

Clinical Article

Endovascular Treatment of Wide-Necked Intracranial Aneurysms Using Balloon-Assisted Technique with HyperForm Balloon

Sang O Youn, M.D., Jae Il Lee, M.D., Jun Kyung Ko, M.D., Ph.D., Tae Hong Lee, M.D., Ph.D., Chang Hwa Choi, M.D. Ph.D.

Department of Neurosurgery, School of Medicine, Pusan National University, Busan, Korea

Objective : To assess the feasibility, safety, and effectiveness of the balloon-assisted technique with HyperForm balloon in the endovascular treatment of wide-necked intracranial aneurysms.

Methods : A total of 34 patients with 34 wide-necked intracranial aneurysms were treated with endovascular coil embolization using balloon-assisted technique with Hyperform balloon. Twenty-nine aneurysms (85.3%) were located in the anterior circulation. The group of patients was comprised of 16 men and 18 women, aged 33 to 72 years (mean : 60.6 years). The size of aneurysms was in the range of 2.0 to 22.0 mm (mean 5.5 mm) and one of neck was 2.0 to 11.9 mm (mean 3.8 mm). The dome to neck ratio was ranged from 0.83 to 1.43 (1.15). Sixteen patients were treated for unruptured aneurysms and the remaining 18 presented with a subarachnoid hemorrhage.

Results : In the 34 aneurysms treated by the remodeling technique with HyperForm balloon, immediate angiographic results consisted of total occlusion in 31 cases (91.2%) and partial occlusion in three cases (8.8%). There were five procedure-related complications (14.7%), including two coil protrusions and three thromboembolisms; Except one patient, all were successfully resolved without permanent neurologic deficit. No new bleeding occurred during the follow-up. Twenty patients (59%) underwent angiographic follow-up from 2 to 33 months (mean 9.2 months) after treatment. Focal recanalization with coil compaction of the neck portion was observed in 5 cases (25%). Only one case showed major recanalization and underwent stent-assisted coil embolization.

Conclusion : The balloon-assisted technique with Hyperform balloon is a feasible, safe, and effective endovascular treatment of wide-necked cerebral aneurysms.

KEY WORDS : Intracranial aneurysms · Wide-necked aneurysms · Endovascular treatment · Balloon-assisted technique.

INTRODUCTION

Since introduction of the Guglielmi detachable coil (GDC) in 1991, endovascular therapy for intracranial aneurysm has evolved rapidly and it has become the alternative choice of modality in the treatment of intracranial aneurysms⁸⁾. Despite enormous advancement in the development of flexible microcatheter, coil configuration, and embolic materials, aneurysms with a wide neck or unfavorable dome-to-neck ratio remain a therapeutic challenge. Using an endovascular

treatment approach may raise problems such as unsatisfactory angiographic results or aneurysmal recurrence. Furthermore, attempts at complete obliteration of wide-necked aneurysms increase the risks of coil protrusion, embolic complication, or a parent artery thrombosis¹⁰⁾.

The balloon-assisted technique is one method which allows for the satisfactory occlusion of wide-necked aneurysms. In 1997, Moret et al.¹⁷⁾ described the "remodeling technique" for the treatment of these difficult aneurysms in which a temporary, inflated balloon was placed in front of the aneurysmal neck during each coil placement to avoid inadvertent coil protrusion into the parent artery. Several investigators have reported the efficacy of this technique^{11,12,21)}. The purpose of this article is to assess the feasibility, safety, and effectiveness of balloon-assisted technique with HyperForm balloon in endovascular coil embolization of wide-necked intracranial aneurysms.

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• Address for reprints : Chang Hwa Choi, M.D., Ph.D.
Department of Neurosurgery, School of Medicine, Pusan National University, 305 Gudeok-ro, Seo-gu, Busan 602-739, Korea
Tel : +82-51-240-7257, Fax : +82-51-244-0282
E-mail : chwachoi@pusan.ac.kr

MATERIALS AND METHODS

A total of 34 patients with 34 wide-necked intracranial aneurysms were treated with endovascular coil embolization using balloon-assisted technique. The group of patients was comprised of 16 men and 18 women, aged 33 to 82 years (mean : 60.6 years). The size of aneurysms was in the range of 2.0 to 22.0 mm (mean 5.5 mm) and one of neck is 2.0 to 11.9 mm (mean 3.8 mm). The dome to neck ratio was ranged from 0.83 to 1.43 (mean 1.15). Among all the patients, all aneurysm located on an arterial bifurcation or small artery.

