

Comparative Outcome Analysis of Enterprise and Neuroform Stent-Assisted Coiling of Cerebral Aneurysms: A Review of the Literature

Abstract

Introduction: One of the popular treatment strategies for complex cerebral aneurysms with wide necks or low dome-to-neck ratios is stent-assisted coiling. The most widely used intracranial stents for stent-assisted coiling are Neuroform (NF) and Enterprise (EP) stents. The purposes of this study are to review the recent literature of the past 5 years to compare outcomes between the EP and NF stent-assist coiling systems so as to comment on the safety, efficacy, complications, and recurrence rate of stent-assisted coiling in general. **Methods:** PubMed was used to search for all published literature of NF or EP stent-assisted coiling of unruptured cerebral aneurysms from January 2014 to August 2019 with the search terms of “Enterprise stent-assisted coiling,” “Neuroform stent,” and “Neuroform vs. Enterprise stent.” **Results:** Twenty two publications met the inclusion criteria which encompass 1764 patients and 1873 aneurysms. Out of these 1873 aneurysms, 1007 aneurysms were treated with EP stent and 866 aneurysms were treated with NF stent. The overall outcome was low rates of thromboembolic complications (4.37%) and intracranial hemorrhage (1.13%), low permanent morbidity (1.70%) and mortality (0.40%), and lower rate of recanalization (11%). Data analysis shows an overall higher rate of complication and recurrence of aneurysm and lower overall rate of aneurysmal occlusion in the patients where EP stent was used in comparison to NF stent. However, this difference was not statistically significant. **Conclusions:** The review of two stent-assisted coiling devices using EP and NF stents including 1873 aneurysms in 1764 patients revealed that overall, it is safe and effective with comparable outcomes.

Keywords: Aneurysm, cerebral aneurysm, Enterprise, intracranial aneurysm, intracranial stents, Neuroform, stent-assisted coiling

Introduction

A wide variety of treatment strategies have evolved over the time for the management of cerebral aneurysms including surgical and endovascular. Endovascular treatment evolved very rapidly with introduction of various devices. One of the popular treatment strategies for complex cerebral aneurysms with wide necks or low dome-to-neck ratios is stent-assisted coiling. The mechanism of action of stents in improving angiographic aneurysmal occlusion is by serving as a scaffold to prevent coil prolapse, increased coil packing density, greater stability to the coil mass, and promoting re-endothelialization.^[1-10]

The first case series of patients treated with stent-assisted coiling was published in 1999 by Lanzino *et al.*^[11] They described 10 patients with vertebral-basilar or proximal internal carotid artery (ICA) aneurysms,

achieving a modest 30% initial complete occlusion rate, and a 33% occlusion rate at 3 months follow-up. This series represents a unique subset of aneurysms that would be “uncoilable” (i.e., 0% occlusion rate) if managed by coiling alone. To date, several publications have reviewed the published literature comparing stent-assisted coiling between various stent used and especially the two most commonly used stents Neuroform (NF; Stryker, Food and Drug Administration [FDA] approved in 2002) and Enterprise (EP; Codman, FDA approved in 2007) stents. NF is a self-expanding stent with an open-cell design and undergone multiple iterations including NF 2, Treo 2, Treo 3 and EZ. EP is a self-expanding stent with a closed-cell design.

Since the publication of the most recent large review by Gross and Frerichs^[12] and King *et al.* (2015),^[13] the number of case

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series published reporting on stent-assisted coiling has been increasing with variable results. Since there is continuous evolution of techniques and newer techniques are coming up such as flow diverters, there is a need to evaluate the latest literature for the past 5 years to ascertain the important place of stent-assisted coiling in treating cerebral aneurysms. The purposes of this study are to review the recent literature of the past 5 years to compare outcomes between the EP and NF stent-assist coiling systems so as to comment on the safety, efficacy, complications, and recurrence rate of stent-assisted coiling in general.

Methods

Data sources

PubMed was used to search for all published literature of NF or EP stent-assisted coiling of un-ruptured cerebral aneurysms from January 2014 to August 2019 with the search terms of “Enterprise stent-assisted coiling,” “Neuroform stent,” and “Neuroform vs. Enterprise stent.” All abstracts of manuscripts or entire articles published in English in the past 5 years were reviewed. Case series, prospective studies, or clinical trials with 9 or more patients containing reported clinical and/or radiological data following intracranial stenting with EP or NF stents for the treatment of cerebral aneurysms were included. Only those patients with clearly listed data for each individual system of EP or NF were included. Patients receiving both EP and NF stents simultaneously were excluded. The choice of stent techniques and configurations was determined by the operator, taking into account the angiographic architecture of the aneurysm and the advantages and challenges of each available stent.

