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Safety and Efficacy of Y-Stenting with Laser Cut Open Cell Stents in Complex Wide Neck Bifurcation Aneurysms

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Abstract

Background: Y-stenting provide a coiling support and protection to the parent artery and its branches. However, the interventional approach requires many steps and represented a technical challenge. This is attributed to the passage of the second stent through the interstices of the first one. In addition, Y-stent leaves a large amount of metal in the healthy parent artery.

Aim and objectives: This study aimed to assess the safety and efficacy of Y-stenting with Laser cut open cell stents in complex wide neck bifurcation aneurysms.

Subjects and Methods: This prospective clinical study included 30 patients, who were selected from the Neuro-Psychiatry center, Tanta university. All were submitted to standard clinical pre-interventional assessment. After the intervention the primary and secondary outcomes were documented. The primary outcome was the successful Application of Y-stenting with laser cut open cell stents and periprocedural complications. The secondary outcomes included the safety and efficacy of Y-stenting with laser-cut open cell stents at follow-up 6 and 12 months of follow up.

Results: At six months after intervention, there were 26 patients [86.7%] with complete occlusion, 2 patients [6.7%] with Neck remnant, 2 patients [6.7%] with recurrence and needs retreatment. After one year, there was 28 patients [93.3%] with complete occlusion, 2 patients [6.7%] had Neck remnant. The risk factors for stroke were hypertension among 7 patients [23.3%], diabetes mellitus in 3 patients [10.0%], 7 patients [23.3%] had dyslipidemia and smoking was reported among 7 patients [23.3%].

Conclusion: Neuroform Atlas stent achieves a safe and effective Y-stenting operation by combining the benefits of open-cell architecture with low-profile deployment microcatheters. This study's positive angiographic and clinical results showed that wide-necked complicated bifurcation aneurysms can be effectively treated endovascularly using Y-stent-assisted coiling using Neuroform Atlas stents.

Keywords: Wide Neck Bifurcation Aneurysm; Endovascular; Stent-assisted Coiling [SAC]; LASER.

INTRODUCTION

Wide neck bifurcation aneurysms [WNBAs] are challenging to treat saccular aneurysms by a neurosurgeon. With introduction of aneurysm coiling, endovascular treatment [EVT] of these aneurysms are challenging for the following causes: the width of neck is a factor that increased difficulty of coils stabilization in the aneurysmal sac. In addition, the coil protrusion and thromboembolic complications risk are increased. WNBAs also have one or more branches arise from the neck. This leads potential occlusion of branches during coiling with higher risk of aneurysmal recanalization due to wider neck [1, 2].

Furthermore, it is technically difficult to completely occlude the aneurysm in the intracranial circulation without impeding flow in the original branch arteries. The documented complete occlusion rate is about 46.3% for all interventional methods [3, 4].

The endovascular treatment of intracranial aneurysms gained wide acceptance with the introduction and advancement of endo-vascular approaches and devices. However, WNBAs is still challenging in their treatment due to the specific anatomical complexities. The existing treatment approaches, include balloon remodeling, use of multiple catheters, single-stent-assisted, diversion of the flow, using neck bridges, and waffle cones. All of them have their limitations with low success rates and high rates of complications [e.g., coil protrusion, aneurysm recanalization and thromboembolic consequences] [5-10].

Stent-assisted coiling was introduced in the past two decades, and has been evaluated in different studies including ruptured and unruptured, wide and narrow-neck aneurysms. The use of a self-expandable stent leads to the creation of a mechanical scaffold in the parent artery aiming to prevent coil protrusion during the endovascular intervention of WNBAs. Many previous research studies have showed the potential safety, durability and efficacy of stent-assisted coiling approaches for the management of WNBAs [11].

The use of Y-stent-assisted coiling [Y-SAC] was initially used by Chow [12]. It was completed by placement of 2 stents passing from the parent artery to be settled in the bifurcation vessels. This leads to the creation of a new bifurcation point, which offers a mechanical scaffold and prevent protrusion of coils. Its feasibility has been confirmed in many retrospective trials, but there has not been adequate data evaluating its safety and efficacy. Better understanding of treatment-related consequences for Y-SAC can help physicians to properly select the lesions effectively treated with this approach [9]. However, the approach needs many steps and is challenging, due passage of the second stent through the apertures of the first one. Y-stent is associated with leaving a large amount of metal in the parent healthy artery [13].

