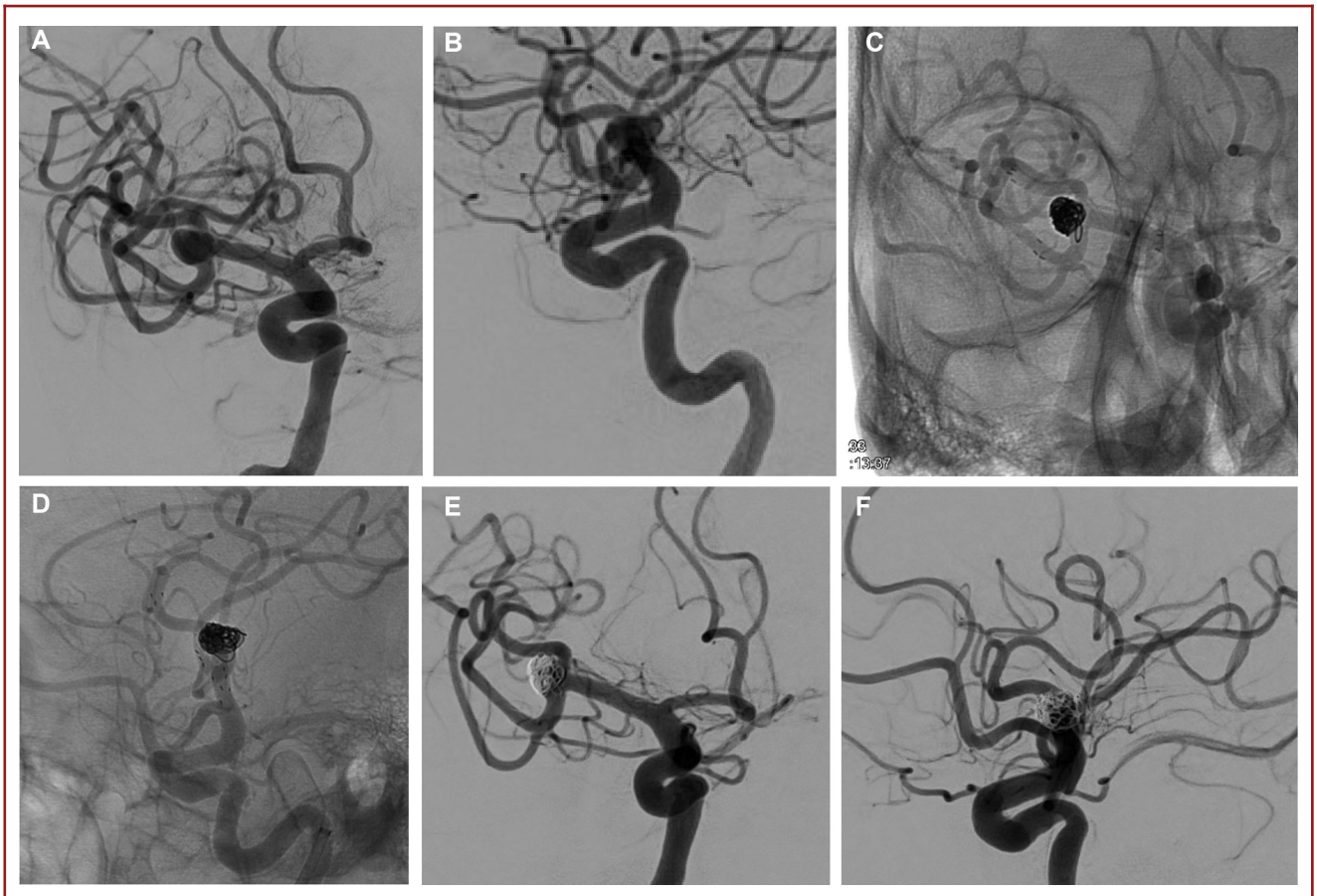


FIGURE 3. *A sexagenarian female presented with a 7-mm right MCA aneurysm during investigation for new onset of headaches. Cerebral catheter-based angiogram AP* **A** *and lateral* **B** *demonstrating a 7-mm aneurysm at MCA bifurcation with symmetric branches. Decision made for Atlas Y-stent-assisted coiling. (*C *and* **D**, *unsubtracted stent and coil mass in place.) Follow-up angiography at 14 mo demonstrated complete aneurysm occlusion with good preservation of stented branches with no major in-stent stenosis* **E**, *AP and* **F**, *lateral.*

of 23 published studies representing 1891 unruptured MCA aneurysms of which 1052 were surgically clipped demonstrated a 95.5% angiographic occlusion rate, although angiographic results were only available for 17% of aneurysms (179/1052).[11] This is consistent with another meta-analysis demonstrating 95% long-term complete occlusion rate after surgical clipping.[7]

