

Stent-Assisted Coiling of Intracranial Aneurysms Using a Nitinol-Based Stent (Neuroform Atlas): A Systematic Review and Meta-analysis

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Abstract

Objective The aim of this systematic review and metaanalysis was to synthesize the latest evidence on the efficacy and safety of Neuroform Atlas-assisted coiling of intracranial aneurysms.

Methods We performed a comprehensive search for articles that assessed the efficacy and safety of Neuroform Atlas-assisted coiling of intracranial aneurysms. The outcome measurement was adequate occlusion, defined as Raymond–Roy Class I (RR1) $+$ Raymond–Roy Class II (RR2) by previous studies.

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Results A total of 557 patients (568 aneurysms) from 13 studies were included. The rate of adequate occlusion after the procedure was 88% (83–94%, I^2 : 72.21%), and the rates of RR1 and RR2 were 68% (60–77%, I^2 : 81.87%) and 21% (15-27%, I^2 : 66.10%), respectively. The adequate occlusion rate at 6 months was 90% (81–99%, I^2 : 58.04%) and 93% (91-96%, I^2 : 0%) at the end of a mean of 9.03 ± 1.03 months of follow-up. Periprocedural complications occurred in 35 patients $[5\% (3-8\%, I^2: 21.28\%)]$. Subgroup analysis of unruptured aneurysms showed that the rates of adequate occlusion were 85% (78–93%), 90% (79–100%) (6-month follow-up), and 93% (90–96%) (at the end of follow-up). For the wide-necked aneurysm subgroup, the rate of adequate occlusion was 86% $(80-93\%)$ and was 93% $(89-97\%)$ at the end of follow-up. Meta-regression showed that initial adequate occlusion was influenced by mean aneurysm neck size $(p = 0.034)$.

Conclusion Neuroform Atlas-assisted coiling is associated with an initial adequate occlusion rate of 88% and a periprocedural complication rate of 6%. The rate of initial adequate occlusion was 85% in unruptured aneurysms and 86% in wide-necked aneurysms.

Level of Evidence Level 2, Systematic review of nonrandomized and single-arm studies.

Keywords Coiling - Endovascular - Intracranial aneurysm - Neuroform Atlas - Stent-assisted coiling

Introduction

Endovascular coil embolization of unruptured intracranial aneurysms is increasingly used [\[1](#page-11-0)] and has become a crucial component of treatment. This method is also reliable in patients with aneurysmal subarachnoid haemorrhage (SAH) [[2\]](#page-11-0). Stent-assisted coiling (SAC) has been shown to be superior to coiling alone in both ruptured and unruptured aneurysms [[3,](#page-11-0) [4](#page-11-0)]. Several stents have been introduced, with open-cell and closed-cell designs; recently, stents deliverable by microcatheters became available [[5\]](#page-11-0).

One of the most important uses of SAC is in patients with wide-necked aneurysm (WNA), which remains a challenge in today's medical world even with the use of coil embolizations. Several adverse effects may arise from the use of coil embolization devices, especially from conventional coiling, including protrusion or luxation into the parent vessel [\[6–8](#page-11-0)]. This adverse event, unfortunately, is closely related to aneurysm type (WNA has a higher risk for coil protrusion). To curtail this anticipated adverse event, SAC is performed in patients with a WNA. With the use of these devices, stents are used as a scaffolding to keep the coil components within the aneurysmal sac of a WNA [[9\]](#page-11-0). One of these SAC devices is the Neuroform AtlasTM (Stryker Neurovascular, Fremont, CA, USA), which consists of a stent system that is intended to hold coil devices in place inside the aneurysmal sac of a vessel. This device received US Food and Drug Administration (FDA) approval on 16 May 2019. The Neuroform Atlas stent consists of a self-expanding nitinol stent [\[10](#page-11-0)]. This stent has a cellular pattern with either an open or closed design. Compared to its predecessor (Neuroform EZ Stent), the Neuroform Atlas has smaller cell sizes, and the cell pattern has also been changed from W-shaped cells into diamondshaped cells in the new Neuroform Atlas stent. These changes are performed to achieve better coil retention inside the aneurysmal sac [\[11](#page-11-0)]. As with other stent-assisting devices, the Neuroform Atlas can be deployed in an X or Y manner in the aneurysmal parent vessel, and the choice of this pattern of deployment depends on anatomical variations and commonly requires multiple stents [\[12](#page-11-0)]. This device is intended to be used in an aneurysm in the brain with a neck size greater than 4 mm or a dome-to-neck ratio less than 2 [\[10](#page-11-0)]. The aim of this systematic review and meta-analysis is to synthesize the latest evidence on the efficacy and safety of Neuroform Atlas-assisted coiling of intracranial aneurysms. To the best of the authors' knowledge, this is the first meta-analysis on the Neuroform Atlas; furthermore, all of the studies were recently published (2018–2019).