Twenty-nine aneurysms (85.3%) were located in the anterior circulation. Sixteen patients were treated for unruptured aneurysms and the remaining 18 presented with a subarachnoid hemorrhage. The location of aneurysms is summarized in Table 1.

All cases were treated by balloon-assisted technique with HyperForm balloon after failure of initial embolization attempts owing to coil instability within the aneurysm, significant impingement of coil loops on the parent artery from the wide neck, or unfavorable dome-to-neck ratios.

The inclusion criteria of this study were a wide-necked intracranial aneurysm, defined as an aneurysm with an unfavorable dome-to-neck ratio (less than 1.5) and/or the neck length of 4 mm or more, as measured manually on the basis of digital subtraction angiography (DSA).

Patients with ruptured aneurysms were clinically assessed at admission using the Hunt and Hess (H-H) grade. All patients were clinically assessed at discharge or at the last visit to our clinic using a modified Rankin Scale (mRS)²¹.

All therapeutic procedures were performed through the right femoral artery under general anesthesia. Electrocardiogram, arterial oxygen saturation, and blood pressure were appropriately monitored. Cerebral angiography was performed to evaluate the morphologic features of the aneurysms such as the size of the neck, width, height of the aneurysm fundus, the presence of daughter sac and anatomic relationship with the parent artery, and major branches, as well as to

establish the optimal visual working projection for coil embolization of the aneurysm. After diagnostic angiography was performed to establish the diagnosis of aneurysm, baseline activated clotting times (ACT) were obtained prior to the procedure. A 6F guiding catheter (Envoy; Cordis Endovascular Corporation, Miami, FL) was positioned in the distal cervical internal carotid artery, and pre-procedural angiograms were then obtained in orthogonal planes. Systemic heparin was administered in the following manner : a bolus of 3,000 IU of heparin was administered intravenously at the beginning of the procedure in cases of unruptured aneurysms, and after microcatheter placement into the aneurysms in cases of ruptured aneurysm. An additional 1,000-IU bolus of heparin was administered every hour to maintain an ACT of longer than 250 seconds throughout the procedure.

After the guide catheters were introduced into the artery harboring the aneurysm, a Hyperform balloon was placed with its Xpedion guidewire (Micro Therapeutics, Irvine, CA, USA) in front of the aneurysm neck under road mapping. And then, a microcatheter was placed within the aneurysmal lumen. The initial coil was then deployed through the microcatheter under the protection of the balloon. The balloon was deflated and 1 to 5 minutes were permitted to elapse before the coil was detached so that stability of its placement could be ascertained. If the coil was positioned without coil herniation into the parent artery and branch origin, the coil was detached and the balloon reinflated before deployment of the next coil. This cycle was repeated as necessary until the aneurysm was densely packed or the treatment was completed. The embolization was stopped when a complete angiographic occlusion had been achieved, when the coils could no longer be inserted into the sac, or to prevent an occlusion of a normal branch next to the aneurysm (Fig. 1).

Immediately after the procedure, all patients underwent non-enhanced brain computed tomography (CT) for an evaluation of possible hemorrhagic complication and 2,850 IU of low-molecular heparin (Fraxiparin, GlaxoSmithKline, Marly-le-Roi Cedex, France) was administered subcutaneously twice or three times a day for 24-72 hours.

After the procedure, multiple angiographic projections were obtained to assess the result. The rate of occlusion was classified as total if there was no contrast filling of the sac and neck of the aneurysm; as subtotal if there was residual filling of the neck of the aneurysm; as partial if there was contrast filling in the sac of the aneurysm.

Follow up angiography was performed at six months after treatment, and then every one or two years to establish coil compaction and recanalization of the aneurysm.

