Scepter XC Balloon Angioplasty for Vasospasm Following Ruptured Aneurysm: Single-Center Experience and Results

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Abstract

Background: Cerebral vasospasm still results in high morbidity and mortality rates in patients after aneurysmal subarachnoid hemorrhage (SAH). The aim of this study was to establish a protocol for the management of vasospasm and demonstrate our experience of angioplasty using the Scepter XC balloon catheter. Methods: An image survey was arranged if early symptomatic vasospasm occurred, or on the 7th day following aneurysmal SAH. In patients with clear consciousness, balloon angioplasties were performed for symptomatic vasospasms, which were not improved within 6-12 hours after maximal medical treatments. In unconscious patients, balloon angioplasties were performed for all patients with angiographic vasospasms. We retrospectively reviewed clinical findings, radiological results, and functional outcomes for these patients. Results: Fifty patients underwent Scepter XC balloon angioplasty among 396 consecutive patients who accepted endovascular or surgical treatments for ruptured aneurysms. All angioplasty procedures were successful without complications. 100% angiographic improvement and 94% clinical improvement were reached immediately after the angioplasties. A favorable functional outcome (modified Rankin Score of ≤2) could be achieved in 82% of patients. Even in patients with poor clinical grading (Hunt–Hess grade 4–5), a clinical improvement rate of 87.5% and favorable functional outcome rate of 70.8% could still be achieved. Conclusion: Balloon angioplasty with Scepter XC balloon catheter is safe and effective for post-SAH vasospasm. This device's extra-compliant characteristics could considerably improve the quality of angioplasty procedures. For all patients, even those with poor neurological status, aggressive evaluation and early treatment of vasospasm can noticeably improve clinical outcomes.

Background

Cerebral vasospasm remains a major cause of delayed cerebral ischemia for patients following subarachnoid hemorrhage (SAH) from ruptured intracranial aneurysms. Of patients with aneurysmal SAH, 30–70% develop cerebral angiographic vasospasm, with delayed neurologic deficits manifesting in 30–50% of patients.[1–3] Noninvasive management approaches, including induction of hypertension, maintenance of euvolemia, and infusion of oral form or intravenous vasodilators, are the most common strategies.[3–6] However, vasospasm still results in mortality rates of 7–20% or permanent disability.[1, 6, 7] Balloon angioplasty is a more invasive procedure that can lead to an immediate and satisfying angiographic result.[8, 9] However, it is usually postponed and reserved for when symptoms are refractory because of a potential risk of thromboembolic complications and even vessel rupture.[10–12] The Scepter XC balloon (4 × 11 mm; Microvention, Tustin, CA, USA) is a user-friendly temporary occlusion balloon catheter consisting of a dual coaxial lumen attached to a low-inflation pressure-compliant balloon. It has excellent trackability and stability, and the extra-compliant design represents technical advancements in endovascular treatment.[13–16] Few studies have reported on the feasibility of the Scepter balloon for vasospasm treatment.[13, 14, 17, 9] In this study, we detailed the largest single-center case experience of Scepter XC balloon angioplasty and provided an aggressive protocol to treat vasospasm after aneurysm rupture with remarkable clinical outcomes.

Methods

Management of post-SAH vasospasm

Between January 2014 and January 2018, 396 consecutive patients accepted endovascular or surgical treatments for ruptured aneurysms in our institution. After securing the aneurysms, patients were sent to the neurosurgical intensive care unit. Standard medical management for vasospasm was continued, including nimodipine usage, fluid infusion to maintain euvolemic status, blood pressure control, and intensive monitoring. A routine image survey by a computed tomography angiography (CTA) was arranged on the 7th day following aneurysmal SAH or if early symptomatic vasospasm occurred to evaluate the level of vasospasm and to eliminate a diagnosis of hydrocephalus or re-hemorrhage. Hyperdynamic therapy was then be maximized to the point of elevating the mean arterial pressure by 15–20% and central venous pressure higher than 8-10cmH20.[8] If the patients did not demonstrate neurological reversal totally within 6–12 hours, they were transferred to the endovascular suite for angiography. In the patients with clear consciousness, endovascular treatments (Scepter XC balloon angioplasty and intra-arterial [IA] nimodipine) were administered for symptomatic vasospasms regarded as refractory to medical treatment. In unconscious patients, because their symptoms were difficult to recognize, balloon angioplasties were performed for all patients with radiological vasospasms. Angiography improvement was defined as at least 30% improvement of vessels diameter after angioplasty; symptoms improvement were defined any clinical improvements of conscious level, muscle power, cognition, or speech. The aggressive protocol and treatment strategy for patients with post-SAH vasospasm are represented in Fig. 1.

