ORIGINAL ARTICLE



Ruptured blood blister like aneurysm: does the best therapeutic option really exist?

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Abstract

Our study aimed to evaluate the outcome of patients with ruptured blood-blister like aneurysm (BBLA) in our institution by comparing microsurgical selective treatment to endovascular treatment using flow-diverter stent (FD). Our study included 18 consecutive patients treated for BBLA between 2004 and 2020. Until 2014, microsurgery was preferred in all patients with BBLA (n = 10). Significant postoperative morbi-mortality was recorded at this time and led us to change therapeutic strategy and to favor FD as first-line treatment in all patients (n = 8). Postprocedural complications and BBLA occlusion were recorded. High WFNS score (> 2) was noted in 6 patients of microsurgical group and in 2 of endovascular group. In microsurgical group, ischemic lesions were noted in 6 patients and led to death in 3 patients. Immediate BBLA occlusion was obtained in all patients. Favorable outcome after 3 months (mRS < 3) was recorded in 4 of the 7 survivors. In endovascular group, ischemic lesions were noted in 3 patients was recorded in 4 patients without rebleeding, but further FD was required in 1 with growing BBLA. Favorable outcome was noted in 6 of the 7 survivors. Although, rate of morbi-mortality appear lower in patients treated with FD, neurological presentation was better and BBLA diagnosis remains questionable in this group. Moreover, persistent BBLA imaging with potential risk of rebleeding after FD deserves to be discussed.

Keywords Blister aneurysm · Bypass · Encircling graft clip · Flow-diverter · Subarachnoid hemorrhage

Introduction

Blood blister like aneurysms (BBLAs) remain rare vascular lesions representing 1% of all intracranial aneurysm. The BBLAs are non-branching aneurysms usually located on the anteromedial supraclinoid segment of the internal carotid

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artery (ICA). Their diagnosis and treatments are challenging. Rates of morbidity and mortality reported in the literature remain high whatever therapeutic option. Indeed, aneurysmal wall fragility [22] is the main contributing factor of severe clinical presentation, challenging diagnosis and treatment, intraprocedural bleeding, and poor outcome. Various microsurgical techniques [11, 15, 29] and endovascular approaches [16, 23, 35] have been reported, but the optimal management remains controversial. In our institution, selective exclusion using various microsurgical techniques was first proposed until 2014. Significant morbidity and mortality were then noted after this treatment, and the emergence of flow-diverter techniques at this time led us to change the treatment strategy and to favor the endovascular procedure using flow-diverter stent (FD) at first-line treatment. Our study aimed to evaluate the outcome of patients with ruptured blood-blister like aneurysm (BBLA) in our institution by comparing microsurgical selective treatment to endovascular treatment using flow-diverter stent (FD).

Materials and method

BBLA diagnosis

The BBLA was defined as small non-branching aneurysm located on supraclinoid segment of ICA [22] responsible for subarachnoid hemorrhage (SAH). BBLA diagnosis was suspected when CT scan, CT angiography, and/or DSA demonstrated cisternal hemorrhage and small vascular irregularity located on the supraclinoid segment of ACI, growing or changing on repetitive imaging examinations if the diagnosis was not sure but suspected on the first angiographic assessment. It is conical and wide-necked with a dissecting/ nonsaccular appearance. When microsurgical treatment was performed, the diagnosis was confirmed during microsurgical procedure. This particular vascular lesion was recognized as a blister with translucent wall without evident neck and covered with clot (Fig. 1). A definitive diagnosis was made from histologic studies.

Inclusion and exclusion criteria

Among 3216 patients with aneurysmal SAH (aSAH), our study included 18 consecutive patients (13 females and 5 males) treated for BBLA in our institution between January 2004 and May 2020. Saccular aneurysms, thrombosed aneurysms, and dissecting aneurysms (Fig. 2) were excluded. Only patients with BBLA arising from supraclinoid segment were included in our study. "Atypical" BBLA arising from other arteries were not taken into account [25].

