Simulation Study of Distal Balloon Protection Systems during Carotid Artery Stenting

T. KUROIWA, N. SAKAI*, M. SAKAGUCHI**, H. ADACHI*, H. IMAMURA*,
C. SAKAI, A. MORIZANE*, H. ISHIHARA*, T. YANO*, S. NAKAO, H. KIKUCHI

Division of Neuroendovascular Therapy, Institute of Biomedical Research and Innovation

**Department of Neurosurgery, Kobe City General Hospital*

***Department of Neurology, Kobe City General Hospital*

Key words: carotid artery stenting, distal balloon protection, PercuSurge GuardWire Plus, pitfalls, tips

Summary

The purpose of our experimental study was to assess the pitfalls of distal balloon protection systems and to learn any technique tips to increase safety.

Silicone carotid artery models were connected to a circulatory system to simulate arterial flow. A distal balloon protection device, PercuSurge GuardWire Plus (GWP, Medtronic Vascular) was delivered to the internal carotid artery (ICA), then was inflated to occlude ICA flow temporarily. A debris aspiration catheter (Export catheter) was delivered just proximal to the GuardWire Plus balloon coaxially, in order to introduce and diffuse particulate debris (200-500micrometers in diameter) in the ICA stump. Then, after debris in the stump was aspirated, the GWP balloon was deflated. We recorded all the processes of our simulation experiments on a digital video and observed the movements of debris during these experiments.

Exp 1) We simulated the movements of debris in the ICA stump when the GWP balloon was gradually deflated to produce a crevice between the balloon and vessel wall, simulating accidental movement of the GWP balloon during the procedure.

Exp 2) In order to assess the optimal placement of the tip of aspiration catheter, the debris in the ICA stump was aspirated from three different

sites (from just below the GuardWire balloon, from 2 cm below it, and from 5 cm below it).

Exp 1) When the crevice appeared between GuardWire balloon and silicone tube, simulated debris began to concentrate just below the balloon. Then, some debris migrated distally from the crevice, and another part crowded in the crevice so that was impossible to aspirate and migrated in the end.

Exp. 2) Debris aspiration was most effective from immediately below the GuardWire balloon, and the aspiration ability declined as the distance between the balloon and aspiration catheter became longer. According to our simulation studies, when the GWP balloon was moved accidentally during CAS procedures, or when the aspiration catheter was not delivered all the way to the GuardWire Plus balloon, distal embolization might still occur, even under protection.

Introduction

Carotid artery stenting (CAS) has been increasingly practiced as an alternative to carotid endoarterectomy (CEA), particularly since the developments of cerebral protection devices^{1,6}. Nowadays, there are three temporary neuroprotection system, i.e. balloon occlusion^{1,3}, filter devices^{4,5}, and systems for flow reversal in the internal carotid artery⁶.

However, intravascular filter devices are not yet available in Japan, and proximal balloon protection are limited in use because of its relatively large profile. The GuardWire Plus (Medtronic Vascular) temporary occlusion and aspiration system³ led to the wide-spread use of CAS because it can be delivered via a unilateral transfemoral approach. Moreover, after crossing the lesion with the balloon, the serial inflation-deflation and aspiration procedures can be performed under distal protection, as in most cases patients tolerate temporary balloon occlusion without symptoms.

Some experts have indicated that the use of these distal protection devices during CAS in general can significantly reduce thromboembolic complication rates⁷ and frequency of microembolic signals during TCD monitoring⁴. However, Schluter et al indicated that neuro-protected CAS is associated in about 25% of cases with predominantly silent cerebral ischemia on postoperative diffusion-weighted MRIs⁸. Other experts suggest that protection device-related complications might occur in some cases and that the ultimate effect remains uncertain^{9,10,11}.

In some cases, the GWP balloon is observed moving vertically during procedures under fluoroscopy, especially during delivery or removal of devices. In other cases, the aspiration catheter cannot be delivered up to the level of GWP balloon due to the angulated lesions. Those cases may carry increased risk for cerebral embolism during procedures, especially after the protection balloon is deflated.

The aim of this experiment was to examine the possible pitfalls of distal balloon protection systems and determine a technique to maximize potential safety by simulating debris capture during the CAS procedures.

Material and Methods

In vitro silicone carotid artery bifurcation models were used for this experiment. The bifurcation models had a parent vessel (common carotid artery, CCA) with an internal lumen 6 mm and one distal vessel (external carotid artery, ECA) with an internal diameter of 3 mm, the other distal tapered vessel (internal carotid artery, ICA) with an internal diameter of 4 mm at the point away from 10 cm distal from the bifurcation.

To simulate the temporary ICA occlusion, the bifurcation model was then connected to a circulatory system and a pump, which provided a pulsatile flow with 15 cm/s from the CCA. Pressure values delivered by the pump were set to match physiologic conditions. The circulating fluid, normal saline solution, was kept at 37 degrees. A distal balloon protection device (PercuSurge GuardWire Plus (GWP)) was placed into the model so that its balloon was in the ICA at 10 cm above the bifurcation. The Export aspiration catheter was placed just below the GWP balloon coaxially. The MicroSeal Adaptor is then attached to occlude ICA flow completely.