Before angiography, vessel conditions for balloon angioplasty were analyzed, and a DSA was arranged to confirm the location and degree of vasospasms. For patients without larger vessel spasms or with only mild larger vessel spasm (< 25% stenosis),[12, 9] simple IA nimodipine infusions were arranged without angioplasty. By this paradigm, 50 patients underwent Scepter XC balloon angioplasty from 2014 to 2018. All surgical, endovascular procedures, and clinical evaluations were executed by 5 neurosurgeons and neurointerventionalists, each with over 5-years' experience performing clipping or embolization. We retrospectively reviewed clinical, radiological, and endovascular findings for these patients, and the correlation between clinical characteristics and functional outcomes were analyzed. This study was approved by the institutional review board (201800342B0).

Procedure Of Scepter Xc Balloon Angioplasty

All interventions were performed under general anesthesia. Initial DSA was performed to reveal the cerebral vasculature. Prior to cerebral angioplasty being performed, a bolus (6000 IU) of heparin was given after the sheath was introduced. A 6 Fr. guiding catheter with a pressure line (50 mg nimodipine in 1000 mL of normal saline solution at a rate of 1 to 2 mL/minute) was navigated to the vessel with the most severe vasospasm. After the guiding catheter reached the target vessel, the dripping speed of the IA

nimodipine line was adjusted to 4 to 5 mL/minute. Blood pressure was continuously monitored via the arterial line throughout the procedure. If a decrease in blood pressure occurred, the anesthesiologist administered a dopamine infusion to maintain systolic pressure at 100 to 120 mm Hg.

A Scepter XC balloon catheter (4 × 11 mm; Microvention, Inc., Tustin, California, USA) was navigated to the most distal part of the vasospastic segment with which the operator was comfortable, such as anterior cerebral artery segment 2 (A2) or middle cerebral artery segment 3 (M3), under the assistance of a 0.014-inch Traxcess microwire (Microvention, Tustin, California, USA). The Scepter XC balloon was then inflated with gentle pressure with the lumen of the balloon not exceeding 60–70% of the normal diameter of the diseased vasculature. Once the balloon reached the desired diameter, it was deflated immediately. Because it takes less than 10 seconds to inflate and deflate the balloon in the diseased segment, prolonged inflation was not necessary. After the vasospastic distal segment was dilated, the balloon was moved proximally to dilate the residual vasospastic vessels. After several sessions of balloon angioplasty were conducted, the vasospastic artery was dilated from distal to proximal. Occasionally, when the vasospasm was so severe that navigation of the balloon catheter was not possible, and if the proximal vessels were not dilated, angioplasty from the proximal to distal would be performed. During the angioplasty procedure, the pressurized nimodipine drip was maintained at 4 to 5 mL/minute. All procedures were performed by three experienced neurointerventionalists.

Results

Between January 2014 and January 2018, 396 consecutive patients accepted endovascular or surgical treatments (clipping) for ruptured aneurysms in our institution. Among the 396 patients, 155 (39.14%) had post-SAH vasospasms found during routine imaging and only 61 patients (15.4%) had symptomatic vasospasms. Twenty-one out of 61 patients, with no obvious large vessels spasms or > 25% stenosis, exhibited improved symptoms after simple endovascular IA nimodipine infusion (between 1 and 3 sessions). The remaining 40 patients underwent balloon angioplasty. Ten patients, who had poor consciousness after operations, presented diffused severe vasospasm in the images study without obvious focal neurologic deficits.