Clinical results were assessed upon discharge from hospital or at the last clinical visit using the mRS.

Table 1. Location of aneurysms

Location	No. of aneurysms (%)	
Anterior cerebral artery		
Anterior communicating artery	20	58.9
A1	1	2.9
Middle cerebral artery		
MCA bifurcation	4	11.8
M1	2	5.9
Internal carotid artery		
ICA bifurcation	2	5.9
Basilar top	4	11.8
Superior cerebellar artery	1	2.9
Total	34	100

RESULTS

Thirty-four aneurysms located on an arterial bifurcation or small artery were successfully embolized with a HyperForm balloon-assisted technique. In the 34 aneurysms treated by the remodeling technique with HyperForm balloon, immediate post-embolization angiographic results included total occlusion in 31 cases (91.2%) and partial occlusion in 3 cases (8.8%).

There were five procedure-related complications (14.7%), including two coil protrusions and three thromboembolisms. One patient with coil protrusion showed flow compromise but flow recovered with intra-arterial abciximab. The other coil protrusion was managed with repeated balloon compression. Two thromboembolic problems were resolved by intra-arterial injection of abciximab. But in a patient with unruptured left anterior communicating artery aneurysm, left A2 thromboembolism developed and only partial recanalization was achieved after using intra-arterial abciximab. The patient discharged with mild neurologic deficit (mRS 3). Except this patient, fifteen patients with unruptured aneurysms returned to their previous work and remained symptom free (mRS 0).

There was no mortality related with subarachnoidal hemorrhage or complication during procedure. But, in patients with ruptured aneurysm, mRS was variable. This may be contributed to initial poor Hunt-Hess grade due to SAH, with low statistic significance (Fig. 2).

Twenty patients (59%) underwent angiographic follow-up from 2 to 33 months (mean 9.2 months) after treatment. No new bleeding occurred during the follow-up period. Focal recanalization with coil compaction of the neck portion was observed in 5 cases (25%) but serial follow up showed no major recanalization. Only one case showed major recanalization and underwent stent-assisted coil embolization (Fig. 3).

The initial and follow-up angiographic results are summarized in Table 2.

DISCUSSION

Since introduction of the Guglielmi detachable coil in 1991, coil-supported endovascular therapy has become an accepted alternative to conventional neurosurgical treatment of cerebral aneurysms⁸. Although many aneurysms are amenable to

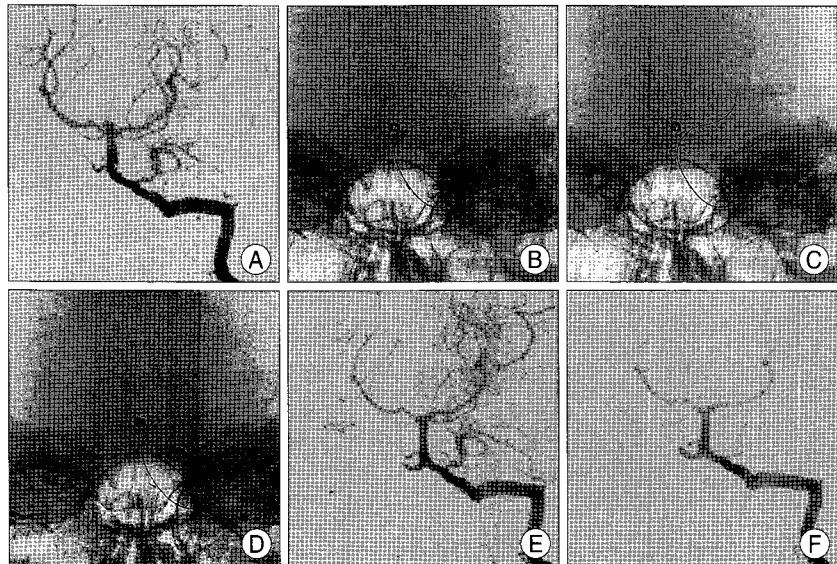


Fig. 1. A 38-year-old man with a ruptured basilar artery top aneurysm. A : Left vertebral artery angiogram shows a basilar artery top aneurysm with unfavorable dome to neck ratio aneurysm. B : HyperForm balloon is positioned across the aneurysm neck and the first coil is inserted into the aneurysm with the balloon inflation and bridging the aneurysmal neck. C : Angiogram after the balloon deflation reveals no coil herniation into parent artery. D : The last coil is inserted into the aneurysm with balloon inflation. E : Immediate post-procedural angiogram demonstrates dense, complete occlusion of the aneurysm without compromising the parent artery. F : Follow up angiogram after 6 months later reveals complete obliteration of the aneurysm.