The use of dual stent-assisted embolization approaches leads to steadily preservation of the coils inside the sac and prevent protrusion of coils into the branched vessels. This method is used to manage the intracranial complex and WNBAs. However, the use of more stents in the original [parent] artery can be associated with increased rate of ischemic events [5].

Another feasible alternative to Y-stenting is the use of waffle-cone approach. It is consisted of deploying the distal end of a stent inside the aneurysmal sac, while the proximal end situated in the parent artery. The distal end of the stent is expanded to perform coiling. The approach main advantage is the that both bifurcation branches are not included in the endovascular treatment. Its safety and efficacy were reported in the small retrospective studies [14].

AIM OF THE WORK

To evaluate the Y stenting with Laser cut open cell stents safety and efficacy in complex WNBAs.

PATIENTS AND METHODS

This prospective clinical trial, which included 30 patients, was selected from the Psychiatry and Neurology Center at Tanta university. Samples were collected by the systematic consecutive method from December 2022 to December 2024.

We **included** patients of both genders, aged 18 to 70 years old, who were diagnosed with complex WNBAs with or without rupture. The WNBAs were defined as aneurysms with a large neck [>4 mm] and/or a fundus-to-neck ratio of < 2. On the other side, patients required surgery, those who had contraindication to general anesthesia or who are on anti-platelet medications and those who refused to participate in the study were **excluded**.

All patients were subjected to clinical evaluation by complete history taking, general and neurological examinations. The neurologic examination focusses on signs meningeal irritation [e.g., Neck Stiffness [Brudzinski's Sign and Kernig's Sign], conscious Level by Glasgow Coma Scale [GCS], focal neurologic deficits and fundus examination for papilledema. Further assessment included routine laboratory workup [e.g., CBC, ESR, C-RP liver and kidney function tests and coagulation profile]. Finally, the radiological assessment included CT brain and computed tomography angiography of cerebral vessels

The treatment procedure:

Patients without a recent history of subarachnoid hemorrhage received dual antiplatelet therapy one week before the intervention. It consisted of aspirin [150 mg] and clopidogrel [75 mg]. All procedures were completed under general anesthesia and heparin anticoagulation to prevent blood clot formation during the procedure. In cases of ruptured aneurysms, tirofiban was administered intravenously with loading and maintenance doses the loading dose was 25 mcg/kg IV infused within 5 minutes, followed by maintenance dose 0.15 mcg/kg/min IV, keeping in mind normal creatinine clearance, if it was CrCl ≤60 mL/min, maintenance dose was reduced 50 % to be 0.075 mcg/kg/min IV. The choice of the stent dimension and type take into consideration the diameters of both distal and proximal vessels. This ensures proper fit and support within the affected blood vessels. Then, navigation with micro-catheter over the guide-wire across the neck was performed, started with difficult branch to deploy one stent then navigation across the stent strut with microcatheter for deployment of the second stent in Y-manner. After deploying the Y-stent, a flat-panel CT [XperCT] was performed to assess the placement and effectiveness of the stent in treating the condition. This was followed by coiling through Stent Struts. This technique helps to secure the aneurysm and prevent further rupture. Angiographic images were taken in different projections [anteroposterior, lateral, and working] both before and immediately after the treatment to assess the results and confirm the success of the procedure. Patients received a dual

antiplatelet therapy for 3 months after the intervention, followed by aspirin alone for an additional nine months.

Outcome Measurements and Follow-up:

Primary outcomes: successful Application of Y stenting with laser cut open cell stents in treatment of complex wide neck bifurcation aneurysms and periprocedural complications occurred immediately with the treatment.