Clinical evaluation

The WFNS score was recorded before treatment in each patient. Postoperative complications were noted. The mRS score

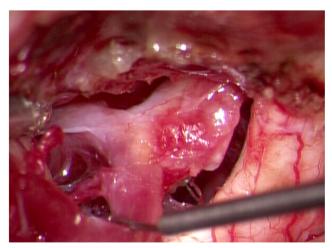


Fig. 1 Ruptured blood blister like aneurysm located on anteromedial portion of ICA. The clot was removed and translucent wall without evident aneurysm neck was surgically exposed

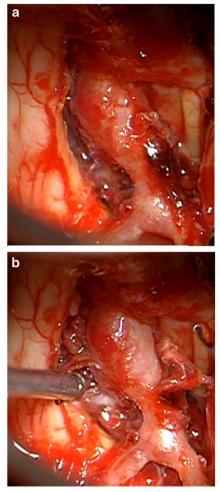


Fig. 2 Ruptured dissecting ICA aneurysm covered by a clot (Fig. 2a). Fusiform dilatation of ICA and stenosis was exposed after removing the clot (Fig. 2b)

was recorded 3 months after treatment. The mRS ≤ 2 was considered as a good functional outcome.

Treatment

Aneurysm treatment was decided after multidisciplinary discussion between intensivists, neuroradiologists, and neurosurgeons. From 2004 to 2014, microsurgical treatment has been preferred in all patients with ruptured BBLA microsurgical group. Microsurgical techniques were "encircling graft clip" (Sundt clip graft), wrapping, and clipping with perforator artery preservation and simple clipping. When BBLA was suspected on first angiogram and depending on its location (close to the dural ring), cervicotomy with ICA exposure was performed at the beginning of procedure in order to allow temporary flow interruption if it was required. No protective bypass technique was performed in this group. The occurrence of intraoperative rupture was always recorded.

Since 2014, we evaluated our microsurgical treatment results and we recorded significant rates of morbidity and

Patient	Age	WFNS	Suspected diagnosis on preoperative angiogram	Location on ICA supraclinoid segment	Type of microsurgical treatment	Intraoperative BBLA bleeding	mRS
1	50	1	yes	AM	Encircling graft clip	no	1
2	39	3	no	AM	Wrapping and clipping	yes	3
3	56	1	no	AM	Simple clipping	no	1
4	66	5	no	AM	Encircling graft clip	yes	3
5	48	5	yes	AM	Encircling graft clip	yes	6
6	46	5	yes	А	ICA trapping	yes	6
7	38	3	no	PL	Simple clipping	no	1
8	42	2	yes	AM	Encircling graft clip	no	6
9	49	1	yes	AM	Encircling graft clip	no	3
10	45	4	no	PL	Wrapping and clipping	yes	1

WFNS: World Federation of Neurologic Surgeons score

AM: Anteromedial

A: Anterior

PL: Posterolateral

ICA; Internal carotid artery

mRS: modified Rankin score 3 months after treatment

mortality; therefore, endovascular treatment using flow diverter device was favored in all patients with ruptured BBLA (endovascular group). The flow diverter device was "Pipeline" in 4 patients and "Silk "in 4 patients. The femoral closure device was 6French Long sheath in each patient.

Antiplatelet protocol was:

P2Y12 142 PRU (Verify now test) was performed 2 days before endovascular treatment to evaluate clopidogrel resistance in each patient. If a resistance was demonstrated, ticagrelor was used instead of clopidogrel.

Antiplatelet loading was aspirin 300 mg associated to clopidogrel 300 mg 6 h before endovascular procedure, and antiplatelet maintenance was aspirin 160 mg associated to clopidogrel 75 mg a day within 6 months after treatment then aspirin 160 mg a day during all life.

Radiological assessment

The pretherapeutic radiographic assessment was the same for open and endovascularly treated patients. Preoperative CT

Table 2 Clinical and radiological data of endovascular group	Patient	Age	WFNS	Suspected diagnosis on preoperative angiogram	Location on ICA supraclinoid segment	Intraprocedural BBLA bleeding	mRS
	1	58	1	Yes	AM	no	1
	2	53	2	Yes	А	no	0
	3	61	4	Yes	А	no	6
	4	57	3	Yes	А	no	3
	5	63	1	Yes	Р	no	1
	6	40	1	Yes	AM	no	1
	7	47	1	Yes	AM	no	1
	8	42	1	Yes	L	no	2

WFNS: World Federation of Neurologic Surgeons score

AM: Anteromedial

A: Anterior

P: Posterior

L: Lateral

ICA; Internal carotid artery

mRS: modified Rankin score 3 months after treatment

scan and CT angiography were performed in each patient to detect any bleeding and aneurysm. Fisher score was noted in each patient. If this exam demonstrated SAH but no presence of aneurysm, digital subtraction angiography (DSA) was also performed. When a BBLA was suspected, repetitive DSA was done to detect any growing of the aneurysm in order to support the diagnosis.

