



Safety and efficacy of intracranial aneurysm embolization using the “combined remodeling technique”: low-profile stents delivered through double lumen balloons: a multicenter experience

Mario Martínez-Galdámez¹ · Kirill Orlov² · Krzysztof Kadziolka³ · Mani Puthuran⁴ · Vladimir Kalousek⁵ · Boris Pabón⁶ · Jorge Escartín¹ · Claudio Rodríguez¹ · Arun Chandran⁴ · Dmitry Kislitsin² · Vadim Berestov² · Pedro Vega⁷ · Carlos Diaz⁶ · Guilherme Dabus⁸

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Abstract

Purpose Since appearance of the balloon-remodeling technique and stent-assisted coiling, complex aneurysms have been treated successfully by endovascular means worldwide. Although these two techniques have been widely proven, the combination of both traditionally made the procedures more complicated technically. The aim of our study was to determine the technical success, safety, and efficacy of the low-profile stents delivered through double lumen balloons.

Methods Clinical, procedural, and angiographic data were analyzed.

Results Eighty-four patients (55 women; age range 20–81 years) harboring 86 aneurysms were included in this study. Aneurysm maximal diameter ranged from 2 to 26 mm, with mean 7.5 mm. There were 62 unruptured, 15 recanalized, and 9 acutely ruptured aneurysms. Aneurysm locations were ACoA (31), MCA (36), supraclinoid ICA (4), carotid bifurcation (2), basilar (7), PCA (3), PICA (2), and VA (1). Ninety-three devices were implanted (63 LVIS jr, 15 LEO Baby, 14 ACCLINO Flex and 1 Neuroform Atlas) through the double lumen balloons (Scepter C or XC and Eclipse 2 L). We found 2 minor clinical events (2.4%) and 1 major event (1.2%). Total intra-procedural technical complication rate was 11.6%. Follow-up was available for 71 patients with an average follow-up of 7 months. Complete and near complete occlusion was 90.1%. Residual aneurysms were seen in 9.9%.

Conclusion The “combined remodeling technique” with low-profile stents delivered through double-lumen balloons is technically feasible, safe, and effective for the treatment of intracranial aneurysms. This technique allows the operator to avoid extra maneuvers.

Keywords Intracranial aneurysm · Double-lumen balloon · Low-profile stent

✉ Mario Martínez-Galdámez
mariomgaldamez@hotmail.com

¹ Endovascular Neurosurgery/Interventional Neuroradiology, Hospital Universitario Fundación Jiménez Díaz, Grupo Quironsalud, Madrid, Spain

² Endovascular Neurosurgery, Neurosurgery Department, National Medical Research Center, Meshalkin Clinic, Novosibirsk, Russian Federation

³ Endovascular Neurosurgery, Neurosurgery Department, The Children's Memorial Health Institute, Western Hospital, Grodzisk Mazowiecki, Poland

⁴ Department of Neuroradiology, The Walton Centre NHS Foundation Trust, Liverpool, UK

⁵ Interventional Neuroradiology, Department of Radiology, Clinical Hospital Center “Sestre Milosrdnice”, Zagreb, Croatia

⁶ Interventional Neuroradiology, Angioteam-Angiosur, Medellín, Colombia

⁷ Interventional Neuroradiology, Radiology Department, Hospital Universitario Central de Asturias, Oviedo, Spain

⁸ Endovascular Neurosurgery, Miami Cardiac and Vascular Institute and Baptist Neuroscience Center, Miami, FL, USA

Abbreviations

CRT Combined remodeling technique

Introduction

Endovascular treatment of intracranial aneurysms has become a routine first-line treatment option for an increasing number of intracranial aneurysms at many neurovascular centers. Although simple coiling is a globally accepted treatment for ruptured and unruptured aneurysms, recanalization is the main limitation for its use, especially for wide-necked and complex aneurysms [1].