Methods

Search Strategy

We performed a comprehensive search for studies that assessed the efficacy and safety of Neuroform Atlas-assisted coiling of intracranial aneurysms with a broad search strategy using keywords (''neuroform atlas'') from the beginning of time until 9 December 2019 using PubMed, EuropePMC, ScienceDirect, ProQuest, and Clinicaltrials. gov. The records were then systematically evaluated using inclusion and exclusion criteria. We also performed a manual search of the references of the included studies. Two researchers independently performed an initial search, and discrepancies (different search results) that arose were resolved by discussion on whether to include the aforementioned studies. This meta-analysis follows the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, and a flowchart of the literature search strategy of studies is presented in Fig. [1](#page-2-0).

Selection Criteria

The inclusion criteria for this study were studies that assess the adequacy of occlusion measured by Raymond–Roy Class (initial and on follow-up) and the safety (complications) of Neuroform Atlas-assisted coiling of intracranial aneurysms. We included all related clinical studies/original articles/case series and excluded case reports, review articles, and non-English language articles.

Data Extraction

Data extraction and quality assessment were performed by two independent authors using a standardized extraction form that included authors, year of publication, study design, aneurysm characteristics, mean neck diameter, dome/neck ratio, sample size, age, proportion of males, periprocedural complications (including aneurysm rupture), mean follow-up length, adequacy of occlusion, Raymond–Roy Class I (RR1), and Raymond–Roy Class II (RR2) immediately after coiling, at the 6-month follow-up, and at the end of follow-up [\[13](#page-12-0)]. WNA is defined by a neck size > 4 mm and/or a dome-to-neck ratio of < 1.5 .

The outcome measurement of this study was adequate occlusion, defined as $RR1 + RR2$ upon immediate angiography, at the 6-month follow-up, and at the end of follow-up. Raymond–Roy Class III (RR3) is considered to indicate inadequate occlusion [\[13](#page-12-0)]. Additionally, we also measured the rate of complications, RR1, and RR2 upon immediate angiography, at the 6-month follow-up, and at

Fig. 1 Study flow diagram

the end of follow-up. These endpoints were derived from previous studies.

Statistics

To perform the meta-analysis, we used STATAMP 16.0 (StataCorp LP). We performed a meta-analysis of proportion to pool the incidence of the primary and secondary outcomes of the Neuroform Atlas-assisted coiling. The inconsistency index (I^2) test, which ranges from 0 to 100%, was used to assess heterogeneity across studies. A value above 50% or $p < 0.05$ indicates statistically significant heterogeneity. The Newcastle–Ottawa Scale (NOS) was used to assess the quality of the included cohort studies; however, since all of the included studies were single-arm studies, the NOS was modified by removing 3 components

that assess comparability and the control group. Subgroup analysis was performed for unruptured aneurysms and WNA. A random-effects meta-regression model was used to explore potential confounders that cause heterogeneity in the outcomes for age, sex, mean neck size, dome-to-neck ratio, proportion of ruptured aneurysms, and proportion of WNA. All p values were two-tailed with statistical significance set at 0.05 or below.