Early (<2 days) postoperative CT angiography was performed in all operated patients to detect any hemorrhage or ischemic lesions related to microsurgical procedure and to confirm BBLA exclusion. When possible, early DSA was done. Control DSA was performed 3 months after treatment and then every year. In case of persistent BBLA imaging repetitive DSAs were done.

Results

Population data

The prevalence of BBLA was 0.5% of all ruptured aneurysms in our institution. The mean age at treatment was 50 years (Range: 38 to 66 years). The mean age at treatment was 48 years (Ranging from 38 to 66) in microsurgical group and 53 years (Ranging from 40 to 61) in endovascular group. Arterial hypertension was noted in 10 patients and Elhers-Danlos syndrome in 1 patient. Multiple intracranial aneurysms were noted only in 2 patients of the endovascular group.

Clinical presentation

Microsurgical group

Initial clinical symptoms were headache in 5 patients, seizure in 4 patients and loss of consciousness in 1 patient. Immediate preoperative WFNS score was high (>2) in 6 patients (Table 1).

Endovascular group

Initial clinical symptoms were headache in 6 patients, seizure in 1 patient, and loss of consciousness in 1 patient. WFNS score was high (> 2) in 2 patients (Table 2).

Radiological presentation

The radiological presentation of the 2 groups is summarized in Tables 1 and 2.

Microsurgical group

supraclinoid ICA in 6 patients and on the left supraclinoid ICA in 4 patients. BBLA was located on the anteromedial portion of the supraclinoid ICA segment in 7 patients.

Before 2006, no preoperative CT angiography was performed but only DSA in the 3 patients with SAH. This exam demonstrated the presence of an aneurysm in the 3 patients, but BBLA had not been suspected. Diagnosis of BBLA was recorded during microsurgical procedure.

After 2006, preoperative CT angiography was performed and demonstrated an aneurysm in 5 of the 7 patients with SAH. DSA was performed and BBLA had been suspected in 5 of the 7 patients with SAH.

Endovascular group

The Fisher score was 2 in 1 patient, 3 in 5 patients, and 4 in 2 patients.

BBLA was located on the right supraclinoid ICA in 4 patients and on the left supraclinoid ICA in 4 patients. BBLA was located on the anteromedial portion of the supraclinoid ICA segment in 3 patients.

Preoperative CT angiography demonstrated an aneurysm in 2 of the 8 patients with SAH. Initial preprocedural DSA demonstrated an aneurysm in 4 of the 8 patients and BBLA was suspected. Repetitive DSA demonstrated appearance of the aneurysm in the other 4 patients, and BBLA was then suspected. Aneurysmal growing was observed in 2 patients on this exam.

Clinical and radiological outcome

Microsurgical group

Diagnosis of BBLA was suspected on preoperative angiographic exams in 5 patients and confirmed during the microsurgical procedure in all patients. Microsurgical procedure using an encircling graft clip was performed in 5 patients, a simple clip in 2 patients, ICA segment trapping in 1 patient (because of intraoperative massive bleeding related to ICA wall lesion), and wrapping and clipping technique in 2 patients.

Intraoperative BBLA rupture was recorded in 5 patients. Early postoperative large infarction of ICA territory conducting to death was noted in 3 patients. A mild postoperative neurological disorder related to ischemic lesions on anterior choroidal artery territory due to microsurgical procedure (encircling graft clip) was noted in 1 patient (Fig. 3). Early postoperative DSA demonstrated complete occlusion of BBLA in all survivors.

Favorable functional outcome (mRS < 3) was noted in 4 of the 7 survivors 3 months after treatment. Control DSA 3 months after treatment demonstrated no recanalization of the aneurysm in the 7 survivors.

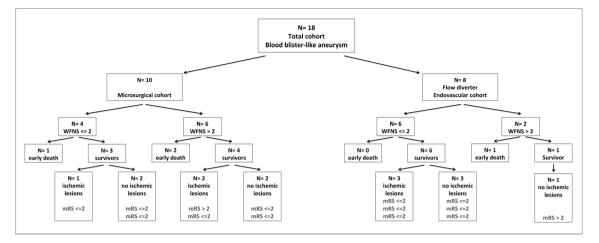


Fig. 3 Clinical outcome of patients after BBLA treatment. WFNS: World Federation of Neurologic Surgeons score. mRS: modified Rankin score 3 months after treatment

At last follow-up, favorable functional outcome with complete BBLA occlusion was observed in 4 of the 7 survivors.