Adjunctive techniques such as balloon remodeling [2, 3] and stent-assisted coiling [4, 5] have expanded the indication of the endovascular technique, allowing the treatment of wide-neck aneurysms, decreasing recanalization rates by potentially achieving higher packing of the aneurysm lumen^{2,3}, and also by flow re-directioning in cases of stent assisted coiling [4, 5]. Both techniques, balloon remodeling, and stent-assisted coiling, have advantages and disadvantages, and the literature does not support a clear superiority of one over the other. Despite the fact that stent-assisted coiling may achieve better complete occlusion rates compared to balloon-assisted coiling, higher thromboembolic and hemorrhagic complications have been described [6, 7].

With the recent advances in balloon and stent technology, endovascular procedures can be technically optimized (combined remodeling technique) decreasing the need for extra maneuvers, and therefore, the risk of complications while potentially improving packing density and recanalization rates [8–10].

To our knowledge, the specific use of low-profile stents through double lumen balloons has been only reported in small series or as a subgroup of case series [8, 9]. We present a multicenter experience in a consecutive series of patients that were treated with the combined remodeling technique (CRT) (double lumen balloon and low-profile stents). The aim of our study was to evaluate the technical success, safety, and efficacy of the low-profile stents delivered through double lumen balloons for the treatment of intracranial aneurysms.

Material and methods

Clinical and radiological data were obtained retrospectively from 86 consecutive patients presenting with ruptured and unruptured aneurysms at 8 centers from January 2015 to December 2017. All cases were treated with low-profile stents delivered through double lumen balloons. The study was approved by each institutional review board. All procedures were performed after obtaining written informed consent.

Data collection included clinical presentation, aneurysm size and location, device or devices used, procedural and angiographic data. Angiographic and clinical data were analyzed, self-reported by each operator. All complications were recorded and reported during the time of hospitalization. Complications were defined as follows: (a) ‘major’ adverse event was considered to be an ongoing clinical deficit at 7 days after the event; (b) ‘minor’ adverse events were considered as events that resolved within 7 days with no clinical sequelae. All major adverse events are included in the neurologic morbidity and mortality rates. Follow-up clinical and imaging data were also obtained. Follow-up imaging was performed with either DSA or MRA depending on each center’s preference.

Statistical analysis (GraphPad Software, Inc., La Jolla, CA, USA) was performed using Fisher exact test for categorical variables association whenever appropriate. Findings were statistically significant if $p < 0.05$.

Procedures

The unruptured cases were premedicated with double antiplatelet therapy 5 days on average before the intervention, and each institution followed its own protocol. Platelet function tests were not performed. In the acute ruptured cases, intravenous infusion of glycoprotein IIb/IIIa antagonists was used as protocol.

An initial 70–100 U/kg of heparin bolus was given and the activated clotting time was maintained at twice the patient’s baseline level intraoperatively. Heparin was discontinued but not reversed at the end of the procedure. Dual antiplatelet therapy was continued after discharge.

The type and size of stent used was based on operator’s criteria. Devices were deployed either through an Eclipse 2 L (Balt Extrusion, Montmorency, France) or Scepter (C or XC)(MicroVention, Aliso Viejo, CA, USA) double lumen-balloons. All clinical events occurring intra and postoperatively were recorded.

Results

Eighty-four patients (55 women, 31 men; age range 20–81 years) harboring 86 aneurysms were included in this study.

Aneurysm maximal diameter ranged from 2 to 26 mm, with mean 7.5 mm. There were 62 unruptured, 15 recanalized (all previously ruptured), and 9 acutely ruptured aneurysms. As mentioned, unruptured aneurysms were treated using standards regimens of anti-aggregation. Ruptured aneurysms were treated using Eptifibatide (3 cases) and Tirofiban (6 cases), followed by standard regimens after treatment. Aneurysm locations were ACoA (31), MCA (36), supraclinoid ICA [4], carotid bifurcation [2], basilar [7], PCA [3], PICA [2], and VA [1] (Table 1).