Secondary Outcomes: Evaluation of the safety and efficacy of Y stenting with laser-cut open cell stents in the treatment of complex wide neck bifurcation aneurysms with at least 1 year of follow-up and follow-up at 6 months and at year

Ethical Consideration: The study protocol was reviewed and approved by the local research and ethics committee review board [the approval code: DFM-IRB 00012367-23-02-008]. An informed consent was taken from conscious patients. The data were anonymized to preserve patient confidentiality.

Statistical Analysis: The collected data was coded, processed and analyzed using SPSS program for windows, version 18 [SPSS Inc., USA, Chicago, USA]. Descriptive statistics were calculated and included means, standard deviations, minimum, maximum, frequencies and percentages.

RESULTS

Regarding patient gender, there was 17 males [56.6 %] and 13 [43.4 %] female. The mean age of Studied Patients was 46.53±12.86 years. The potential risk factors included hypertension, diabetes mellitus, dyslipidemia and smoking, and these were reported among 23.3%, 10.0%, 23.3% and 23.3% successively **[Table 1]**

All patients received one session, One Neuroform stent, with coil but without balloon, another stent or other device was used. Two patients [6.7%] complicated by clot formation intraprocedural that was responded to aggrestat with complete resolution. In another patient [3.3%], there was perforation, SAH with no clinical sequalae. In addition, no correlation was reported by the follow up duration and the maximum size of the aneurysm [r =0.273, p = 0.144] [Data not tabulated].

Table [2] showed that, as regard Location there was 10 patients [33.3%] had aneurysm at Anterior communicating artery, 13 patients [43.3%] had aneurysm at middle cerebral artery bifurcation, 7 patients [23.4%] had aneurysm at Basilar tip. The mean of Maximum size was 7.9 ± 2.7. The mean of Neck size was 4.72 ± 1.38. None of patients had branch, as regard Type of aneurysm all patients had Saccular aneurysm.

Table [3] showed that, as regard follow up after 6 months there was 26 patients [86.7%] had complete occlusion, 2 patients [6.7%] had Neck remnant, 2 patients [6.7%] Recurrence with retreatment. As regard follow up after 1year, there was 28 patients [93.3%] had complete occlusion, 2 patients [6.7%] had Neck remnant.

Table [4] showed that, as regard Primary safety end points there was 1 patient [3.3%] had Major ipsilateral stroke, none of patients had Neurologic death, as regard Secondary end points there was 1 patient [3.3%] had Subarachnoid hemorrhage, 3 patient [10.0%] had Device-related serious adverse event, 1 patient [3.3%] had Target aneurysm rupture,

Table [1]: Demographic Characteristics and potential risk factors among Study Patients.

		Studied Patients [n=30]
Gender	Male	17 [56.6 %]
	Female	13 [43.4 %]
Age	Mean ±SD	46.53±12.86
Risk factors [n,%]	Hypertension	7[23.3%]
	Diabetes mellitus	3[10%]
	Dyslipidemia	7[23.3%]
	Smoking	7[23.3%]

Table [2]: Aneurysm data of Studied Patients.

		Studied Patients [n=30]
Location [n,%	A-com	10 [33.3%]
	MCA bifurcation	13[43.3%]
	Basilar tip	7[23.4%]
Maximum size	Mean ±SD	7.9±2.7
Neck size	Mean ±SD	4.72±1.38
Branching		0[0%]
Type [n,%]	Saccular	30[100%]

SD; Standard Deviation A-com: Anterior communicating artery ; MCA; middle cerebral artery

Table [3]: Follow up data of Studied Patients.

Variable	Studied Patients [n=30]	
	At 6 months after intervention	**At one year after intervention**
C.O	26 [86.7%]	28 [93.3%]
N. R	2 [6.7%]	2 [6.7%]
Recurrence with retreatment	2 [6.7%]	-
MRS	0	-

C.O; complete occlusion N. R; Neck remnant MRS; magnetic resonance spectroscopy

Table [4]: Safety Outcomes among study subjects

		Studied Patients [n=30]
Primary safety end points [n,%]	Major ipsilateral stroke	1[3.3%]
	Neurologic death	0 [0%]
Secondary safety end points	Subarachnoid hemorrhage	1[3.3%]
	Device-related serious adverse event	3 [10%]
	Target aneurysm rupture	1[3.3%]

Cases presentation:

Case no [1] was for a 52 years old female, who had hypertension and presented by headache. On CT brain, there was a SAH. The 3D angiographic view revealed RT MCA aneurysm with wide neck **[Figure 1A]**, which was confirmed in the working [coiling] view **[Figure 1B]**. The DSA showed deployment of first stent of RT MCA aneurysm **[Figure 1C]**, which **[Figure 1D]** revealed DSA showed deployment of second stent of RT MCA aneurysm. Finally, **[Figure 1E]** revealed DSA showing coiling with Y stent of RT MCA aneurysm with wide neck.