Endovascular group

Endovascular treatment using flow diverter device was performed in the 8 patients.

No intraprocedural rupture occurred. Massive rebleeding related to persistent BBLA imaging occurred 5 days after treatment in 1 patient (Patient 13), and large cerebral hemispheric infarction was noted in this patient. Postprocedural ischemic lesions located on MCA, anterior cerebral artery (ACA) and ophthalmic artery territories (visual disturbance) were noted in 3 other patients. Retroperitoneal hematoma related to wall injury of the iliac artery was recorded in 1 patient. Surgical evacuation was needed in this patient. Asymptomatic Scarpa hematoma without surgical evacuation was observed in 2 patients. Early postprocedural DSA demonstrated persistent BBLA in 4 survivors. Control DSA 3 months after treatment demonstrated growing BBLA in 1 patient (Patient 14). stability of BBLA imaging in 2 patients, and decreasing of BBLA in 1 patient. BBLA complete occlusion was demonstrated on the conventional angiography 8 months after endovascular treatment in 2 of these 4 patients. No new rebleeding was recorded with a mean follow-up of 9 months (Ranging from 3 to 18). After 1 year, no BBLA regrowing was recorded.

Favorable functional outcome was noted in 6 of the 7 survivors 3 months after treatment. At last follow-up, favorable functional outcome with complete BBLA occlusion was observed in 5 of the 7 survivors.

Complications related to hemorrhage

Acute hydrocephalus with external ventricular drain (EVD) was noted in 5 patients of microsurgical group and in 2

patients of endovascular group. Takotsubo syndrome was noted in 1 patient in this group.

In the microsurgical group, ischemic lesions related to vasospasm were noted in 2 patients. One of these 2 patients had persistent hemiplegia. In the endovascular group, an asymptomatic regressive vasospasm was noted in 2 patients.

Ventricular peritoneal shunt was required in only one patient in the endovascular group.

Discussion

Morbidity and mortality of BBLA aneurysm rupture remain significant in both endovascular and microsurgical groups even if they appear lower after endovascular treatment using FD. Persistent BBLA imaging in certain cases after this treatment requires repetitive DSA and more investigations to evaluate the risk of late rebleeding and to define the future management of patients.

BBLA diagnosis

BBLA diagnosis is challenging. Confusion with dissecting aneurysm, saccular aneurysm, or thrombosed aneurysm remains possible [22]. The results of the various series reported in the literature [39] must be interpreted with caution, especially when endovascular treatment was performed. Indeed, these series can include a non-homogeneous population of patients with different aneurysmal variants. The presence of a unique non-branching aneurysm, absence of other associated intracranial aneurysms, anteromedial location on the supraclinoid segment of ACI, and rapid growth are indirect evidence factors of diagnosis [13]. However, the diagnosis can only be confirmed by intraoperative surgical findings. Indeed, in our series, non-anteromedial location was noted in 3 patients of microsurgical group and in 5 patients of endovascular group. Locations on middle cerebral artery (MCA) or anterior cerebral artery (ACA) were reported by some authors [6, 30] but remain rare. In a similar vein, the presence of multiple intracranial associated saccular aneurysms was detected in 2 patients of endovascular group. Their non-branching aneurysm can be a saccular aneurysm and not a BBLA. Therefore, BBLA diagnosis deserves to be discussed in this group.

Poor neurological presentation (WFNS score > 2) was usually noted in patients with BBLA. Indeed, poor neurological presentation was recorded in 6 patients of microsurgical group, while it was only in 2 patients of endovascular group. This result can partly explain the better clinical outcome in endovascular group. Indeed, the neurologic status remains, by far, the main determinant of prognosis and/or complications; of course, this warns us of greater fragility of the vessel and subsequent trend to rupture on surgery, in cases of BBLA. Moreover, rates of acute hydrocephalus and symptomatic vasospasm appear higher in microsurgical group even if these results must be interpreted with caution because of our limited population. Acute hydrocephalus and vasospasm are predictive factors of poor prognosis in patients with aSAH according to many authors [8, 9, 12].

Concerning patient 13 who had an endovascular treatment, post-treatment CT angiography demonstrated a persistent BBLA and the appearance of a second BBLA on the same ICA segment. Patient died from a massive rebleeding. The diagnosis of ICA dissection better explains the posttreatment radiological findings than the diagnosis of BBLA. However, association between arterial dissection and BBLA was suggested by some authors [24]. ICA dissection after endovascular procedure is another possible hypothesis.