This study also demonstrates an acceptable safety outcome with 84% having good neurological outcome determined by their follow-up mRS of 0 to 2. Three patients had major ipsilateral ischemic strokes. Two of these were caused by intraoperative technical complications, whereas the third patient suffered a stroke 5 mo after the procedure in the setting of intrinsic disease, discontinuation of an antiplatelet medication, and history of recurrent strokes. There were 2 deaths in this group, both considered to be unrelated to aneurysm treatment. Technical procedure success was achieved in all patients, attesting to the Atlas stent's relative ease of use and navigability, potentially because of its lower profile as compared to prior generation cerebrovascular microstents.

Limitations

The pivotal ATLAS IDE is limited by the lack of a concurrent control group. Nonetheless, assessment by an independent central imaging core lab and independent clinical event committee were used to reduce bias. Moreover, differences in indications and selection criteria may limit comparison to microsurgical clipping and flow diverters use. The small number of MCA aneurysms treated also makes extrapolation of the results harder.

Interpretation

Given the beforementioned limitations, results must be approached with caution. In spite of that, this study provides valuable information and poses the Neuroform Atlas Stent as a viable alternative for wide-necked MCA aneurysms treatment.

TABLE 1. Baseline Characteristics of the ATLAS Trial MCA Group

Characteristics	Summary statistics (n = 35)
Demographic	
Age, mean ± SD (N)	60.3 ± 11.4
Female	73.1%
White	80.8%
Target aneurysm characteristics (site-reported), mean ± SD (N)	
Aneurysm neck width (mm)	4.4 ± 1.2
Aneurysm size (mm)	6 ± 1.8
Dome/neck ratio	1.1 ± 0.3
Parent vessel diameter proximal to the aneurysm neck (mm)	2.7 ± 0.4
Parent vessel diameter distal to the aneurysm neck (mm)	2.2 ± 0.3
Target aneurysm location, % (n/N)	
MCA bifurcation	77.1%
MCA-M1	14.3%
MCA-M2	8.6%

TABLE 2. Primary Safety and Efficacy Endpoints

Endpoint	% subject with events
Primary efficacy endpoint	74.1% (20/27)
Primary safety endpoint	8.6% (3/35)
Major ipsilateral stroke	8.6% (3/35)
Neurological death	0.0% (0/35)

TABLE 3. Secondary Efficacy Endpoints at 12-Month Follow-up

Endpoint	% subject (n/N)
Procedural technical success (per subject)	100.0% (35/35)
Raymond class (Core Lab)	
1	80.8% (21/26)
2	15.4% (4/26)
3	3.8% (1/26)
Raymond class 1 and 2 combined	96.2% (25/26)
Recanalization[a]	11.1% (3/27)
Progressive occlusion at the target aneurysm location (Core Lab)	
Same	53.8% (14/26)
Better	38.5% (10/26)
Worse	7.7% (2/26)
Parent artery stenosis > 50% (Core Lab)	0.0% (0/26)
Incidence of stent migration (Core Lab)	0.0% (0/26)
Incidence of retreatment (site-reported)	5.7% (2/35)

[a]Recanalization was defined as Raymond Roy of 3 at 12 visit or retreatment due to aneurysm dome filling.

Generalizability

This is a prospective, multicenter, single-arm, open-label study in which an independent Imaging Core Laboratory and the Clinical Events Committee performed adjudication of the primary endpoints. Lack of comparison with alternative approaches, such as microsurgical clipping and flow diverters, may limit the study's generalizability.

CONCLUSION

Despite the limitations of this subgroup analysis of a single-arm prospective study, the Neuroform Atlas Stent has been demonstrated to be a viable alternative to clipping in selected cases. Our results demonstrate strong utility in allowing for stent-assisted coiling of unruptured wide-necked MCA aneurysms with excellent complete occlusion rates and an acceptable safety profile. The angiographic results are better than historical data and in line with recent studies using modern stents.

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