Data extraction

All studies that met our inclusion criteria were reviewed in full, and from each study, we extracted the sample size for each stent system used and the following outcome measures: thromboembolic events (defined as transient ischemic attack, stroke, or development of asymptomatic thrombus during procedure), new periprocedural intracranial hemorrhage (ICH), permanent morbidity (present at last follow-up), mortality, deployment failure, delayed in-stent stenosis (defined by the presence of the term “moderate,” “severe,” or “symptomatic” or if not clearly defined by the authors), initial complete (100%) or near-complete (Raymond–Roy Class 1 and 2) angiographic occlusion of the aneurysm after treatment, complete or near-complete occlusion of the aneurysm at last follow-up, and recanalization or recurrence of the aneurysm at follow-up.

Studies that used terms such as “recanalization,” “recurrence,” those that listed progression of aneurysm remnant, or those that listed progression to a higher Raymond grade on follow-up were included in the last outcome measure. Aneurysm filling was graded using

the Raymond–Roy classification.^[14] Class I aneurysms were those that remained completely occluded, Class II aneurysms were those that had residual contrast filling at the aneurysm neck, and Class III aneurysms were those that had residual contrast filling centrally within the coil mass beyond the neck or along the aneurysm wall beyond the neck.

All recorded data were verified by a second reviewer and collected on a standardized spreadsheet. Deployment failure, initial complete occlusion, complete occlusion at follow-up, and recanalization were assessed per aneurysm while the remaining outcome measures were assessed per patient. If data on a particular outcome measure were not available for a given study, the patients from that study were excluded from the denominator during the analysis of that outcome measure. Statistical analysis was done by SPSS (Statistical Package for Social Sciences, developed by IBM, New York, USA) which was used to determine significance. $P < 0.05$ was considered statistically significant.

Results

Twenty-two publications [Table 1] met the inclusion criteria and included in our study.^[15-36] A total number of 1764 patients with total 1873 aneurysms were treated during the above said period of publication. Of these, 1007 aneurysms were treated with EP and 866 were treated with NF. The majority of the included studies were retrospective in nature. The duration of follow-up was variable from 6 to 24 months among different studies. Data were collected in the manner described above and compiled in tabular form [Table 2] which shows the overall rates of clinical complications and complete or near-complete angiographic occlusion, recanalization as well as the comparative analysis between stent types for all patients. Data analysis shows an overall higher rate of complication and recurrence of aneurysm and lower overall rate of aneurysmal occlusion in the patients where EP stent was used in comparison to NF stent. However, this difference is not statistically significant as the P value turned out to be >0.05 for all parameters.

Discussion

Our study represents the review of the current literature of the past 5 years from January 2014 to August 2019 on stent-assisted coiling using EP and NF intracranial stents. Our study includes total 1873 aneurysms in 1764 patients in 5 years which makes it as the largest study which evaluated the current trend and evolution in stent-assisted coiling of intracranial aneurysms. Although it is not as large as done by King *et al.* 2014,^[13] it is exploring the latest trend. Overall, this analysis demonstrates that stent-assisted coiling has evolved over last few years and giving better results than earlier. When the overall figures were compared with those analyzed in the study by King *et al.*,^[13] we found that there is further improvement in almost all assessment

Table 1: Details and salient points of various studies included in our review

Study	Year of publication	Duration of study	Stent used	Number of patients	Number of aneurysms	R1/2 occlusion at last follow-up	Recanalization
Nakazaki <i>et al.</i> ^[15]	2017	2010-2015	NF	31	32	19	4
			EP	48	49	29	6
Wang <i>et al.</i> ^[16]	2018	2009-2016	NF	103	109	82	9
			EP	57	61	35	7
Linzey <i>et al.</i> ^[17]	2017	2005-2012	NF	92	92	82	10
			EP	30	30	19	11
Lim <i>et al.</i> ^[18]	2018	2012-2016	NF	25	27	20	7
			EP	179	195	174	21
Cay <i>et al.</i> ^[19]	2018	2015-2017	NF	48	51	48	3
Kühn <i>et al.</i> ^[20]	2016	2006-2012	NF	22	24	23	1
			EP	19	20	16	4
Ulfert <i>et al.</i> ^[21]	2018	2016-2017	NF	36	37	37	0
Lee <i>et al.</i> ^[22]	2018	2012-2016	NF	25	27	19	8
			EP	176	192	157	35
Gentric <i>et al.</i> ^[23]	2015	2008-2010	NF	97	97	80	13
Durst <i>et al.</i> ^[24]	2014	2002-2012	NF	77	77	67	10
			EP	53	53	51	6
Tsai <i>et al.</i> ^[25]	2019	January-December 2018	NF	56	56	52	4
Ten Brinck <i>et al.</i> ^[26]	2019	2015-2016	NF	27	27	18	8
Goertz <i>et al.</i> ^[27]	2019	2014-2018	NF	37	37	35	2
Quintana <i>et al.</i> ^[28]	2019	2015-2017	NF	30	30	28	2
Jankowitz <i>et al.</i> ^[29]	2019	June-September 2015	NF	30	30	26	3
Caragliano <i>et al.</i> ^[30]	2019	2016-2017	NF	113	113	104	106
Xu <i>et al.</i> ^[31]	2018	2013-2016	EP	44	44	39	2
Feng <i>et al.</i> ^[32]	2018	2014-2016	EP	111	142	131	11
Herweh <i>et al.</i> ^[33]	2018	April-December 2015	EP	9	9	8	1
Ge <i>et al.</i> ^[34]	2016	2014-2015	EP	98	112	105	6
Kim <i>et al.</i> ^[35]	2015	2012-2014	EP	55	57	53	4
Ye <i>et al.</i> ^[36]	2015	2010-2012	EP	36	43	37	2