Table. 1 Aneurysm population and occlusion results

Aneurysm size population, N:86	Aneurysm occlusion rate Raymond–Roy classification (RR)	Immediate post treatment angiographic result, N: 86	Last follow-up: ≤6 months, N:35	Last FU: > 6–< 12 months, N:12	Last FU ≥ 12 months, N: 24	According to last follow-up at any time (average 7 months), N:71
Small aneurysms, N: 76						
	Complete occlusion (RR 1)	60/86 (69.8%)	29/71 (40.8%)	11/71 (15.5%)	11/71 (15.5%)	51/71 (71.8%)
	Residual neck (RR 2)	14/86 (16.3%)	2/71 (2.8%)	1/71 (1.4%)	3/71 (4.2%)	6/71 (8.45%)
	Residual aneurysm (RR 3)	2/86 (2.3%)	0	0	5/71 (7%)	5/71 (7%)
Large aneurysms, N: 9						
	Complete occlusion (RR 1)	7/86 (8.1%)	2/71 (2.8%)	0	4/71 (5.6%)	6/71 (8.45%)
	Residual neck (RR 2)	2/86 (2.3%)	0	0	1/71 (1.4%)	1/71 (1.4%)
	Residual aneurysm (RR 3)	0	1/71 (1.4%)	0	0	1/71 (1.4%)
Giant aneurysms, N: 1						
	Complete occlusion (RR 1)	0	0	0	0	0
	Residual neck (RR 2)	1/86 (1.2%)	0	0	0	
	Residual aneurysm (RR3)	0	1/71 (1.4%)	0	0	1/71 (1.4%)

*Follow-up was available for 71 aneurysms. Only last follow-up occlusion rate was considered for analysis

Small aneurysms: < 10 mm

Large aneurysm: ≥10–< 25 mm

Giant aneurysm: ≥ 25 mm

Scepter C or XC and Eclipse 2 L double-lumen balloons were used in 71 and 15 aneurysm treatments respectively. All the low-profile stents available in the market were evaluated, both braided and laser-cut (63 LVIS junior (MicroVention, Aliso Viejo, CA, USA), 15 LEO Baby (Balt Extrusion, Montmorency, France), 14 ACCLINO Flex (Acandis GmbH & Co. KG, Pforzheim, Germany) and 1 Neuroform Atlas (Stryker Neurovascular, Fremont, CA, USA). In 52 of 86 cases, the operator decided to use the combined technique as first option; in the remaining 34 cases, combined technique was used as a bailout because of branch occlusion, coil protrusion, or instability during balloon remodeling (Table 2). Ninety-three devices were implanted (63 LVIS jr, 15 LEO Baby, 14 ACCLINO Flex, and 1 Neuroform Atlas) through the double lumen balloons. Navigation and compatibility were effective in 100% of the cases; every stent/device was successfully deployed in the target location. Six out of the 78 total braided stents (5 LVIS Jr. and 1 Leo Baby) used required post-deployment angioplasty (7.7%) compared to 0% of the laser cut ($p=0.58$). Initial wall apposition was excellent in 42 devices immediately after deployment. Forty devices fully-opened after the removal of a jailed microcatheter. Angioplasty was performed in 6 and mild stent

underexpansion (device not fully apposed to the vessel wall (75%–99%) was seen in 5 cases.

Immediate angiographic results demonstrated Raymond 1, 2, and 3 occlusion rates of 77.9%, 19.7%, and 2.3% respectively.

All the clinical events occurred in elective cases: 2 minor clinical events (2.4%) and 1 major event (1.2%). The two minor events were both mild transient upper extremity weakness that resolved after 48 and 72 h. The major event was a case where two stents were used as bailout strategy after a WEB (WEB™ Aneurysm Embolization System, MicroVention, Aliso Viejo, CA, USA) deployment resulting in mortality. While one minor event was attributable to the stent (branch thrombus), the other was secondary to a microwire distal perforation (focal SAH). In the case of the major event, the bailout strategy failed to recanalize the previously occluded branches. Considering the 86 aneurysms treated, the total intra-procedural technical complication rate was 11.6% ($n=10$): 3 in-stent thrombosis, 2 of which resolved with medication (1 stent thrombosed resulted in death); 4 branch thrombus treated with medication (1 had transient upper extremity weakness lasting 2 days (mRS 0), and 3 cases with no clinical consequences) and 3 focal SAHs controlled