The GWP balloon was inflated to 4.5-mm to occlude ICA flow completely. Then, from the Export catheter we diffused simulated particulate debris (Sodium polyAcrylate gel suspension dyed in the toluidine blue, 200- 500 micro meter in diameter) in the ICA stump (figure 1A). After 20 cc of liquid was aspirated over approximately 20s, the GWP balloon was deflated, restoring antegrade flow.

We recorded all the processes of our experiments on a digital video and observed the movements of debris under distal protection systems.

Experiment 1: Assuming that the GuardWire plus balloon was moved accidentally during a CAS procedure, we simulated the movements of debris in the ICA stump when the GWP balloon was gradually deflated to produce a crevice between the balloon and vessel walls.

When the debris was observed to move, we stopped to deflating the GWP balloon.

Experiment 2: To assess the optimal place of the tip of the Export catheter, we placed it at different sites to aspirate the debris. The tip of that catheter was placed at three different sites (just below the GuardWire balloon, 2 cm below it, and 5 cm below it), then debris was aspirated from those locations.

Results

Experiment 1: After the GWP balloon was incrementally deflated, a crevice between GWP balloon and the silicone tube was produced, and then simulated debris began to concentrate just below the balloon (figure 1B).

Figure 1 A) Simulated particulate debris is diffused in the ICA stump under temporary distal balloon occlusion. B) When the occlusion balloon was deflated gradually, debris concentrated just below the balloon rapidly. C) Some debris migrated distally from the crevice between the balloon and the vessel. D) Some debris was not able to be aspirated in the crevice.

Then, even when the deflation was stopped, some debris might migrate distally from the crevice (figure 1C), and other debris accumulated in the crevice so that was impossible to aspirate completely (figure 1D) and finally migrated distally after the GWP balloon was deflated.

Experiment 2: When the tip of the aspiration catheter was placed just below the GWP balloon, debris in the ICA stump was aspirated rapidly and completely (figure 2A). The longer the distance between the tip of aspiration catheter and the GWP balloon, the less complete the aspiration (figure 2B,C). The debris just below the GWP balloon could not be aspirated when the aspiration catheter was placed farther away, and the residual debris in the stump migrated distally after the GWP balloon was deflated.

Discussion

The PurcuSurge GuardWire Plus temporary occlusion and aspiration system (Medtronic Vascular) is one of the distal balloon protection devices available for use during carotid artery stenting³. Once the balloon on a wire crosses the stenotic lesion, the serial inflation-deflation and aspiration procedures can be performed under distal protection with most tolerating temporary balloon ICA occlusion without symptoms. PTA balloons, stents, and debris aspiration catheter can be delivered over the wire smoothly, so the percutaneous intravascular procedures can be performed via a unilateral transfemoral approach.

However, Schuster et al reported that 5.2% of patients suffered peripocedural complication during CAS procedures even with GuardWire protection¹². They also indicated that new is-

Figure 2 A) When the tip of the Export catheter was placed just below the occlusion balloon, almost all of the debris can be aspirated. B) When the tip was placed 2 cm away from the balloon, debris cannot be aspirated completely. C) When the tip was placed 5 cm away from the balloon, debris persisted in the stump.

chemic foci after the elective neuroprotective CAS procedures were observed in ten of 42 cases (22.7%) using postinterventional MRI⁸. Al-Mubalak et al suggest that the use of the GWP balloon system during CAS significantly reduces the frequency of multiple embolic signals (MES) in particular during stent deployment, predilation, and postdilation, but that MES in the protection groups were still detected predominantly during sheath placement, guidewire manipulation and distal-balloon deflation. They also showed the possibility of asymptomatic embolization into the ipsilateral MCA through collateral circulation (ECA) during CAS with distal-balloon protection¹⁴. So, the ultimate effect of this protection system remain uncertain^{9,10,11}, and there may be some pitfalls in this system.

In clinical cases we sometimes observe vertical movement of the GWP balloon predominantly during the exchange of PTA balloon, stent, and aspiration catheter, so MES on the TCD could be detected simultaneously. It is probably because the soft elastomeric balloon material tends to elongate, maintaining only one atm of pressure on the vessel wall and to move easily without much force.

When the aspiration catheter could not be placed just below the GWP balloon due to the kinking of the lesion and the protruded struts of stents, MES were detected after the GWP balloon was deflated.

In such dangerous cases there would be some pitfalls of this distal balloon protection system, so the movement of particulate debris in the ICA stump should be observed in an in-vitro vascular model. The purpose of this experimental study was to examine the pitfalls and acquire some tips of preventing distal embolization.

When the occlusion balloon accidentally was moved during some clinical cases, some MES are detectable on intraoperative TCD, and so there may be a crevice between the balloon and the vessel wall. In this experimental model, we selected the incremental deflation of the GWP balloon to simulate the crevice intentionally. In fact, we tried to simulate the vertical movement of the occlusion balloon in this experimental model, but it was impossible probably due to the friction between GWP balloon and silicone vascular model.