A total of 50 patients with a mean age of 50 (range 28–68 years, 38 women and 12 men) underwent Scepter XC balloon angioplasties and were enrolled in this study. The clinical and angiographic characteristics and various results for the 50 patients are summarized in Table 1. Twenty-six patients (62%, 26/50) had a low clinical grade (Hunt–Hess grade 1–3; ten patients were grade 3), and 24 patients (48%, 24/50) had a high clinical grade (Hunt–Hess grade 4–5). Fifteen patients (30%) had Fisher grade 1–2 bleeding pattern, and 35 patients (70%) had Fisher grade 3–4 hemorrhagic pattern. The most commonly treated vessels were middle cerebral artery (MCA) M1 segments (94%, 47/50), followed by M2 segments (70%, 35/50), distal internal carotid arteries (ICA) (50%, 25/50), anterior cerebral arteries (ACA) (16%, 8/50), and vertebral arteries (VA) (14%, 7/50). In four cases, the balloon could reach proximal M3 branches for successful angioplasties. All angioplasty procedures were successful without any vessels rupture, dissection, or thromboembolic complications. The severity of vasospasm improved immediately

and significantly (100%) after angiography. 94% (47/50) of patients exhibited symptom improvement within 24 hours. Only one patient required secondary angiography for symptomatic vasospasm 3 days later on the opposite side, which exhibited no obvious vasospasm in the first angiography. Even in patients with a high clinical grading and poor hemorrhagic pattern, the immediate rate of improvement also reached approximately 90% (87.5% and 91.4%, respectively). Two of the patients in this study died. One death was resulted from sustained cerebral ischemia, brain swelling, and uncal herniation. The other patient who died had intractable status epilepticus with respiratory failure. Overall, after 3 months of clinical follow-up, 82% of patients had favorable clinical outcomes (modified Rankin Score, [mRS] $\leq$ 2). Even in patients with initial poor clinical grading (Hunt–Hess grade 4–5), the 3-month favorable outcome rate still reached 70.8% (Table 1 and Table 2); A 92.3% favorable outcome rate was observed for patients with a low clinical grade (Hunt–Hess grade 1–3) and a 100% favorable outcome rate was observed for patients with a Hunt–Hess grade of 1–2. 60% (6/10) of patients with unconsciousness before angioplasty could regain consciousness; 70% of them could improve symptoms and 40% recover to achieve an excellent clinical outcome (Table 2). The results encouraged operators to aggressively treat post-SAH vasospasm.

Table 1

Characteristics of patients who accepted Scepter XC balloon angioplasty

	Total patients	H-H Gr 1–3	H-H Gr 4–5	Fisher Gr 1–2	Fisher Gr 3–4
Patients number	50	26 (52%)	24 (48%)	15 (30%)	35 (70%)
Age	50.0	48.0	50.9	48.5	50.4
Gender male female	12 38	4 22	8 16	2 13	10 25
Symptomatic vasospasm	40	24 (60%)	16 (40%)	13 (32.5%)	27 (67.5%)
Unconscious asymptomatic	10	2 (20%)	8 (80%)	2 (20%)	8 (80%)
Angioplasty Location: ICA MCA M1 M2 M3 ACA A1 A2 VA BA	25 47 35 4 8 8 7 6	9 15 10 0 3 2 1 1	16 32 25 4 5 6 6 5	8 16 14 0 3 2 0 0	17 31 21 4 5 6 7 6
Need 2nd angioplasty	1 #	0	1	0	1
Image Improving (%)	100%	100%	100%	100%	100%
Symptoms improving (%)	94% (47/50)	100%	87.5% (21/24)	100%	91.4% (32/35)
3 months good outcome (mRS < = 2) (%)	82% (41/50)	92.3% (24/26)	70.8% (17/24)	100% (15/15)	74.3% (26/35)
Mortality *	2	0	2	0	2

H-H: Hunt and Hess grade; mRS: modified Rankin scale

* Mortality: 1 case of infarction with uncal herniation; 1 case of status epilepticus

