FEASIBILITY, SAFETY AND COST EFFECTIVENESS OF SINGLE STENT ASSISTED **COILING TECHNIQUE IN SPECIFIC DIFFICULT ANATOMIES** (A SERIES CASE REPORT - TWO CENTRES EXPERIENCE)

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Accepted July 27, 2018

The goal of this paper is to expose the advantages of single stent assisted coiling technique in specific difficult anatomies as well as costs effectiveness in our cases selection over flow diverter technique. In our opinion the stent assisted coiling technique represents a safe and feasible technique when preserving the bifurcation and complete exclusion of aneurismal sac is achievable with only one intracranial stent. Objective: To assess the safety and efficacy of single stent-assisted coiling, in addition to analysing the costs per case in our retrospective series. Methods: A retrospective analysis of all aneurisms treated with a single stent-assisted coiling technique in two Romanian hospitals between August 2015 and August 2017 (2 years) was performed. Clinical and angiographic evaluation was collected and also complication rate and costs per patient were quantified. Results: A total of 6 aneurysms (2 ruptured and 4 non-ruptured) were treated with single stent-assisted coiling. No morbidity/mortality occurred. Immediate occlusion was complete in 5 of 6 cases and only one presented incomplete occlusion at 12 months follows up. Conclusion: The treatment of bifurcation wide neck aneurysms or side-wall carotid aneurysms using single stent technique for stent-assisted coiling is safe and effective. More over costs per patient has been quantified and were below the treatment with flow diverter technique. In certain anatomies needs future randomised studies between single stent assisted coiling technique and flow diverter technique in order to respond to long term recanalization rate or treatment related complication rate.

Keywords: Intracranial aneurysm, single stent assisted coiling technique, coils embolization, flow diverter technique.

INTRODUCTION

Endovascular treatment (EVT) nowadays is preferred to surgical clipping for both ruptured and unruptured intracranial aneurisms as ISAT, Clarity and ATENA studies proved in last years¹⁻³. Several well developed and safe techniques are now available on our field: balloon-assisted coiling, stent-assisted

coiling, flow diversion, bifurcation-bridging and intrasaccular devices^{4, 5}. Last two techniques are increasing and still "young" but promising to offer new approaches especially in wide neck aneurysms^{6,7}. The technical limitation of treatment for wide neck aneurisms with branch arising from the sac is remaining even in present a challenge in our field⁸. We still don't know if flow diverter stent, in a middle cerebral artery bifurcation aneurysms is safe or not, due to covered branch thromboembolic

Proc. Rom. Acad., Series B, 2018, 20(3), p. 207-216

events which were evaluated by different teams with different results^{9, 10} .WEB device can be a perfect solution only to a part of bifurcation aneurisms in cases where the rapport of neck versus maximal diameter is equal or higher than 1.In those cases where this rapport is below 1 stent assisted coiling or flow diverter technique remain preferable options for EVT^{11,12}. In this situation an important aspect is that the stent assisted technique remains the only feasible solution, especially in nondeveloped countries that health system doesn't reimburse the FD stent costs.

MATERIALS AND METHODS

The retrospective study was approved by the Ethics Committees in our two institutions (County Emergency Hospital "Pius Branzeu" of Timisoara and Sanador Hospital Bucharest). Written informed consent was obtained from each subject or their representative. We identified a number of 6 patients treated in our two institutions (County Emergency Hospital "Pius Branzeu" of Timisoara and Sanador Hospital Bucharest) between August 2015 and August 2017 (2 years). Two of this patients presented subarachnoid haemorrhage (SAH) 3-4 weeks before endovascular treatment and due to anatomic location (vertebro-basilar junction-VBJ in first case and left para-ophtalmic aneurism in second case) surgical clipping was excluded. Both patients were classified grade 1 according to the Hunt and Hess (HH) scale. The other 4 non-ruptured aneurysms were asymptomatic and represented incidental findings. The mean age was 45.1 years (range from 27 to 61 years). All patients underwent conventional angiography of both carotid and vertebral arteries.3D-DSA was performed to depict aneurism morphology and branches incorporated in the aneurism base. The median aneurism diameter was 6.28 mm, the median neck size was 5.45 mm and median high was 4.98 mm as showed in Table 1.Most of them (3 out of 6) were located in ophthalmic segment of internal carotid artery, one was situated in terminal carotid segment as side wall aneurysms, one was situated at middle cerebral artery bifurcation and the 6'th one was situated at the vertebra-basilar junction level.