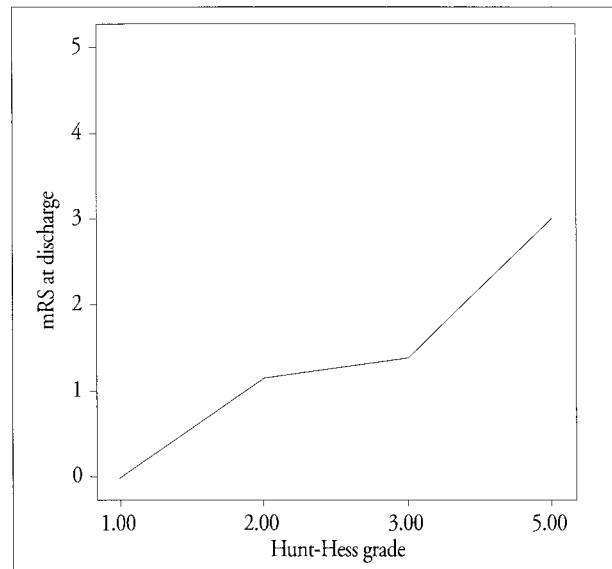


Fig. 2. Relationship between initial Hunt-Hess grade and mRS at discharge. $p = 0.454$ by Pearson correlation coefficient. mRS : modified Rankin Scale.

coiling without the use of adjunctive techniques, certain aneurysms characterized by a wide neck or by unfavorable geometric characteristics have proven technically challenging and problematic in terms of coil protrusion into parent vessel and difficulty in achieving uniformly complete coil packing of the aneurysm⁶. Recently, published results from the Cerebral Aneurysm Rupture after Treatment Study⁹ suggest that an inverse relationship exists between the degree of endovascular

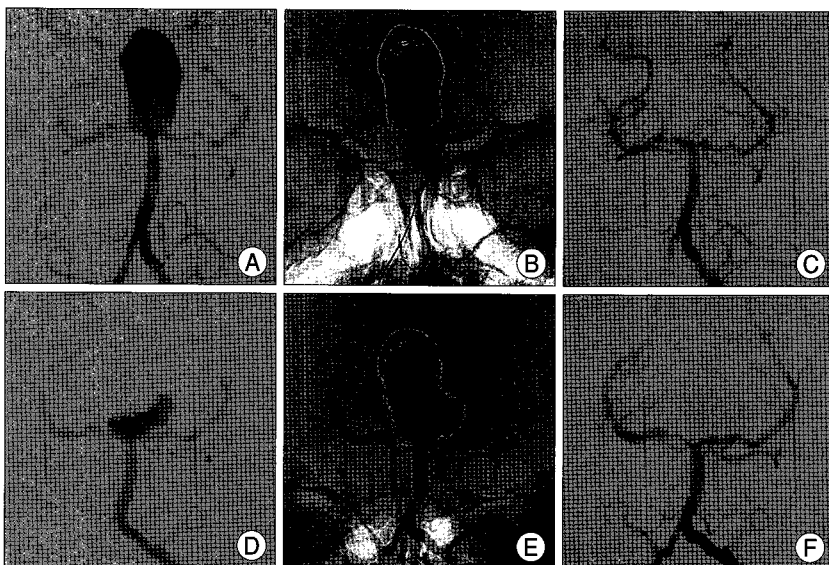


Fig. 3. A 62-year-old man with an unruptured basilar artery top aneurysm. A : Left vertebral artery angiogram reveals a 22.6 mm × 14 mm sized wide-necked basilar artery top aneurysm. B : The last coil is inserted into the aneurysm with balloon inflation. C : Final angiogram demonstrated total occlusion of the aneurysm. D : Follow up angiogram after 12 months later reveals regrowth of the coil-embolized aneurysm. E : Complete occlusion of the regrowth aneurysm with Y-configuration stent-assisted coil embolization. F : Final angiogram shows total occlusion of the aneurysm without parent artery flow compromise.