Vasospasm occurred and angioplasty was performed on a different vessel

Table 2

Outcome of balloon angioplasty in unconscious patients and high clinical grading

Patients	Patients number	Angiography improving	Clinical improving	3 months mRS < = 2
High clinical grading (H-H Gr. 4–5)	24	100%	21 (87.5%)	17 (70.8%)
Unconscious patients	10	100%	7 (70%)	4 (40%)
H-H: Hunt and Hess grade; mRS: modified Rankin scale				

Discussion

Aggressive endovascular procedure

Cerebral vasospasm remains a major cause of morbidity and mortality among patients after they survive initial SAH and undergo definitive aneurysm treatment. Of patients with aneurysmal SAH, 30–70% develop cerebral angiographic vasospasm, with death or permanent disability noted in 7–20%.[1, 6, 7] Younger age, poor presenting grade, and diffused subarachnoid clot are well-known risk factors for post-SAH vasospasm.[18, 2, 8] However, despite less favorable outcomes, patients with poor neurological status and even ischemic changes on CT scan, still appear to benefit from early endovascular therapy.[6, 8] Patients with poor consciousness status need not be excluded from this life-saving intervention. This is well demonstrated in our study of patients with significant vasospasm: the majority were of a younger age (mean age = 50 years), 68% presented with at least a Hunt–Hess grade of 3, and 70% had thick diffuse subarachnoid blood (Fisher grade > = 3). In our study, 70.8% of patients with a high clinical grade (Hunt–Hess grade 4–5) could still attain a favorable outcome (mRS < = 2); 60% (6/10) of patients with unconsciousness before angioplasty could regain consciousness and 40% recover to achieve an excellent clinical outcome. In these patients, the symptoms of vasospasm could not be detected easily and early. Therefore, early diagnosis by routine image study during the high-risk period of post-SAH vasospasm was necessary.

In the past, the endovascular approach was often required only in patients with symptoms that were refractory to medical management. However, no definite waiting time was suggested for “refractory.” In our study, 100% of angiographic and 94% of symptomatic vasospasms improved after angioplasty combined with balloon angioplasty and IA nimodipine, without any complications. These results compare favorably to those of other studies. In the recent literatures, the efficacy of mechanical balloon angioplasty was nearly 90 to 100%, associated clinical improvement rate of 60–75% and a complication rate of 5%.[8, 18, 17, 19, 20] For comatose and high clinical grading patients, the reports were rare and only 0 to 30% patients had good clinical result.[20, 8] Our results demonstrated that in patients with symptomatic or severe vasospasm, neurosurgeons and neurointerventionalists should treat the condition more aggressively and endovascular therapy should be performed as soon as possible.

Simple IA vasodilator therapy is also effective but often transient, time insufficient, and requires multiple treatment sessions. Balloon angioplasty is suitable in larger vessels and has been reported as a relatively safe, effective, and durable procedure.[21, 12] Therefore, we recommend a combined procedure of balloon angioplasty in major vessels and continuous nimodipine infusion, which was effective for distal and diffuse vasospasm during the procedure. In our study, only one patient (2%) required a secondary session of angioplasty treatment. However, because the target vessel was different, the durability of balloon angioplasty remained apparent.

Superiorities Of Scepter Xc Balloon For Angioplasty

The Scepter XC balloon had favorable performance in the treatment of cerebral vasospasm in all consecutive patients without procedure-related complications in our series. The Scepter XC balloon was extremely trackable, facilitated safe, and was able to navigate distally into the intracranial circulation (the A2 and M3 segments). The Scepter XC balloon accommodates a larger 0.014-inch microwire, which provides significant stability to the balloon during navigation of tortuous vessels and distal advancement.[13, 16] Furthermore, during the balloon inflation, the 0.014-inch microwire provided increased stability, which resulted in less slippage along the vessel wall relative to the single lumen balloons that have been used previously. Last, we can use a single balloon for multiple segments with repeated inflation and deflation without the need to replace the balloon.