ENDOVASCULAR PROCEDURE

Endovascular treatment was performed for all 6 patients under general anaesthesia and systemic

heparinization. Doubling the baseline of activated clotting time (ACT) was achieved in all our patients by bolus infusion of heparin (30-50 IU/kg body weight) and followed by continuous drip (1000 to 1500 IU/h). In all non-ruptured cases was administrated, 1 day before treatment, Ticagrelor 2*90 mg per day and Aspirin 150 mg per day. The double antiplatelet therapy was prescribed for 3 months post procedure and after this period only Aspirin 150 mg per day was recommended for next 9 months. For the two ruptured aneurysm the fact that the treatment was performed at 3-4 weeks after haemorrhagic event was judged to be safe to premedicate this patients only one day prior to EVT. A loading dose of 300 mg Plavix 75 mg and after the double antiplatelet therapy (Plavix 75 mg per day and Aspirin 150 mg per day) was prescribed for 3 months post procedure and after this period only Aspirin 150 mg per day was recommended for the

Our treatment strategy consisted in all cases in placement of a conventional self-expandable stent in front of aneurism neck. After this stage the micro-catheter was carefully placed inside the aneurism sac through the stent struts and coiling was performed. Jailing technique was not used in our series cases. No stent was retrieved after the procedure. Three types of stents were used: in 4 cases Solitaire AB (ev3 Neurovascular, Irvine, CA, USA), in one case Barrel stent (Medtronic, Minneapolis, Minnesota, USA) and in one case LVIS stent (Microvention, CA, USA). The first 3D coil cage was placed through the micro-catheter (Echelon 10- ev3 Neurovascular, Irvine, CA, USA, used in all 6 cases) positioned in the centre of the aneurismal sac. During coiling, angiographic controls have been performed in order to exclude clot formation. After EVT patients were transferred in the intensive care unit and neurological status and blood pressure were carefully monitored for the next 24 hours.

next 9 months.

RESULTS

TECHNICAL RESULTS

Single stent assisted coiling technique was used in all our series for anatomic but also for financial reasons. All 6 stents were implanted with successful complete coverage across the aneurysm neck and parent artery patency. Coiling was realised by Axium (ev3 Neurovascular, Irvine, CA, USA) or by Microvention (Microvention, CA, USA) coils.

ANATOMIC RESULTS

All cases were evaluated according to the simplified three-point Jean Raymond classification scale: complete occlusion, neck remnant, and aneurysm remnant. Complete occlusion was achieved in 5 of 6 aneurisms and in the case of VBJ, the small aneurysm remnant was considered acceptable due to anatomic conditions.

CLINICAL RESULTS

Intra-procedural complication were not observed. No delayed thromboembolic or haemorrhagic events were noticed in our 6 cases. Clinical outcome was graded according to the modified Rankin Scale (mRS). There was no procedure – related morbidity or mortality.

COSTS ANALYSIS

In all 6 cases the total cost of materials used to treat the patients was quantified. The micro catheter used for delivering the stents (Rebar 27- ev3 Neurovascular, Irvine, CA, USA or Headway 21-Microvention, CA, USA) and also micro-wire (all cases Avigo- ev3 Neurovascular, Irvine, CA, USA wire was used) and guide catheter Neuromax 6F(Penumbra, Inc., Alameda, California, USA) war quantified for total cost per procedure. In all 6 cases the cost was below (average cost was 6.983 Euro per patient) the price of flow diverter technique that could has been used instead (11.000-12.000 Euros for FD technique).This aspect is important especially when the procedures are done in public health systems. Moreover the good sizing of coils leads in the end to less materials costs and sac manipulation due to less number of coils used.