Table 2. Initial and follow-up angiographic results of 27 aneurysms treated with balloon-assisted technique using Hyperform balloon

Angiographic results	Initial results (n = 34)	Recanalization rate at follow-up (n = 20)
Total embolization	91.2% (31)	21% (4/19)
Partial embolization	8.8% (3)	100% (1/1)
Total	100% (34)	25% (5/20)

occlusion and risk of subsequent aneurysm rerupture, strongly supporting efforts to achieve as complete an aneurysm exclusion as possible. To address these technical problems in complicated aneurysms, several trials including complex shaped coils, neck-bridging devices, and the use of stent-assisted coiling or balloon remodeling techniques have been incorporated into the treatment paradigm^{2,5,15,19,24}.

However, advances in coil design have not completely resolved the problem of treating lesions with complex features. Stent-assisted technique, which is a method including a microstent placement at the aneurysmal neck, followed by the insertion of a coil through the stent. With this, it was possible to overcome the technical difficulty of endovascular treatment. In recent years, the use of stent-assisted coil placement has been reported by several researchers^{1,3,13,22}, and from these reports, it seems that the stent is a very helpful device which facilitates the endovascular treatment of wide-necked intracranial aneurysms. However, the stent-assisted method is subject to limitations^{1,7,13}. Initially, the deployment of the stent into the parent artery is rather difficult, especially in the carotid siphon. Stent malposition, mainly proximal to the

aneurysm neck or within the aneurysmal lumen, can also occur and eventually result in procedure failure. To ensure that the stent adequately bridges the neck, determining the location of stent deployment in the tortuous vessels requires great attention. Second, the risk of the vessel stenosis or the formation of thrombosis must also be considered. Because the stent can induce neointimal hyperplasia, thrombosis or occlusion of the smaller arteries, the necessity of dual antiplatelet therapy in conjunction with stent-assisted coil embolization increases the risk of intracranial hemorrhage and possibly rebleeding from a ruptured aneurysm²⁵.

The balloon-assisted technique, in which a non-detachable balloon is advanced into the parent artery and inflated to occlude the neck of aneurysm, stabilizes the microcatheter in the

aneurysm during coil delivery and prevents the coil impinging on the parent artery. Unlike stents, the balloon is not permanent device within an intracranial vessel. Further, neither antiplatelet preparation nor long-term medication is required. HyperForm balloon was used in this study. HyperForm is a super-compliant non-latex balloon that adapts its shape to the anatomy of the arterial bifurcation, and with its super-compliancy and suppleness, may change its shape to bulge into the origin of the branches coming off the aneurysm neck. The HyperForm balloon can take the shape of the bifurcations even if its tip is directed into one of the bifurcation branches, or it can also be kept just at the neck or bifurcation during endosaccular packing without bypassing the aneurysm neck as in the round balloon technique⁴.

Another important technical advantage of this technique is the achievement of complete and stable occlusions, the aim of endovascular treatment. Moret et al.¹⁶ first described the clinical use of the balloon-assisted technique in humans and described their results on 52 aneurysms in 50 patients, achieving complete occlusion in 77%, subtotal occlusion in 17%, and incomplete occlusion in 6%. In the present study, immediate angiographic occlusion was total in 91.2%, subtotal in 8.8%, and recanalization of the neck with coil compaction was found in five cases (20%). But among these, only one recanalization was major and needed retreatment (5%). These results seem to be favorable comparing results by other techniques with or without stents. When the Guglielmi detachable coil procedure was first introduced in the literature, it was