Studies have reported a complication rate of 1–4%; such complications are arterial rupture, dissection, and thrombus formation during angioplasty for vasospasm.[10, 12] Theoretically, the improved stability of inflation and the extra-compliant characteristic should be protective against arterial injury and rupture.[15] In our experience, during inflation, the extra-compliant design of the Scepter XC balloon tended to conform to the course of the vessel concurrent with radial expansion. The Scepter XC balloon was elliptically shaped at full inflation with two enhanced tips at both ends of the balloon. During inflation, the balloon gradually dilated from the central area and then bilaterally expanded evenly along the vessel wall (Fig. 2A, 2B, & Fig. 3A). This conformation to the native vessel shape reflects the extra soft nature of the balloon and, in our opinion, leads to a more controllable and gentler balloon inflation. When the operator observes the balloon gradually expand near the two end markers of the balloon, the procedure could be ceased and deflation should be initiated; this characteristic of Scepter XC could prevent over-inflation, which causes vessel rupture (Fig. 2C & Fig. 3B). Generally, it takes less than 10 seconds to deflate the fully-inflated balloon in the diseased segment. Careful planning prior to endovascular treatment can reduce procedure time and lead to maximal improvement of cerebral vasospasm.

Moreover, simultaneous IA administration of nimodipine or other calcium channel blockers through the double lumen balloon catheter can augment the results of cerebral angioplasty, especially at distal circulation.[12, 9] In our experience, after a full angioplasty session, both target vessels, which were treated by balloon angioplasty, and distal vasospasms, treated by nimodipine, were improved simultaneously (Fig. 2D & Fig. 3C). After the diameter of proximal vessels was regained, more cerebral

blood flow and more vasodilator effects could reach distal regions and increase cerebral perfusion. That may be why the effect of angioplasty is so durable and the functional outcome is so remarkable.

Limitation

The limitation of this study includes retrospective nature of the data analysis and absence of randomization between study groups. We were not able to distinguish the improvement from IA nimodipine alone, angioplasty, or combined effect; and to compare with diffident types of balloons and time interval between onsets of new deficits to intervention. However, we believed the result of the combination of an aggressive protocol and Scepter XC balloon angioplasty is extremely reliable because of high successful rate, good result, and low complications. Additionally, the clinical results may come from multivariable factors, such as hydrocephalus, surgical complications, infection, underlying comorbidities, and rehabilitations. Despite these factors, the effect might be minimized because of the single center with the same treatment protocol.

Conclusion

Balloon angioplasty with Scepter XC balloon catheter is safe and effective for the treatment of cerebral vasospasm following SAH. Utilizing its extra- compliant characteristic could significantly improve the quality of angioplasty procedures. For all patients, even those with poor neurologic status, aggressive evaluation and early treatment of vasospasm can improve clinical results.

List Of Abbreviations

SAH: subarachnoid hemorrhage; CTA: computed tomography angiography; DSA: digital subtraction angiography; MCA: middle cerebral artery; ICA: internal carotid arteries; ACA: anterior cerebral arteries; VA: vertebral arteries

Declarations

Ethics approval and consent to participate: The study was a retrospective reviews. Informed consent was obtained from all patients after a detailed consultation that delineated the risks, benefits, and alternatives of the procedures, as part of multidisciplinary neurosurgical and neurointerventional decision-making. The database of all patients and endovascular procedures was retrospectively reviewed. All the images or clinical details in the study are presented anonymously. This study was approved by the institutional review board (201800342B0) by Chang Gung Memorial Hospital, Linkou Medical Center.

Consent for publication: All images or clinical details in the study are presented anonymously.

Availability of data and materials: All data generated or analysed during this study are included in this published article and its supplementary information files.

Competing interests: All authors certify that there are no actual or potential competing interests in relation to this article, and there are no financial interests to disclose.