PATIENT FOLLOW-UP

Conventional angiography was performed for one patient at 12 months follow up. Second patient was controlled by MRA at 7 months post EVT. The other 4 patients were treated just 1 month prior to the article submission and didn't benefit from follow up control.

CASE 1

VBJ - Vertebro-basilar junction fusiform shape challenging are still for both aneurysms neurosurgical and neuro-endovascular approaches. The case referred to our department was an 68 y old female, with subarachnoid bleeding Ficher 3, Hunt Hess Scale = 1, due to an ruptured fusiform shape aneurism, 3 weeks before EVT with the particularity that both distal vertebral arteries presented important stenosis (more than 50%) immediate before entering inside aneurism sac. Due to this anatomic situation and also the initial CGS =14the endovascular treatment had been intentionally postponed 22 days after the acute bleeding episode and the patient benefit of an external ventricular derivation due to progressive hydrocephalus and neurological deterioration with good clinical result, CGS = 15 at day 12 post SAH.



Figure 1. Pre-op Angio Ct Volume Rendering (A) and MIP (B) reconstructions showing vertebro-basilar junction fusiform shape aneurism and also distal vertebral bilateral atherosclerotic stenosis (around 50-60%).

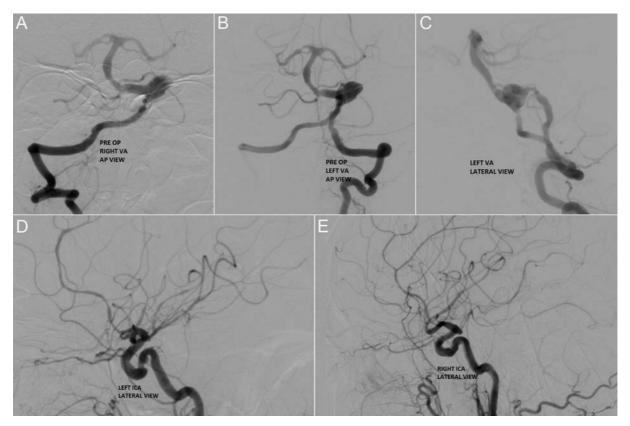


Figure 2. Pre-embolization angiographic evaluation.

The angiographic evaluation confirmed the Angio-Ct findings and revealed that the stent placement was mandatory due to fusiform shape and involvement of both vertebral arteries as seen in Fig. 1. In the same time due to distal vertebral bilateral atherosclerotic stenosis the flow-diverter or braded stents and balloon angioplasty also were judged to have a higher risk of intra-procedural or post-operative acute thromboembolic events. Both posterior communicating arteries were evaluated and the fact that they had very thin calibre imposed that the vertebro-basilar junction had to be reconstructed as only endovascular treatment solution (Fig. 2).

In this conditions jailing technique together with laser cut detachable stent placed between inferior part of basilar artery and the less stenosed vertebral artery – left vertebral artery (Medtronic, Solitaire AB 4*20 mm detachable stent) ware chosen as strategy of EVT (Fig. 4). Placement of the stent between left vertebral artery and basilar trunk was decided due to slightly better distal calibre of this artery and also due to anatomic configuration of the aneurism sac allowing having in the end of the embolization both vertebral arteries patent (as draw in Fig. 3). Via the jailed Echelon 10 micro catheter we deployed 7 Microvention Coils without any incident allowing a good angiographic exclusion of the aneurism (Fig. 5).

First an Echelon 10 micro catheter over an Avigo micro-wire was placed in the aneurismal sac via an Envoy 6F catheter placed in left vertebral artery. Secondary a Rebar 18 micro catheter over an Avigo micro-wire was placed in the distal part of basilar artery. A 4*20 mm Solitaire AB stent was placed but not detached between the inferior third part of basilar artery traversing the aneurism itself and the distal end of left vertebral artery (Fig. 4).