Results

Study Selection and Characteristics

We identified a total of 123 articles. There were 92 records after the removal of duplicates. Seventy-four records were

excluded after screening the title/abstracts. After assessing 18 full texts for eligibility, we excluded 5: (1) studies that predicted complications $(n = 1)$; (2) evaluations of stent apposition $(n = 1)$; (3) a study with only 1 use of the Neuroform Atlas $(n = 1)$; (4) a study with rescue stenting $(n = 1)$; and (5) a study in which dissection of carotid and vertebral arteries was performed $(n = 1)$. We included 13 studies in the qualitative synthesis and meta-analysis [\[5](#page-11-0), [9](#page-11-0), [11,](#page-11-0) [12,](#page-11-0) [14–22](#page-12-0)] (Fig. [1](#page-2-0)) There were a total of 557 patients (568 aneurysms) in 13 studies. All studies were non-randomized, and most were retrospective cohorts. The subjects had unruptured and ruptured aneurysms. The patients were mostly female, and the mean/median age ranged from 51 to 63 years old. The mean follow-up duration was 9.03 ± 1.03 9.03 ± 1.03 9.03 ± 1.03 months (Table 1). The mean NOS score was 5.00 ± 0.23 (out of 6) (Table S1).

Rate of Adequate Occlusion

The technical success rate was 100% in 12 studies and 98% in 1 study. Immediate angiography after the procedure showed an 88% (83–94%, I^2 : 72.21%) rate of adequate occlusion (Fig. [2A](#page-6-0)). The rates of RR1 and RR2 were 68% $(60 - 77\%, \, l^2: 81.87\%)$ and 21% $(15 - 27\%, \, l^2: 66.10\%).$ respectively. At the 6-month follow-up, adequate occlusion was found in 90% (81–99%, I^2 I^2 : 58.04%) (Fig. 2B) of the aneurysms, and the rates of RR1 and RR2 were 70% $(59-82\%, I^2: 37.95\%)$ and 16% $(9-24\%, I^2: 0\%)$, respectively. At the end of follow-up, the rate of adequate occlusion was 93% (91–96%, I^2 : 0%) (Fig. [2C](#page-6-0)), and the rates of RR1 and RR2 were 80% (73–88%, I^2 : 70.84%) and 12% (8-16%, I^2 : 0%), respectively. The rate of occlusion in individual studies is presented in Table [2.](#page-8-0) The mean follow-up duration was 9.03 ± 1.03 9.03 ± 1.03 9.03 ± 1.03 months (Table 3).

Periprocedural Complications

Periprocedural complications occurred in 35 patients [5% $(3-8\%, I^2: 21.48\%)$ $(3-8\%, I^2: 21.48\%)$ $(3-8\%, I^2: 21.48\%)$] (Fig. 2D). There were 13 ischaemic complications (including transient neurological deficits and transient stent-associated thrombosis), 3 temporary clots, 2 thromboembolic events, 2 stent dislodgements, 2 coil-related problems, 3 haemorrhagic events (including aneurysm rupture), 2 asymptomatic left vertebral artery dissections, 1 case of diabetic ketoacidosis-hypoxic brain damage, and 5 undefined complications (Table [1\)](#page-4-0).

Unruptured Aneurysm Subgroup

A subgroup analysis of studies with unruptured aneurysms showed that the rate of adequate occlusion after the procedure was 85% (78–93%, I^2 : 64.22%) (Fig. [3A](#page-9-0)), 90% (79–100%, I^2 : 55.7%) (6-month follow-up), and 93%

(90–96%, I^2 : 0%) (at the end of follow-up; Fig. [3B](#page-9-0)). Periprocedural complications occurred in 9% (2-15%, I^2 : 58.33%) of the patients. The mean follow-up duration was 8.93 ± 1.41 8.93 ± 1.41 8.93 ± 1.41 months (Table 3).

Wide-Necked Aneurysm Subgroup

Studies with $> 90\%$ WNA were included in this subgroup analysis. The rate of adequate occlusion was 86% $(80-93\%, T^2: 74.26\%)$ (Fig. [4A](#page-9-0)), 88% (75-100%, T^2 : 71.99%) at the 6-month follow-up, and 93% (89–97%, I^2 : 29.75%) (Fig. [4](#page-10-0)B) at the end of follow-up. The rate of periprocedural complications was 6% (3–9%, I^2 : 38.09%). The mean follow-up duration was 8.61 ± 1.46 months (Table [3\)](#page-8-0).