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Author's contribution

CT performed the conception and design of the study, analysis and Interpretation of data, and drafting the article. CC contributed to the design of the study, acquisition of data, analysis and Interpretation of data, critically revising the article, approved the final version of the manuscript, statistical analysis, and study supervision. YC contributed to the interpretation of data, drafting the article, and study supervision. YM had technical and material support of this study. SC had technical support and reviews the images of this study. PC had technical and material support of this study. MC had material support of this study. SY had material support of this study. YJ helped to draw the figures. All authors read and approved the final manuscript

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Figures

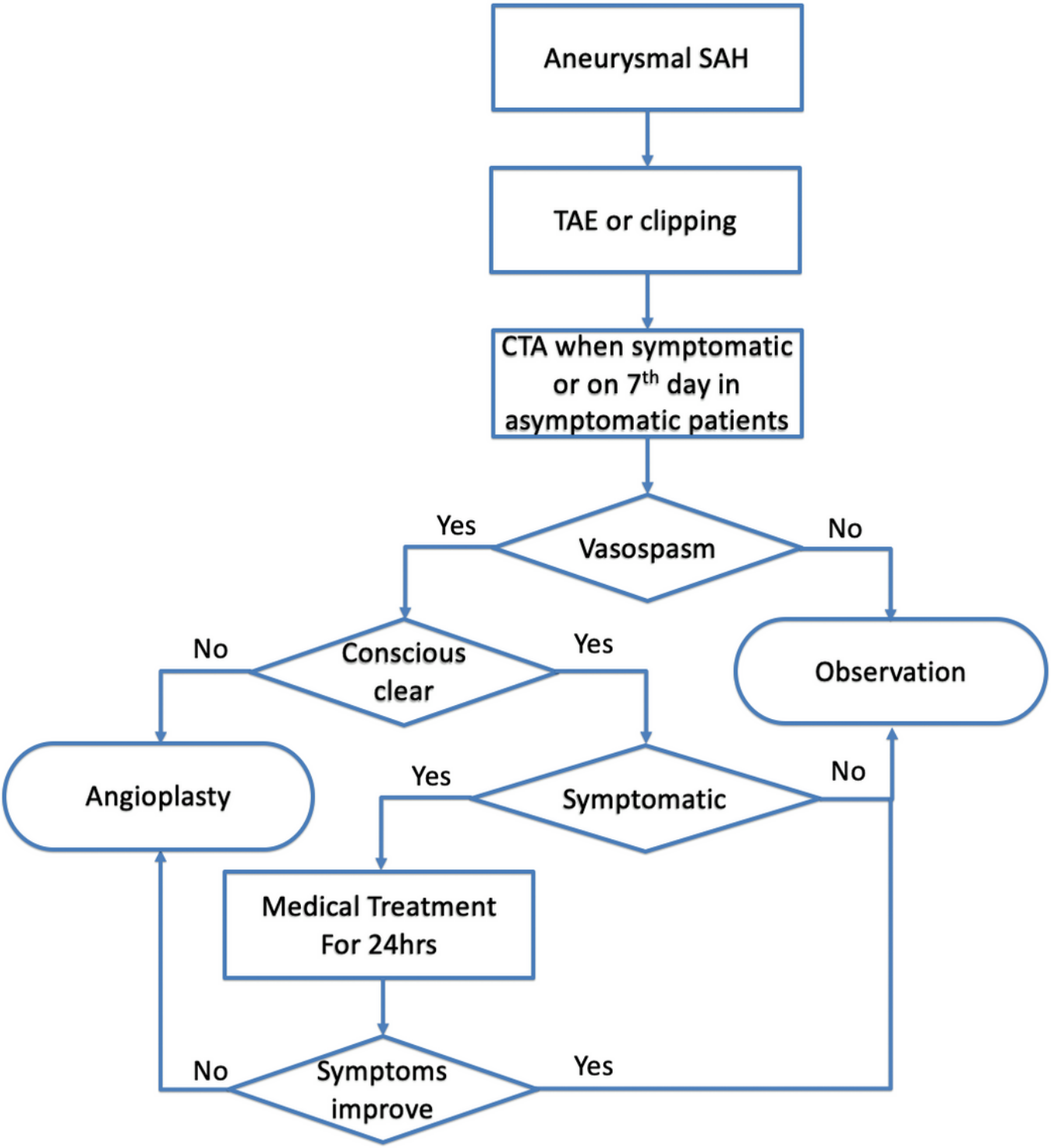

Figure 1

Flowchart of treatment for patients with post-SAH vasospasms in our institution

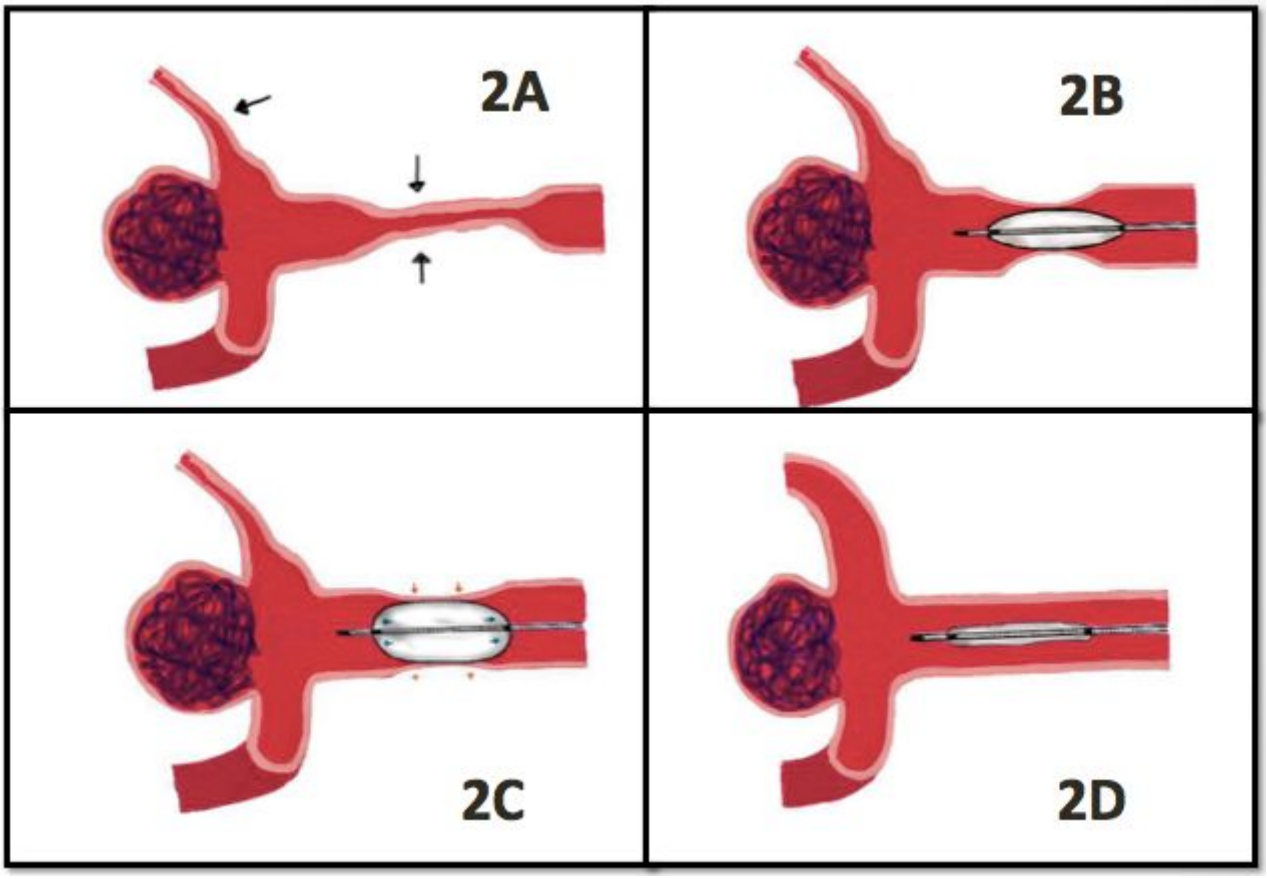

Figure 2

Demonstration of Scepter XC balloon angioplasty: (A) Middle cerebral artery vasospasm at M1 and M2 segments (black arrows). (B) Scepter XC balloon gradually inflated from the central area. (C) Even and gentle expansion of the balloon (blue arrows) along the vessel wall (red arrows). (D) Improvement of vasospasm after angioplasty at M1 and nimodipine treatment in M2 segment during the same session.