The post-embolization angiographic evaluation of both vertebral arteries confirmed their patency and also almost complete exclusion of the fusiform aneurismal lesion.

The patient was pre-medicated with 300 mg of Plavix and 150 mg of Aspirin 24 h before the procedure. The double anti-platelet therapy was prescribed for 3 months (75 mg per day Plavix and 150 mg per day Aspirin) and another 9 months after this period mono – platelet therapy (150 mg per day Aspirin). Patient has been discharged 10 days after endovascular procedure the without anv neurological deficits. In our opinion due to atherosclerotic lesions present over both vertebral arteries the flow diverter technique may be dangerous in these types of anatomies as well as balloon angioplasty after the stent placement.

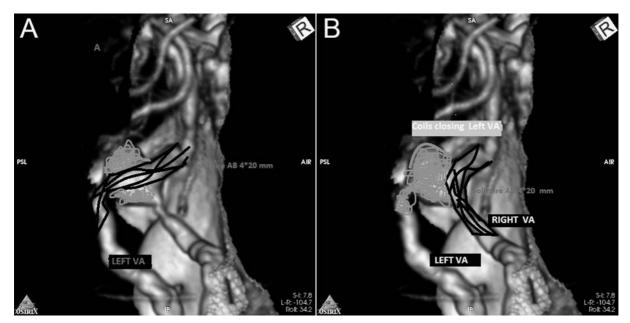


Figure 3. The two endovascular stent assisted coiling solutions who had been possible for this case. In the end the option A) was applied due to better flow preservation in vertebro- basilar system then in option B).

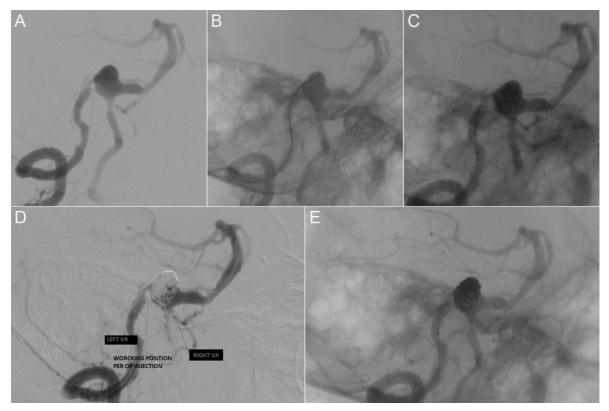


Figure 4. Per-embolization angiographic evaluation – working position.

This patient, 55 years old female was referred to Sanador Hospital, Bucharest with a non-ruptured right 7 mm P-com aneurysm as incidental finding. Due to fibro-dysplastic aspect of cervical portion of right ACI the flow diverter placement was judged to be unsafe mainly because of lack of support of guide wire catheter which was mandatory to be kept below this segment. Solitaire AB 6*30 mm was successfully placed in front of the aneurism neck and coiling was performed after passing the Echelon 10 inside the aneurism sac (Fig. 6).

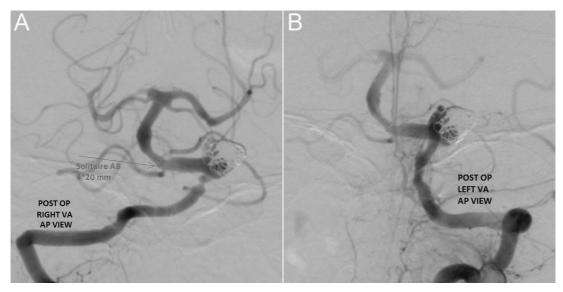


Figure 5. Post Op -embolization angiographic evaluation.