Meta-regression

The rate of adequate occlusion after the procedure was not affected by age ($p = 0.191$), sex ($p = 0.797$), proportion of ruptured aneurysms ($p = 0.163$), or proportion of WNA $(p = 0.103)$. The initial adequate occlusion rate was affected by the mean aneurysm neck size $(p = 0.034)$ (Fig. [5A](#page-11-0)). The RR1 rate was not affected by age $(p = 0.211)$, sex $(p = 0.295)$, mean aneurysm neck size (0.651) , proportion of ruptured aneurysms $(p = 0.417)$, or the proportion of WNA ($p = 0.480$). The rate of RR2 was not affected by sex ($p = 0.216$), mean aneurysm neck size $(p = 0.299)$, proportion of ruptured aneurysms $(p = 0.116)$, or the proportion of WNA ($p = 0.383$). However, it was affected by the patient's age $(p = 0.013)$ (Fig. [5B](#page-11-0)).

The heterogeneity of adequate occlusion at the end of follow-up was 0%; hence, we only performed meta-regression for mean aneurysm neck size $(p = 0.899)$, which was shown to affect the rate of adequate occlusion after the procedure. The rate of RR1 was not affected by age $(p = 0.486)$, sex $(p = 0.447)$, mean aneurysm neck size (0.839), the proportion of ruptured aneurysms ($p = 0.777$), or the proportion of WNA ($p = 0.479$).

Discussion

Neuroform Atlas-assisted coiling is associated with an 88% initial occlusion rate, which improves on follow-up to $a > 90\%$ adequate occlusion rate. However, the rate of periprocedural complications is concerning, reaching 5% of the procedure with predominantly ischaemic sequelae. The initial adequate occlusion rate was 85% in unruptured aneurysms and 86% in WNA, increasing to $> 90\%$ on follow-up. The rate of adequate occlusion was affected by the mean aneurysm neck size after the procedure but not at the end of follow-up. The aneurysm neck size has been

Table 1 continued

Fig. 2 Rate of occlusion and complications. Forest-plot showing the rate of adequate occlusion (RR1 $+$ RR2) of intracranial aneurysm immediately after procedure (A) , 6-month follow-up (B) , and at the end of follow-up (C). The rate of complications was shown in D. ES effect estimate, RR1 Raymond–Roy Class I, RR2 Raymond–Roy Class II

identified as a predictor of complete occlusion by coil embolization [\[23](#page-12-0)]; however, the association was not observed at the end of follow-up.

Meta-regression analysis revealed that the aneurysm neck size affects the initial adequate occlusion. The association was previously described in an earlier study [\[8](#page-11-0)]. Complete coil occlusion of the WNA is difficult because the instable coil mass potentially leads to coil migration or impingement into the parent artery [\[24](#page-12-0)]. This problem potentially leads to a lower initial occlusion rate. The definition of WNA varies greatly [[25\]](#page-12-0), and the mean aneurysm neck size varies across studies; hence, meta-regression may provide more information regarding the influence of aneurysm neck size. Previously, older age was found to be an independent predictor of aneurysm recanalization in patients undergoing stent-assisted coiling, and the mechanism was hypothesized to be due to a weaker neointimal response in older patients [\[26](#page-12-0)]. Such

Fig. 2 continued

phenomena may explain the significance of age on the aneurysm occlusion found in the meta-regression.