The second case **[Figure 2]** was for a male, 49 years old hypertensive smoker patients who was presented by severe headache. On CT brain, he had SAH. **[Figure 2A]** represented 3D angiographic

view showing the LT MCA bifurcation aneurysm with wide neck. **[Figure 2B]** showed the working [coiling] view. **[Figure 2C]** represented DSA show y stent and coiling of LT MCA aneurysm with wide neck.

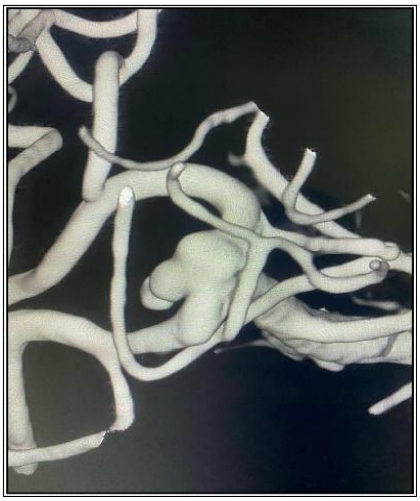

Figure [1A]: 3D angiographic view showing RT MCA aneurysm with wide neck

Figure [1B]: Working [coiling] view

Figure [1C]: DSA show deployment of first stent of RT MCA aneurysm.

Figure [1D]: DSA show deployment of second stent of RT MCA aneurysm

Figure [1E]: DSA show coiling with Y stent of RT MCA aneurysm with wide neck

Figure [2A]: 3D angiographic view showing the LT MCA bifurcation aneurysm with wide neck

Figuer [2B]: Working [coiling] view

Figure [2C]: DSA show y stent and coiling of LT MCA aneurysm with wide neck

DISCUSSION

The first stent introduced in 2002 to support the coiling of WNBAs. The insertion of the stent into the wide aneurysmal neck creates a mechanical scaffold preventing coils protrusion. In addition, the aneurysm thrombosis is progressively promoted and re-canalization impeded by the hemodynamic and biological characteristics of the stent [15, 16]. However, the endovascular management of complex bifurcating aneurysms remains a challenge due to presence of more than one side branch. This usually needs dual stenting in different configurations [17].

Chow *et al.* [12] introduced Y-sent assisted coiling, including the use of a combinations of open- and/or closed-cell stents. The stents introduced through microcatheters [with internal diameter of 0.027 or 0.021] [12, 18]. These catheters are often difficult in manipulation. Thus, they navigate through the sharp angled and small-sized side branches of aneurysmal bifurcations. In addition, trials to do catheterization during Y-stenting with large profile catheters through the struts of the first applied stent might results in the dislocation and deformation of the stent [19]. This led to development and introduction of the low-profile stents. This stent can be introduced by microcatheters [internal diameter of 0.0165 inch] [20].

This permits easily introduction and navigation through the small-sized vessels. This was associated with improved safety of stenting for distal WNBAs, which was confirmed in studies using Neuroform Atlas stents [6, 18, 21, 22].

The current prospective clinical trial, included 30 patients and aimed to evaluate the safety and efficacy of Y-stenting with Laser cut open cell stents in complex WNBAs. There were 17 [56.6%] males and 13 [43.4%] females. Their mean age was 46.53±12.86 years. These results are quite different than Aydin et al. [23] who included a total of 30 [20 females and 10 males]. Their mean age 52.4 ± 8.9 years old [range, 34-66 years old]. This may be explained by the different inclusion criteria and racial differences. In addition, Jadhav et al. [24] included 60 subjects. The mean age was 59, and 28.3% were men. Furthermore, **Cagnazzo *et al.*** [9] demonstrated that the mean age was 56.6 years [22–80 years], and males representing 36.0%.