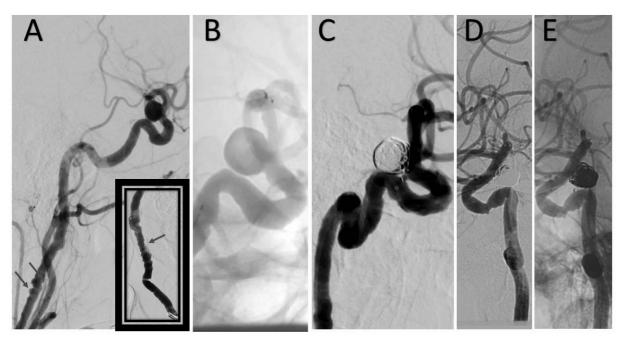


Figure 6. Pre Op (A), Per Op -Solitaire AB6*30 mm placed in carotid siphon Post Op Immediate (C); 12 months Post Op (D,E) angiographic evaluation.

Third case was the second ruptured aneurism described in our series. The EVT was performed 4 weeks after haemorrhagic event (Fischer 2, Hunt and Hess class 1) and in these conditions the patient was premedicated with 300 mg of Plavix 75mg as loading dose one day prior to treatment. Despite a good indication for flow-diverter technique due to public system financial constraints the stent assisted coiling technique was chosen for this case (Fig. 7). Patient was discharged with normal neurologic examination 5 days after the intervention.

CASE 4

The 4th case was represented by a 30 years old female who presented 2 mirror carotid siphon aneurysms. First of them, right ICA siphon 5 mm diameter aneurism was treated without incident by remodelling technique. Second aneurysm was a carotid-ophthalmic aneurysm of 4 mm diameter. First option was flow diverter technique but due to public system financial constraints the stent assisted coiling technique was chosen for this case (Fig. 8). Patient was discharged with normal neurologic examination 3 days after the intervention.

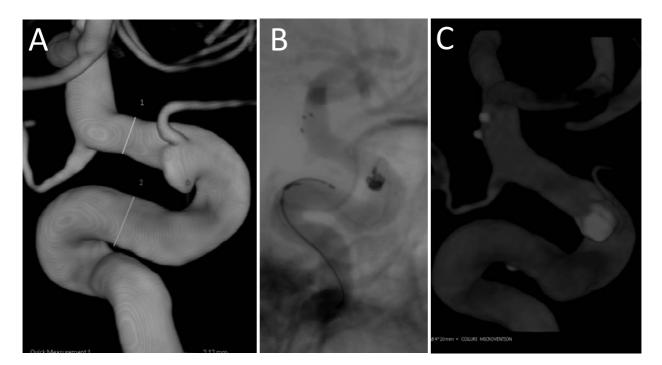


Figure 7. Pre Op 3DRA (A);Per Op -Solitaire AB 6*30 mm placed in carotid siphon Post Op and 2 Microvention coils were deployed (B); Post Op Immediate 3DRA(C).

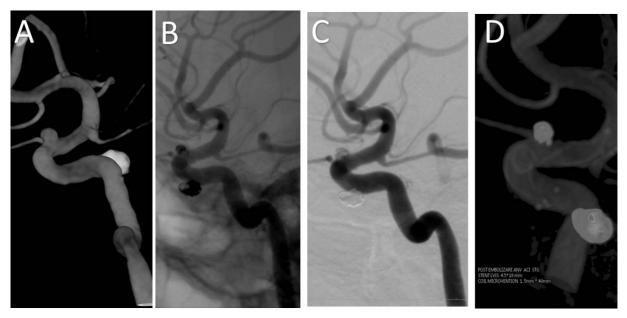


Figure 8. Pre Op 3DRA (A);Post Op – LVIS 4.5*18 mm placed in carotid siphon non-subtracted (B) and subtracted DSA (C);Post Op 3DRA(D).

The 5th patient, 28 years old male, presented as incidental finding a large neck (6.7 mm) and 5.6 mm non-ruptured aneurism situated at the right Tcarotid /right M1 junction. Right A1 segment was not present; both anterior cerebral arteries were supplied by a patent anterior communicant artery via left A1 segment. First option for treatment was Solitaire AB 6*30mm stent and coiling of aneurismal sac (Fig. 9). Placing a flow diverter in this anatomic configuration could lead easily to thromboembolic delayed events due to coverage of lenticulo-striates arteries arising from proximal part of right M1 segment. Patient was discharged with normal neurologic examination 2 days after the intervention.