Table 2 Intraprocedural complications

Procedural complication	Aneurysm max diameter (mm)/location	Aneurysm status	Management	Clinical consequence	Aneurysm last follow-up result
Stent thrombosis	7 mm /MCA bif	Unruptured	PTA + iv Eptifibatide Resolved	No	Residual neck/12 months
Stent thrombosis	7 mm/Basilar tip	Unruptured	PTA + iv Eptifibatide Not resolved	Death	NA
Stent thrombosis	3 mm/AcoA	Unruptured	iv Eptifibatide Resolved	No	Total occlusion 9 months
Branch thrombus	9 mm/AcoA	Recanalized, previously ruptured	IVAbciximab Resolved	No	Complete occlusion/12 months
Branch thrombus	4 mm/ACA A2–A3	Ruptured	iv Tirofiban Resolved	No	Total occlusion 12 months
Branch thrombus	8 mm/MCA bif	Unruptured	iv Tirofiban Resolved	No	Total occlusion 7 months
Branch thrombus	11 mm/MCA bif	Ruptured	iv Tirofiban Resolved	Transient upper extremity weakness	NA
Focal SAH	6 mm/MCA bif	Unruptured	Balloon inflation bleeding discontinued	No	Total occlusion 9 months
Focal SAH	9 mm/AcoA	Recanalized, previously ruptured	Balloon inflation bleeding discontinued	Transient Upper extremity weakness	Total occlusion 9 months
Focal SAH	4 mm/MCA bif	Unruptured	Balloon inflation bleeding discontinued	No	Total occlusion 6 months

with balloon inflation (2 with no clinical manifestation despite 1 secondary vasospasm, and 1 transient upper extremity weakness lasting 3 days (mRS 0) (Table 2).

Two intra-procedural complications occurred in patients that presented with ruptured aneurysms (two branch occlusions) while the others occurred in patients with unruptured aneurysms. Thromboembolic complications (either in-stent thrombosis or branch thrombus) were similar ($p = 1.0$) when comparing braided versus laser cut stents: 6 out of 78 (7.7%) versus 1 out of 16 (6.2%). Follow-up was available for 71 patients (85% of the cases), with an average follow-up of 7 months (range 3 to 14 months). Complete and near complete occlusion was 90.1%. Raymond-1 occlusion rate was 80.3% (57 out of 71), and Raymond-2 with stable neck remnant in 9.9% (7 cases). Residual aneurysm (Raymond-3) was seen in 9.9% (7 out of 71) in follow-up. There were no stent thrombosis or late complications reported during follow-up.

Discussion

Our results demonstrate that CRT for treatment of intracranial aneurysms is safe (1 major and 2 minor events) and effective with 90.1% rate of complete/near complete occlusion at an average follow-up period of 7 months.

Endovascular therapy has become the first-line treatment for most types of intracranial aneurysms; however, endovascular coiling can be challenging especially in wide-

necked or complex aneurysms. The major drawback of endovascular therapy is high rate of aneurysm recanalization [1, 2]. In a systematic review of the literature that included 8161 coiled aneurysms, Ferns et al. [11] reported aneurysm recanalization in 20.8% of cases and retreatment in 10.3% and identified posterior circulation location and size 10 mm or greater as risk factors for aneurysm recanalization.

Balloon remodeling or balloon-assisted coiling has been successfully used throughout the years to treat wide-necked aneurysms. Shapiro et al. [3] demonstrated that balloon usage was associated with superior initial and follow-up angiographic occlusion rates. Similar results were reported by Dabus et al. [12] in a prospective series.

The use of assist devices such as balloons or self-expanding stents has remarkably improved the long-term durability of endovascular treatment [13, 14]. It has been proposed that stent-assisted coiling achieves better complete occlusion rates compared to balloon-assisted coiling, but with the downside of higher thromboembolic and hemorrhagic complications. Although an interesting thought, this has not been supported by the literature in cases of unruptured aneurysms [5–7]. Even more, as Gentric et al. [15] demonstrated, there may be a synergistic effect of the combined strategy, since balloon remodeling may improve angiographic results of stent-assisted coiling of unruptured intracranial aneurysms with no added morbi-mortality.