Microsurgical treatment

Selective exclusion or ICA occlusion with protective bypass can be discussed. Case reports demonstrated that conservative treatment was always fatal because of high risk of rebleeding [31]. Simple clipping and wrapping are two techniques associated to high risk of aneurysmal regrowing and rebleeding according to many authors [11, 21]. Moreover, Ogawa [22] reported postoperative ischemic lesions related to clip induced-ICA stenosis after simple clipping. In our series, ischemic lesions were noted in 1 of the 2 patients who had simple clipping technique.

Other authors suggested that "wrapping and clipping" technique was the best surgical option [1, 31]. Nevertheless, this technique can be associated with a significant risk of aneurysmal regrowing or rebleeding. Indeed, an incomplete wrapping of the ICA segment affected by the disease may occur after this surgical technique. Moreover, anterior choroidal artery occlusion can occur after ICA wrapping. In our series, favorable outcome was recorded in the unique patient who underwent this surgical technique.

Both wall artery reconstruction and BBLA exclusion may be achieved with an encircling graft clip [15, 16]. However, temporary interruption of the ICA flow before clipping is usually required during this procedure with an increased risk of cerebral ischemia. Moreover ICA stenosis after clipping can also occur. In our series, intraoperative indocyanine-green video-angiography demonstrated good patency of vessels after using an encircling graft clip in the 5 patients who had this treatment, but postoperative ischemic lesions were noted in 3 patients. Temporary interruption of the flow during surgical procedure and occurrence of significant vasospasm were probably exaggerated the negative consequences of clip induced-stenosis. All these surgical techniques are associated to a significant risk of intraoperative bleeding related to surgical ICA dissection or clipping a fragile aneurysm wall [27]. In our series, intraoperative aneurysmal bleeding occurred in 5 patients with microsurgical treatment and ischemic lesions were noted in 3 of these 5 patients.

To limit the occurrence of ischemic complications, some authors suggested ICA occlusion with or without previous protective bypass. However, ICA occlusive test is more difficult to do in the context of subarachnoid hemorrhage. Moreover some authors reported that ICA occlusion without bypass is correlated with poor prognosis outcome due to poorer tolerance to vasospasm even in case of adequate collateral capacity on preoperative occlusion test [20, 32]. Indeed, in Meling's [20] series of 14 patients with BBLA, cerebral infarcts developed in the 7 patients treated with ICA sacrifice, directly postoperatively in 2 and after delay in 5. The authors concluded that sacrifice of the ICA within 48 h of an SAH led to very poor outcome, even in patients with adequate collateral capacity on preoperative angiograms, probably because of vasospasm-induced compromise of the cerebral collaterals. Other authors^{11,13} proposed to perform protective high flow bypass before ICA occlusion only in the case of absence of collateral capacity on preoperative angiogram. However, this technique is associated with significant morbidity and mortality [4, 28] (respectively 7 and 2%). The role of a prior protective bypass is still discussed by some authors [33, 34, 37] even in the case of adequate collateral capacity on preoperative angiogram. In Meling's meta-analysis [19] including 98 patients with BBLA who had bypass procedure, mRS was ≤ 2 in 79% of patients and 4% had mRS 6 (death). However, the author noted that data reporting quality was low in a lot of included studies, precluding any firm conclusions. In our perspective, a systematic prior STA-MCA (M3 or M4) anastomosis can be performed in all patients at the beginning of procedure. Depending on preoperative angiogram with collateral capacity evaluation, on preoperative and intraoperative flow measurements on ICA, STA branches, M1, M2 and M3 segments and on necessity of ICA intraoperative sacrifice, a

high flow bypass can be discussed during the procedure. If high flow bypass is required, the prior protective STA-MCA bypass done at the beginning of procedure can also maintain the flow in distal part of MCA territory during proximal MCA flow interruption to perform high flow anastomosis [2]. If high flow bypass is not required, the prior STA-MCA anastomosis can play a positive role in case of postoperative vasospasm.

Endovascular treatment

Endovascular treatment by simple coiling was associated with a high risk of intraprocedural aneurysm rupture [11, 23, 26]. Regrowing and rebleeding rates are respectively 30.4 and 17.3% with this technique according to some authors [11].

Endovascular treatment using stent and coils is also associated with significant risk of BBLA perforation and high rate of regrowing according to Lee's study [16]. Moreover, antiplatelet treatment in periprocedural period increases the risk of bleeding [16–18]. Stent in Stent technique was reported by some authors, but it was associated with a risk of BBLA remnant or regrowth in 50% of cases [10].