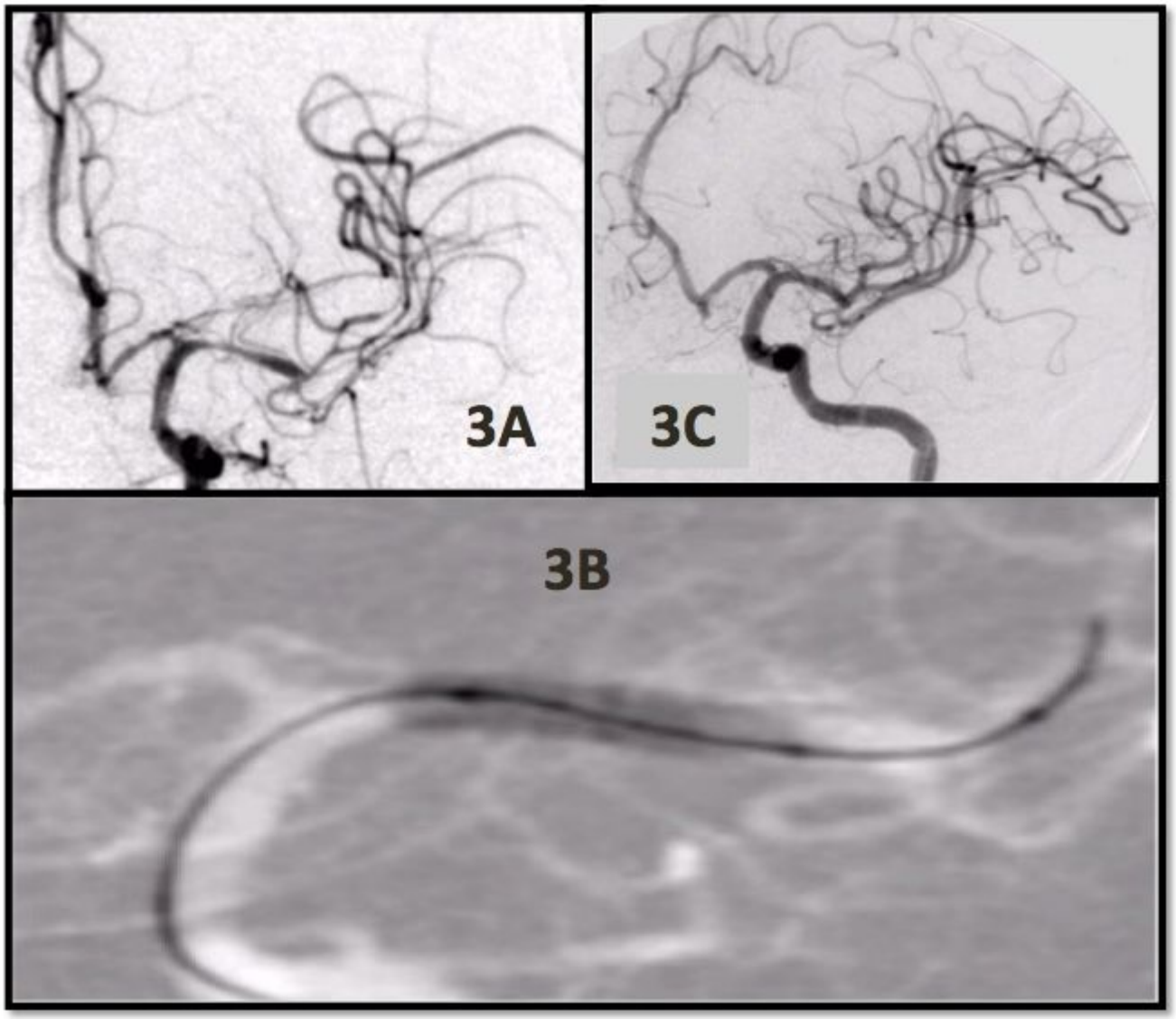

Figure 3

Case demonstration: (A) Diffused vasospasms at MCA, M1, M2, & M3 branches before angioplasty. (B) Scepter XC balloon angioplasty at M1. (C) After M1 angioplasty and simultaneous nimodipine infusion, the angiographic improvement is obviously.