Despite the promising results, the technical execution of the remodeling technique followed by stenting was relatively

complex, as it was necessary to withdraw the remodeling balloon, place a microcatheter distal to the aneurysm neck and, finally, deploy the stent. Additional steps like exchange maneuvers or multiple approaches were necessary, increasing the technical complexity, procedural time, and the potential for complications. Also navigability was limited, considering that delivery of the first available self-expandable stents as Neuroform or Enterprise, was only possible through 0.021 to 0.027-in. microcatheters [16–18].

In the last years, the issue of trackability has been solved after the introduction of new-generation stents deliverable via 0.0165 in., called “low-profile stents” (LVIS jr [19], Leo Baby [20], Neuroform Atlas [21] and Acclino stents [22]. Shankar et al. [19] published a retrospective multicenter analysis of 100 patients treated with LVIS jr with 3% permanent neurological deficits and 1% mortality. Aydin K et al. [20], reported a 3.8% of permanent morbidity rate and no mortality in 80 patients treated LEO Baby. Derya Tureli et al. [22] showed a series of 47 patients treated with the Acclino stent (laser cut, closed-cell), with overall procedure-related morbidity of 4.2% and no permanent neurological deficits. Cay F et al. [21], showed a 55 consecutive aneurysms treated with Neuroform ATLAS, reporting only a minor stroke in a patient who completely discontinued antiplatelet therapy on postoperative day 4, and no clinical events with permanent sequelae.

New double lumen-balloons, which are compatible with 0.014” microwires, are more stable compared to first generation balloons that used 0.010” microwires, and also having two independent lumens, gives the operator the opportunity to navigate coils or low-profile microstents while the balloon is still inflated.

The specific use of low-profile stents through double lumen balloons has been only reported in small series or as a subgroup of case series. Kadziolska et al. [9] and Spiotta et al. [8], described the successful combination of double lumen balloons with LVIS jr Stent in 2 and 1 cases respectively, with no technical complications.

In our series, all available low-profile stents were used. Technical success was 100%, with no compatibility or trackability limitations. However, 6 of the 78 total braided stents (5 LVIS Jr. and 1 Leo Baby) used required post-deployment angioplasty (7.7%).

Higher complication rates have also been reported when stents were used for bailout [22]. In our series, the combined technique was used as a bailout in approximately 40% of the cases and was responsible for the 2 minor clinical events (2.4%) and 1 major event—death (1.2%) seen in our series.

The CRT combines the advantages of the two techniques. Balloon assistance allows neck remodeling, protective inflation in case of intra-procedural perforation,

and angioplasty in case of stent mal-apposition. On the other hand, stent placement may improve recanalization rates and can be used as bailout in case of coil instability and parent artery/branch protection. These concepts have been corroborated in our series considering that recanalization rate at follow-up was only 9.9%, and stent placement was used as bailout in 39.5% of cases. Additionally, there were 3 perforations controlled with balloon inflation and another 6 cases that required in-stent angioplasty. Also, using CRT no additional exchange or extra maneuvers were needed decreasing the procedural risks.

Despite the promising results, larger prospective series of cases are needed to corroborate the effectiveness and safety of this treatment method and its superiority to other techniques.

Limitations of the study

This study has a number of limitations. First, this was a retrospective, non-randomized study, which introduces selection bias; therefore, comparing results between different stent types is not possible. Second, there is great variability in how operators perform the procedure, which may lead to different safety and occlusion outcomes. Third, like most of the other reported series, the team of treating physicians adjudicated the angiographic and the clinical results. Despite the encouraging angiographic results on the patients that have completed short-term follow-up, drawing conclusions in regard to recurrence and recanalization based on this number patient follow ups is limited.

Conclusion

Our study indicates that the “combined remodeling technique” using low-profile stents delivered through double-lumen balloons is technically feasible, safe, and effective for the treatment of intracranial aneurysms. This technique allows the operator to avoid extra maneuvers.

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Compliance with ethical standards

Conflict of interest GD consults for Microvention/Terumo.

Ethical approval All procedures performed in the studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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