The current study showed that, all patients required just one session, 29 patients [96.7%] used Neuroform stent, while the other one [3.3%] used Enterprise type stent, and all patients received two stents, with coil but non used balloon. An additional stent or device did not require for any subject. The content complications were in the form of intraprocedural clot formation [resolved by aggrestat], perforation and SAH with no clinical sequalae among 6.7%, and 3.3% respectively. Complications were hematoma, cerebral edema, thrombus and stroke among 6.7%, 6.7%, 3.3% and 3.3% successively, reflecting safety of the procedure. This is comparable to **Aydin *et al*.** [23] who reported that Neuroform Atlas stent had the advantages of both low-profile insertion microcatheters and the open-cell structure to provide a successful and potentially safe Y-stenting approach. The same authors demonstrated that Y-stenting was successfully completed without technical complications for all included patients [success rate of 100.0%]. However, the direct post-interventional angiography showed a total occlusion rate of 83.3%. the mean follows up duration was 11.8 months. The complete occlusion rate at the last follow up visit was 93.3%, with no mortality. The overall complications rate was 6.7%, with permanent morbidity for 3.3%.

In the current work, we reported a favorable angiographic and clinical outcome. This reflected that the use of Y-stent-assisted coiling offers an effective and a potentially safe, and durable endovascular treatment approach for WNBAs.

These results are in line with **Spiotta *et al.*** [25] who reported on the medium-term outcome of Y-stent-assisted coiling using the first- and second-generations of the Neuroform stents. The peri-procedural complications rate was 31.6%, which is slightly higher than the current study. The thromboembolic complications were recorded for 10.6%.

In addition, **Bartolini *et al.*** [20] reported a complications rate of 19.6% with permanent morbidity for 10.0% after Y- or X-stent-assisted coiling procedures. **Akgul *et al.*** [26] reported on the value of Y-stent-assisted coiling with various combinations of stents. They reported a permanent morbidity rate of 9.1%.

In the current work aneurysm was located in the Anterior communicating artery [10 patients; 33.3%]. However, 13 patients [43.3%] had aneurysm at middle cerebral artery bifurcation, 7 patients [23.4%] had aneurysm at Basilar tip. The mean of Maximum size was 7.9 ± 2.7. The mean of Neck size was 4.72 ± 1.38. None of patients had branch. All aneurysms were of the Saccular type.

Our results comparable to **Aydin *et al.*** [23] who demonstrated that there were 17 [56.7%] middle cerebral artery bifurcation [MCA], 10 [33.3%] anterior communicating artery [Acom], Basilar tip 2 [6.7%] and pericallosal artery 1 [3.3%]. Moreover, **Jadhav *et al*.** [24] reported that commonest presenting anatomic locations were the basilar apex [56.7%; 34/60], anterior communicating artery [20.0%; 12/60], and middle cerebral artery bifurcation [11.7%; 7/60].

In addition, **Bartolini *et al*.** [20] reported that 105 aneurysms were treated. There were 54.2% in MCA, 28.6% for anterior communicating artery, 16.2% for basilar tip, and 1.0% for ICA termination aneurysms.

This study showed that at the end of the sixth month of follow up, there were 26 patients [86.7%] had complete occlusion, 2 patients [6.7%] had neck remnant, 2 patients [6.7%] had recurrence with retreatment. At 12 months, there were 28 patients [93.3%] with complete occlusion, 2 patients [6.7%] with neck remnant. The potential risk factors for stroke were reported as the following: 7 [23.3%] had hypertension, 3 [10%] had diabetes mellitus, 7 [23.3%] had dyslipidemia, and 7 [23.3%] were smokers.

These results are comparable to **Aydin *et al*.** [23] who demonstrated that the mean follow-up time was 11.8 ± 7.8 month. At 6-month follow-up, one patient ha persistent filling of the aneurysmal sac. This patient was re-treated by coiling. Their 12-month follow-up demonstrated complete aneurysmal occlusion. The final follow-up showed successful occlusion in 93.3% and partial occlusion in 6.7%. The follow-ups of 6.7% with partial direct occlusion showed complete occlusion [progressive occlusion over time].