NF – Neuroform; EP – Enterprise

Table 2: Clinical outcomes of patients having aneurysm following stent-assisted coiling using Enterprise and Neuroform stents

Factor	Total, n (%)	EP, n (%)	NF, n (%)
Number of patients	1764	915	849
Number of aneurysms	1873	1007	866
Thromboembolic events	77 (4.37)	45 (4.92)	32 (3.77)
Periprocedural intracranial hemorrhage	20 (1.13)	11 (1.20)	9 (1.06)
Permanent morbidity	30 (1.70)	17 (1.86)	13 (1.53)
Mortality	7 (0.40)	4 (0.44)	3 (0.35)
Deployment failure	32 (1.71)	19 (1.89)	13 (1.50)
In-stent stenosis	24 (1.28)	15 (1.49)	9 (1.04)
Initial complete or near-complete occlusion	1521 (81.21)	774 (76.86)	747 (86.26)
Last follow-up complete or near-complete occlusion	1594 (84.81)	854 (84.81)	740 (85.45)
Recurrence/re-canalization	206 (11.00)	116 (11.52)	90 (10.39)

NF – Neuroform; EP – Enterprise

parameters. These devices in our study versus in King *et al.*^[13] 2014 study produce low rates of TE complications (4.37% vs. 6.4%) and ICH (1.13% vs. 2.6%), low permanent morbidity (1.70% vs. 4%) and mortality (0.40% vs. 2.3%), and lower rate of recanalization (11% vs. 12%).

Though data of satisfactory angiographic occlusion is not comparable across different studies because they used different criterias for defining satisfactory angiographic occlusion. In our study, we used Raymond Grade 1 and 2 as satisfactory occlusion; on the other hand, their study

used Raymond Grade 1 (100%) occlusion as satisfactory. Regarding satisfactory aneurysmal occlusion rate, our study shows a very encouraging result of 81.21% of initial occlusion rate and 84.81% at last follow up. The low clinical complication rate and high degree of occlusion are particularly encouraging, given that most aneurysms treated with stent-assisted coiling are done so for aneurysms with wide necks, poor dome-to-neck ratios, or other complex features that may incur a higher risk of coil prolapse or TE complication if coiling primarily, as well as a higher likelihood of recanalization. Furthermore, the low ICH rate is also encouraging given the requirement for dual antiplatelet therapy after stent deployment. Overall, this large literature review suggests that stent-assisted coiling is a safe and effective treatment strategy for intracranial aneurysms.

In contradiction to the previous largest review by King *et al.*, our study shows the superiority of NF stent over the EP stent in all the studied parameters though it is not statistically significant. However, our study clearly defies the statistically significant superiority of EP stent over NF stent as shown by King *et al.*^[13] in terms of the rates of deployment failure, ICH, mortality, complete aneurysm occlusion at follow-up, and recanalization.