Currently, there are multiple stents that are available to be used in stent-assisted coiling procedures, namely, Solitaire (Medtronic Inc, Mansfield, MA), Neuroform (Stryker Neurovascular, Fremont, CA), Enterprise (Cordis Neurovascular, Inc., Miami Lakes, FL), Leo (Balt, Montmorency, France), Leo Baby (Balt, Montmorency, France), and Low-profile Visualized intraluminal support (LVIS Jr) (MicroVention-Terumo, Inc., Tustin, CA). Compared to other stents, the Neuroform Atlas stents are available from diameters ranging from 3 to 4.5 mm and can be placed in vessels ranging from 2 to 4.5 mm with multiple stent lengths available. These wide ranges of

Table 3 Result of the meta-
analysis

RR1 Raymond–Roy Class I, RR2 Raymond–Roy Class II, WNA wide-necked aneurysm

Fig. 3 Rate of occlusion in unruptured aneurysm subgroup. Forest-plot is showing the rate of adequate occlusion $(RR1 + RR2)$ of unruptured aneurysm subgroup immediately after the procedure (A) and at the end of follow-up (B). ES effect estimate, RR1 Raymond–Roy Class I, RR2 Raymond–Roy Class II

available stents are supposed to improve the accuracy and stability of stent placement within the vessel [[11\]](#page-11-0).

Neuroform stents (Earlier model) and Enterprise stents were the most widely used intracranial stents for stentassisted coiling; the former was associated with 2.3% deployment failure, and the latter was associated with 0.2% deployment failure [\[27](#page-12-0)]. In the present meta-analysis, the rate of deployment failure was 0.17%, a significant improvement compared to the earlier model. Moreover, Neuroform Atlas stents have been shown to have good apposition even in vessels with strong curvature [\[28](#page-12-0)]. However, due to its partially open-cell design, resheathing of the device is not possible, and thus, accurate and reliable measurements of the target vessel must be performed prior to choosing the stent size $[11]$ $[11]$.

Stent-assisted coiling has been shown to be superior to coiling alone in both ruptured and unruptured aneurysms [\[29](#page-12-0), [30\]](#page-12-0). Furthermore, stent-assisted coiling seemed to be Fig. 4 Rate of occlusion in wide-necked aneurysm subgroup. Forest-plot is showing the rate of adequate occlusion (RR1 + RR2) of wide-necked aneurysm subgroup immediately after the procedure (A) and at the end of follow-up (B). ES effect estimate, RR1 Raymond–Roy Class I, RR2 Raymond–Roy Class II

non-inferior compared to the balloon remodelling technique, or even superior, although more evidence is needed [\[31](#page-12-0), [32\]](#page-12-0). Stent-assisted coiling was also shown to be more appropriate than the balloon remodelling technique in ruptured WNA [\[33](#page-12-0)]. This meta-analysis demonstrated that the rate of adequate occlusion for WNA using the Neuroform Atlas was 86% initially, increasing to 93% after a mean 8.61 months follow-up with a periprocedural complication rate of 6%. Other methods of assisted coiling using low-profile stents, such as the LVIS Jr stent, have an 89.6% adequate occlusion rate but a concerning periprocedural complication incidence (11.2–17.2%) [[12,](#page-11-0) [34](#page-12-0)]. Woven Endobridge is another device that can be used to assist coiling; it has an 82–85% adequate occlusion rate at approximately 12 months of follow-up with a good safety profile [\[35](#page-12-0), [36](#page-12-0)]. Another option that can be used is T-stentassisted coiling, which has been shown to result in an 83% complete occlusion rate, increasing to 90% at a mean

Fig. 5 Meta-regression. Bubble-plot showed that the rate of adequate occlusion after procedure was affected by mean aneurysm neck size (A). Meanwhile, the rate of RR2 was affected by age (B). RR2 Raymond–Roy Class II

30-month follow-up along with a 13.7% rate of periprocedural complications [[37\]](#page-12-0).

A limitation of this systematic review was the unavailability of randomized controlled trials (RCTs); all of the studies were only single-arm studies and therefore lack direct comparison to the other devices. Furthermore, most of the studies were retrospective in design. RCTs are necessary to establish evidence on whether the Neuroform Atlas is superior to other devices. Additionally, the 6-month outcome was inadequately powered.

Conclusion

Neuroform Atlas-assisted coiling has 88% initial adequate occlusion, which increases on follow-up. The mean aneurysm neck size seemed to affect the initial adequate occlusion. Initial adequate occlusion was 85% in unruptured aneurysms and 86% in WNA. The rate of periprocedural complications was 6%. Nevertheless, RCTs are needed to provide direct comparisons with other devices.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

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