reported that total aneurysm occlusion could be achieved in only 15% of wide-neck aneurysms⁶⁾. Sedat et al.²²⁾ reported that long-term complete aneurysmal occlusion was obtained in 71% of wide-necked aneurysms using stenting and coiling. Additionally, Raymond et al.²⁰⁾ treated 501 aneurysms with detachable coils only and reported that recurrences were found in 33.6% of treated aneurysms at mean of 12.31 months follow-up. They described that the width of the aneurysmal neck was one of the most significant predictors of a recurrence; the rate of recurrence was 23.7% in small-necked aneurysms and 52.3% in wide-necked aneurysms ($p < 0.001$). In our study, complete occlusion was achieved in thirty-one patients (91.2%) and partial occlusion was 3 patients (8.8%). The high rate of complete and stable occlusion may have resulted from balloon-assisted technique because the technique can enable denser packing of the aneurysm fundus and neck region or help mold the coil mass to improve its interface with the parent vessel.

The balloon-assist method has two additional benefits. First, the balloon microcatheter outlines the three-dimensional course of the parent vessel during angiography and serves as a reference point in the two-dimensional space of the angiographic plane. This feature enables the operator to achieve the optimal orthogonal projection for observation of the aneurysm neck. Second, the presence of the balloon microcatheter in its uninflated or partially inflated state may be sufficient to deflect a loop of coil that would otherwise herniate into the parent artery¹⁴⁾.

There are potential problems with this technique such as thromboembolism and aneurysmal perforation during the procedure. The adjunctive use of balloons may theoretically lead to an increased incidence of thrombus formation and thromboembolic events, even under optimized anticoagulation. This theoretic risk is due to several factors. First, the presence of a balloon in the parent vessel promotes stasis and can lead to thrombus formation or platelet aggregation. Second, the presence of any foreign material in the vascular system can be a nidus for thrombus formation. Third, repeated inflations and deflations of the balloon, which may lead to intimal injury¹⁷⁾. To prevent thromboembolic complication during balloon-assisted coiling, operators should consider pretreating patients with a combination of aspirin and clopidogrel before intervention. In this study, thromboembolic complications occurred in three cases (8.8%). Compared with other remodeling techniques using stents, the risk of thromboembolism is not any greater. A literature review reported the incidence of thromboembolic complications at 8.1% during balloon-assisted embolization²³⁾. Sedat et al.²²⁾ reported that 9.5% of cases experience symptomatic thromboembolic complications during stent-assisted embolization.

Another potential problem with balloon-assisted technique is that the microcatheter may impinge against the wall of the aneurysm during balloon inflation, which may result in aneurysm perforation. This occurs in two types of situations. The first situation may occur when the balloon is inflated and the microcatheter is pinned against the wall. During coil delivery, because the catheter is pinned and has decreased freedom, advancement of the coil may result in its rupture through the aneurysm wall (pinning). The second situation may occur when balloon inflation actively deflects the microcatheter against the wall (perimeterization). These two phenomena emphasize the fact that operators must be aware of both the state of the balloon catheter and the position of the microcatheter, to avoid the transmission of excess local stress to the dome and the risk of aneurysmal rupture¹⁴⁾. The presence of the balloon was, however, helpful in sealing the aneurysmal rupture and may have contributed to the excellent clinical outcome. Paradoxically, the presence of the balloon seems to be salutary in the event of aneurysmal rupture, provided that the microcatheter is already within the aneurysm and in position to deliver additional detachable coils while the balloon is occluding blood flow¹⁸⁾.

The recently published largest-to-date literature review with meta-analysis did not demonstrate a higher incidence of thromboembolic events or iatrogenic rupture with the use of adjunctive balloon remodeling compared with unassisted coiling. Balloon remodeling appears to result in higher initial and follow-up aneurysm occlusion rates²³⁾.

CONCLUSION

In this study, complete embolization was achieved in 31 out of 34 patients (91.2%) and procedure-related complication with sequela was observed in only one case (2.9%). Among twenty patients with angiographic follow-up, recanalization which required retreatment occurred in one patient (20%). The result shows that the balloon-assisted technique using HyperForm is feasible and safe, and effective for achieving a complete and stable occlusion of wide-necked cerebral aneurysms. The technique seems to be the optimum treatment modality for wide-necked aneurysms.

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