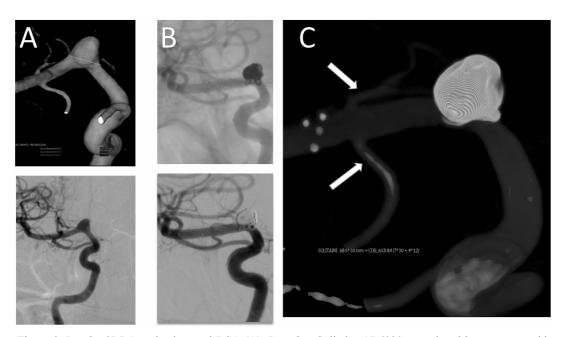


Figure 9. Pre Op 3DRA and subtracted DSA (A); Post Op -Solitaire AB6*30 mm placed between carotid siphon and M1 segment subtracted and non-subtracted DSA (B); Post Op 3DRA, white arrows indicating two lenticulo-striates branches of M1 segment, the argument for our team not to use flow diverter technique (C).

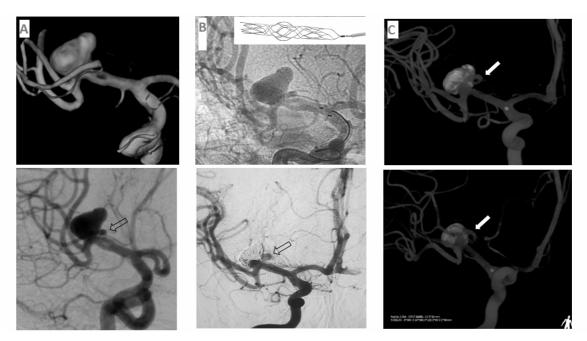


Figure 10. Pre Op 3DRA and subtracted DSA, superior right M2 branch origin at the neck level, black arrow (A); Post Op –Barrel stent 3.5–5*20 mm placed between inferior right M2 division and right M1 segment non-subtracted DSA (upper photo) and after coiling of aneurismal sac (inferior photo) (B); Post Op 3DRA, white arrows indicating the patency of superior division of M2 branch (C).

 6^{th} patient was also an incidental finding of 9 mm non ruptured middle cerebral bifurcation aneurism with large neck (6.3 mm). As showed in Fig. 10 the base of the aneurism was incorporating the M2 superior branch. In this case a Barrel 3.5–5*20 mm stent was preferred in order to preserve

the superior M2 branch and complete exclusion of the aneurism sac was achieved by delivering 5 Axium coils. In this type of situations the role of flow diverter technique is still controversial and may conduct to delayed thromboembolic events. Patient was discharged with normal neurologic examination 2 days after the intervention.

In all 6 cases presented in this small series the deployment of cerebral stent was mandatory in order to preserve the parent vessel and to safety coil the aneurismal sac. The most important advantage of Solitaire AB and Barrel stents is their technical ability of being fully retrievable and due to repositioning is relatively simple to be done. In our opinion the use of a stent offers two main advantages: first there are no limitations if the neck is very wide and secondly improvement and stabilization of anatomical results. The Solitaire AB stent is a laser-cut closed-cell micro-stent that has 4 distal platinum markers and one distal platinum marker. In all our 4 cases we used 6*30 mm stent and no per-procedure technique incident was noticed. The Barrel stent is a laser-cut closed-cell micro-stent that has a unique design with a bulged centre section for better coverage of the aneurysm neck to support coiling (Fig.10). It has one spiral strut construction proximal and one distal of the centre section for the purpose of preventing kinking. The device has 12 platinum markers: one longer marker at the proximal tip, one proximal and distal centre marker, six markers at the centre section, and three distal tip markers. This design was found to be very useful and helpful in repositioning the centre section inside the aneurism sac.