In addition, **Gunkan *et al*.** [6] investigated the safety and efficacy of the newer Y-stent-assisted coiling for the treatment of WNBAs. The complete occlusion rate was 98.0%. After a follow-up of 15 ± 2.4 months, good clinical results were observed in 98%. The recorded a rate of 1.3% and 0.4% for procedure-related complications and mortality, respectively. Furthermore, **Cagnazzo *et al*.** [9] demonstrated that the immediate occlusion rate was 82.2%, whereas the long-term occlusion rate was 95.4%. The aneurysm recanalization was reported

for 3% and half of these aneurysms need retreatment. The treatment-related complications were reported for 8.9%. **Chalouhi *et al*.** [27] reported that the recurrence risk was significantly lower for aneurysms treated with stent-assisted coiling than for aneurysms treated with primary coiling or balloon remodeling approaches. Stents have a biological and hemodynamic characters to promote the progressive aneurysmal occlusion and reduce the risk of recurrence. **Limbucci *et al*.** [28] reported that the immediate occlusion rate was 87.5% for patients treated by Y-stent-assisted coiling. On the other side, **Kim and Chung** [29] aimed to report on Neuroform Atlas Y-stenting for unruptured WNBAs. They reported that the direct aneurysmal occlusion rate was 46.7%, which was relatively lower than previous studies.

The correlation analysis revealed that follow up exhibit no correlations with maximum size and regarding the primary safety end points, there was 1 [3.3%] with major ipsilateral stroke, and none of patients had Neurologic death. In addition, the secondary end points revealed that, there was 1 [3.3%] with SAH, 3 patient [10.0%] had device-related serious adverse event, 1 [3.3%] had target aneurysm rupture. Our results are comparable to **Jadhav *et al*.** [24] who reported that treatment of WNBAs using the Neuroform Atlas Stent System resulted in complete aneurysmal occlusion without stenosis of the parent artery or the need for aneurysm retreatment in 81.1% and major ipsilateral stroke or neurological death was recorded for 1.7% of subjects.

It is important to confirm that, not all locations of bifurcation aneurysm are amenable to intra-Saccular device placement and occlusion rates are largely depend on the anatomy and size of the treated aneurysms [30,31]. For example, **Bartolini *et al*.** [20] reported that, placement of Y-stent to treat 87 aneurysms, X stent used to treat 7 aneurysms, while 9 procedures failed for 11 aneurysms. There were 10.0% procedure-related permanent neurologic deficits and 1.0% death. The direct angiographic studies showed a complete occlusion in 47.6% and a partial occlusion in 52.4%. the recanalization rate was 5.9%. At the final follow-up records, the mRS score was 0 in 83.5%, 1 in 4.1%, 2 in 3.1%, 3 in 4.1%, 4 in 3.1% and 6 in 2.1%.

Cekirge *et al*. [32] described a “flow remodeling effect” in aneurysms treated by Y closed-cell stents. However, these stents demonstrated a promising outcome in their study of 193 bifurcation aneurysms, with a recanalization rate of 2.2%. Finally, Kim and Chung [29] concluded that Neuroform Atlas Y-stent is an effective treatment method for the complex bifurcation aneurysms. **Jadhav *et al*.** [24] concluded that Y-stent–assisted coiling of WNBAs using the Neuroform Atlas Stent System is a potentially safe and effective with several advantages over the conventional Y-stent–assisted coiling approaches.

Conclusion: The Neuroform Atlas stent achieves a safe and effective Y-stenting by combining the benefits of open-cell architecture with low-profile deployment microcatheters. This study's positive angiographic and clinical results confirmed that wide-necked complicated bifurcation aneurysms can be effectively treated endovascularly using Y-stent-assisted coiling. This procedure is safe, long-lasting, and effective. However, results must be treated cautiously due to small sample size, future studies using on large scale with longer duration of follow up are highly recommended.

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