In the same objective of diverting the flow, endovascular treatment using "flow diverter" stent was reported by many authors [5, 7, 38]. However, BBLA occlusion is not immediately obtained with a persistent risk of rebleeding during this period, increased by the use of high-dose antiplatelet agents in order to reduce risk of stent thrombosis. In our series, one patient died from a BBLA rebleeding and 3 patients had a Scarpa hematoma. Retroperitoneal hematoma expansion occurred, and surgical evacuation was required in one of these 3 patients. The risk of periprocedural hemorrhage related to antiplatelet treatment appears high in our series, and it should not be neglected. Moreover, in the case of hydrocephalus occurrence, ventriculostomy and VP shunt placement in the presence of antiplatelet therapy are problematic because of the potential hemorrhagic risk during the surgical procedure. Short discontinuation of antiplatelet treatment can also be associated to ischemic lesions because of the flow diverter device presence. In the same way, some authors reported the occurrence of ischemic lesions after endovascular treatment using flow diverter stent [3, 38]. Indeed, ophthalmic artery or anterior choroid artery occlusion can occur after flow diverter stent deployment. In our series, symptomatic ischemic lesions after endovascular treatment were noted in 3 patients with impossibility to the deployment of flow-diverter stent in one of these 3 patients. In Yoon's series of 11 patients with BBLA [38], 3 (27%) had major periprocedural complications after flow-diverter stent treatment: middle cerebral artery territory infarction, vision loss, and death. However, early clinical outcomes were favorable (modified Rankin Scale score, 0-2) in all 10 survivors. In our series, clinical outcomes 3 months after treatment were favorable in 6 of the 7 survivors after endovascular treatment. In Cinar series [18] of 7 patients

with BBLA, early clinical outcomes were favorable in 5 patients. Nevertheless, immediate complete BBLA occlusion was not obtained in all these reported studies. In our series, early postprocedural DSA demonstrated a persistent BBLA in 4 patients. Control DSA 3 months after treatment demonstrated growing BBLA in 1 patient (Patient 14), stability of BBLA imaging in 2 patients, and decreasing of BBLA in 1 patient. Fortunately no rebleeding was recorded. The BBLA occlusion may be sometimes progressive with a blood stagnation in the BBLA after endovascular treatment with FD. Moreover, some authors reported a delayed ipsilateral parenchymal hemorrhage following treatment of intracranial aneurysm with flow-diverter stent [14, 36]. In Zhu's meta-analysis [39] including 165 patients with BBLA, complete occlusion after flow-diverter stent treatment rate was 72%. Recurrence and rebleeding occurred respectively in 13 and 3% of patients. In our opinion, the potential persistent imaging of BBLA after endovascular treatment using flow diverter stent requires more investigations to better define the future management of patient. Therefore, radiological follow-up using repetitive DSA appears mandatory to control the BBLA evolution.

Conclusion

The clinical outcome of patients with ruptured BBLA remains severe whatever therapeutic option. However, rate of morbidity and mortality appears lower in patients with endovascular treatment using flow-diverter stent. Nevertheless, in our series, initial neurological presentation was better and the diagnosis of BBLA was questionable in this group. Moreover, persistent BBLA imaging with a potential risk of rebleeding after flow-diverter stent treatment deserves also to be discussed. Prior systematic protective STA-MCA bypass and possible high-flow bypass depending on intraoperative flow measurement could improve the prognosis of microsurgical treatment and therefore must be evaluated.

Authors' contributions Rabih Aboukais, MD, PhD^{1*}, Marie Charlotte Tétard, MD², Antoine Devalckeneer, MD¹, Pierre Boussemart, MD³, Philippe Bourgeois, MD¹, Nicolas Bricout, MD⁴, Barbara Verbraeken, MD⁵, Tomas Menovsky, MD, PhD⁵, Xavier Leclerc, MD, PhD⁴, Jean-Paul Lejeune MD, PhD¹ contribute to collect data, to write the manuscript, to review the manuscript.

Data availability Yes

Compliance with ethical standards

Ethics approval Ethical approval was waived by the local Ethics Committee of University in view of the retrospective nature of the study and all the procedures being performed were part of the routine care.

Lille University Hospital Ethics committee approved this work.

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

The authors have no relevant financial or non-financial interests to disclose.

Code availability Not Applicable.

Consent to participate Not Applicable.

Consent for publication Not Applicable.

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