When the occlusion balloon deflated gradually during temporary occlusion, the debris in the stump concentrated gradually just below the balloon, and then some migrated distally from the crevice with the balloon inflated. De-

bris that was trapped in the crevice finally migrated distally when the balloon was deflated. So when the temporary occlusion balloon is moved accidentally in some clinical cases, the same phenomenon may occur and cause embolic complications. That phenomenon would be due to a rapid flow in the crevice between the occlusion balloon and vessel wall in some clinical cases as in this experimental model.

Therefore, in the beginning of temporary occlusion, the GWP balloon should be fixed to the vessel wall. In order to fix the GWP, its balloon should be inflated a little larger than the internal diameter to be appeared "egg-shaped", not be "round-shaped" under fluoroscopy. The soft, elastomeric balloon material tends to elongate, maintaining only one atm of pressure on the vessel wall and likely does not cause vessel injury. During CAS procedures, the GWP balloon should be pushed forward a little during removal of devices, and should be pulled slightly backward during the delivery of devices in order to minimize movement of the balloon.

In some clinical cases of tortuous ICA, when the struts of stents have interfered with the delivery of the aspiration catheter, the aspiration catheter could not be navigated below the temporary occlusion balloon. In those cases MES would be detected during the deflation of the occlusion balloon. In this experimental model, the longer the distance between the GWP bal-

loon and the tip of aspiration catheter, the lesser the volume of aspiration debris, and the more debris remained in the carotid stump. So the optimal position of the tip of the aspiration catheter was recognized to be just below the GWP balloon.

Therefore, for preventing distal embolization, the aspiration catheter should be delivered to just below the occlusion balloon, and in the case of tortuous vessels we should twist the aspiration catheter so as not to hit the protruding strut of the ICA. We should use the 0.035 inch guidewire coaxially in the aspiration lumen to increase the pushability of the device.

Conclusions

The use of distal balloon protection systems can significantly reduce thromboembolic complications during carotid artery stenting. However, our experimental study showed a potential pitfall in case of accidental movement of the occlusion balloon, and in case of suboptimal delivery of the aspiration catheter. In order to prevent distal embolization using this protection system, the temporary occlusion balloon should be fixed to the vessel wall, especially during delivery and removal of PTA/stenting devices so as not to move accidentally. The aspiration catheter should be delivered to just below the protection balloon to maximize the aspiration of particulate debris.

References

- 1 Theron JG, Payelle GG et Al: Carotid artery stenosis: Treatment with protected balloon angioplasty and stent placement. *Radiology* 201: 627-636, 1996.
- 2 Albuquerque FC, Teitelbaum GP et Al: Balloon-protected carotid angioplasty. *Neurosurgery* 46: 918-923, 2000.
- 3 Whitlow PL, Lylyk P et Al: Carotid artery stenting protected with an emboli containment system. *Stroke* 33: 1308-1314, 2002.
- 4 Jaeger H, Mathias K et Al: Clinical results of cerebral protection with a filter device during stent implantation of the carotid artery. *Cardiovasc Intervent Radiol* 24: 249-256, 2001.
- 5 Reimers B, Corvaja N et Al: Cerebral protection with filter devices during carotid artery stenting. *Circulation* 104: 12-15, 2001.
- 6 Adami CA, Scuro A et Al: Use of the Parodi anti-embolic system in carotid stenting: Italian trial results. *J Endovasc Ther* 9: 147-154, 2002.
- 7 Henry M, Amor M et Al: Angioplasty and stenting of the extracranial carotid arteries. *Tex Heart Inst J* 27: 150-158, 2000.
- 8 Schluter M, Tubler T et Al: Focal ischemia of the brain after neuroprotected carotid artery stenting. *J Am Coll Cardiol* 42: 1007-1013, 2003.
- 9 Taylor S, Alcocer F, Jordan WD Jr: Controversies in carotid stenting. *Vasc Endovascular Surg* 37: 79-87, 2003.
- 10 Cremonesi A, Manetti R et Al: Protected carotid stenting: clinical advantages and complications of embolic protection devices in 442 consecutive patients. *Stroke* 34: 1936-1941, 2003.
- 11 Ohki T, Veith FJ: Critical analysis of distal protection devices. *Semin Vasc Surg* 16: 317-325, 2003.
- 12 Schluter M, Tubler T et Al: Feasibility and efficacy of balloon-based neuroprotection during carotid artery stenting in a single center. *J Am Coll Cardiol* 40: 890-895, 2002.
- 13 Al-Mubarak N, Roubin GS et Al: Microembolization during carotid stenting with the distal-balloon antiemboli system. *Int Angiol* 21: 344-348, 2002.
- 14 Al-Mubarak N, Vitek JJ et Al: Embolization via collateral circulation during carotid stenting with the distal balloon protection system. *J Endovasc Ther* 8: 354-357, 2001.

Terumasa Kuroiwa, M.D.
 Institute of Biomedical Research
 and Innovation
 Division of Neuroendovascular Therapy
 2-2, Minatojima minamimachi, Chuo-ward,
 Kobe, Hyogo, 650-0047; Japan