Detachment of the stent was done after micro-wire and micro-catheter sac catheterisation and coiling of the aneurism. Due to this approach in the hypothetical case of failure of aneurismal sac catheterisation the operator has the option to convert to jailing technique after stent retrieval. From clinical point of view, we had neither morbidity nor mortality despite the selected patient's population which were cases with difficult anatomy. From anatomical point of view, immediate occlusion was adequate in 5 out of 6 cases and incomplete in 1 case. In our opinion the single stent assisted coiling remains a safe and feasible technique in situations that flow diverter technique may be tempting. Moreover in cases of ruptured aneurisms as described in our 2 cases, the flow diverter technique is not protecting the patient of rebreeding while single stent assisted coiling provides immediate angiographic exclusion of aneurism sac. One more argument for cases like those described above is also the cost per patient using stent assisted coiling is bellow flow diverter technique. Intraaneurismal flow disrupters WEB as device (Microvention, CA, USA) are also a relatively new solution for wide neck bifurcation aneurisms but in "difficult" anatomies it still remains challenging. One of the main disadvantages of this device is that sizing in irregular shapes of aneurisms has proved to not be easy task for the operator.

	Average	Pac 1	Pac 2	Pac 3	Pac 4	Pac 5	Pac 6
Age	45.1	61	46	58	30	27	49
Ruptured Aneurism	2 out of 6	1	0	1	0	0	0
Nonruptured aneurism	4 out of 6	0	1	0	1	1	1
Aneurism location		VBJ	Carotido-opl	Carotido-ophta	Carotido-op	T-carotid	MCA
Aneurism shape		fusiform	saccular	side wall	saccular	side wall	saccular
Maximal diameter	6.28	9	5.9	3.2	3.3	5.3	11
Hight	4.98	8	6.1	1.5	2.4	5.4	6.5
Neck	5.45	8	5.4	2.9	3	7.1	6.3
Biffurcation aneurism	2 out of 6	1	0	0	0	0	1
EVT							
Stent used		Solitaire AB	Solitaire AB	Solitaire AB	LVIS	Solitaire AB	Barrel
No of coils used	3,66	7 Axium	5 Microventi	2 Microvention	1 Microventi	2 Axium	5 Axium
Cost evaluation (Euro/patient)	6983	9000	7800	6000	4800	6000	8300
Adjuvant techniques used	No	No	No	No	No	No	No
Per procedural complications	0	0	0	0	0	0	0
Post procedural complications	0	0	0	0	0	0	0
mRS at discharge	0	0	0	0	0	0	0

Table 1

Demographic and morphologic characteristics of our 6 patients treated
by stent assisted coiling - costs and materials used and outcome at discharge

HIGHLIGHTS

• The goal of this paper is to expose the advantages of single stent assisted coiling technique in specific difficult anatomies as well as costs effectiveness in our cases selection over flow diverter technique. Mastering flow diverter stent deployment requires specific training and sufficient experience as first operator and also needs the skills to recognize the complications related to imperfect deployment of the device situation that can lead to delayed thromboembolic events.

• Moreover the price of this device still remains at high level and makes us to prefer the single stent assisted coiling technique in specific situations described below.

• The future randomized studies are mandatory and has to respond to neuro-interventional community to specified questions like: which techniques are safer between: balloon remodelling, single or Y stent assisted coiling, flow diverter technique and also intrasaccular flow disrupter techniques? Which one of those techniques is more adapted to bifurcation large neck aneurisms? Which one of those is long term more efficient? What difference is in cost effectiveness between all of them?

ABBREVIATIONS AND ACRONYMS

EVT: Endovascular treatment

VBJ: Vertebro-basilar junction

SAH: subarachnoid haemorrhage

DSA: digital subtracted angiography

ATENA Study: Analysis of Treatment by

Endovascular Approach of Nonruptured Aneurysms ISAT Study: International subarachnoid aneurysm trial

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