There are several possible explanations for these contradictory findings. The NF was the first self-expanding intracranial stent and became available in a clinical trial in Europe in 2001.^[2] Since then, this stent underwent multiple modifications to NF 2, NF 3, and now NF Atlas. Many studies covered under our review had used the latest version of NF stent. Linzey *et al.*^[17] found similar packing densities in both groups, so this was an unlikely contributor. Both the EP and NF stents are made of nitinol with approximately 5% metal coverage. NF stent construct is an open-cell design, which improves wall apposition in curving arterial segments. In contrast, the EP stent has a rigid closed-cell design, which hinders the apposition of the stent to the vessel wall, particularly in tortuous anatomy, potentiating the risk of endoleak.^[37,38] The rigid structure can also lead to kinking, making recrossing the stent for coiling very difficult.^[38] EP stent is having parylene coating which is not in the case of NF stent. Parylene is a biologically inert polymer that provides a slick surface.^[39] This coating is to prevent sticking in the microcatheter during deployment. Previous studies have hypothesized a potential role of the parylene coating in the increased risk of embolic complications with the EP stent.^[39] However, in our study, the thromboembolic rate was found to be higher in EP group, but it is not statistically significant. Further studies may help to elucidate the effects caused by the unique properties of the NF and EP stents in the aneurysm microenvironment.

Stent-assisted coiling is one of the popular treatment strategies for complex cerebral aneurysms with wide necks

or low dome-to-neck ratios. The mechanism of action of stents in improving angiographic aneurysmal occlusion is by serving as a scaffold to prevent coil prolapse, increased coil packing density, greater stability to the coil mass, and promoting re-endothelialization.^[1-10] That endothelialization at the aneurysm neck encourages progressive aneurysmal occlusion through a flow remodeling phenomenon.^[40,41] Some studies have given their conclusion that stent-assisted coiling has lower recanalization rates than the aneurysmal coiling without stent assistance.^[41]

Flow diverters are popular alternative means of treating wide-necked or complex cerebral aneurysms. There is a monumental advancement in the ability to exclude aneurysms from the circulation and also to reconstruct the parent vessel. The mechanism of action of aneurysmal occlusion is to reduce intra-aneurysmal flow, stasis of blood, and thrombosis, with neo-endothelialization of the stent to finally reconstruct the parent vessel. It does not require direct aneurysm catheterization. Pipeline embolization device (PED) was first introduced in 2008 and gained popularity very fast. In a literature review by Murthy *et al.*^[42] including 905 patients and more than 1000 aneurysms treated with the (PED; ev3-Covidien, Plymouth, Minnesota, USA), both ICH and mortality occurred in 2.3% of patients. The complete aneurysmal occlusion rate was 80% at a 6-month follow-up. Furthermore, recent cost-effectiveness analyses have favored flow diversion over alternative endovascular treatments, an effect that becomes more pronounced as aneurysm size increases.^[43-45] However, the results of our study seem to be more promising in terms of ICH, and mortality rate occurred in 1.13% and 0.40% only with a higher occlusion rate of 84.81% at last follow-up. Although we did not analyze the statistical significance of these differences in outcome associated with stent assisted coiling and flow diverters. Our results are marginally in favour of stent assisted coiling in contrast to the results of review done by Murthy *et al.*^[42] This difference might be because of use of newer stenting devices. However, PED is currently only FDA-approved for wide-necked aneurysms from the petrous to superior hypophyseal segment of the ICA, a restriction not shared by ENT or NEU. The present study suggests that stent-assisted coiling has comparable safety and efficacy to the PED but appears to have more versatility given that it may be used efficaciously in smaller parent arteries or at bifurcation sites without the need for off-label use. Furthermore, newer technology, i.e., PED requires additional training to master procedural nuances. For these reasons, stent-assisted coiling will likely remain a strong consideration for aneurysms with wide necks or poor dome-to-neck ratios, even in light of the increasing popularity of flow diversion.

Apparent limitations of our study are biases of the individual studies and the large number of retrospective series, and heterogeneity between studies creates the problem in making the results generalized. Additional

limitations of our study are exclusion of demographic information, variable reporting using different definitions, the number of stents used, nonavailability of long term follow up data which together makes direct comparisons difficult. Given that a large portion of the data are self-reported, the reported recanalization rate of 11% probably significantly underestimates the true rate as numerous studies have demonstrated that self-reported data consistently overestimate effect size compared with core laboratory-adjudicated data.^[46,47] As suggested by Gross and Frerichs,^[12] different stents may be more or less applicable depending on factors such as the baseline parameters of the patient, the clinical characteristics of the aneurysm, and operator training. In addition, the differences in cost or availability of these devices may drive the selection of devices.

Conclusions

Our study represents the review of the current literature of the past 5 years which is the largest for this period. The review of two stent-assisted coiling devices using EP and NF stents including 1873 aneurysms in 1764 patients revealed that overall, it is safe and effective, with low rate of complications, morbidity, mortality, and recurrence and with high rate of aneurysmal occlusion. Comparative analyses of data show better results in all aspects with NF stent. However, this difference is not statistically significant. However, this is indicating toward improved outcome with NF stent in contrast to earlier studies.

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Conflicts of interest

There are conflicts of interest.

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