

New System of Cerebral Protection for Carotid Stenting

a report by

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The use of cerebral protection during carotid stenting is being less and less contested. The protection systems currently available present a certain number of inconveniences.

The new system that the authors propose is an evolution of the cerebral protection concept by temporary occlusion of the distal internal carotid.¹⁻³ Experience with several hundred endovascular treatments of the carotid bifurcation process concluded several strong points that have been used to simplify the technique:

1. Temporary closure of the internal carotid is the most efficient protection^{4,5} if a complete closure of the carotid is achieved. The Percusurge (Medtronic) device, although based on the authors' original concept of cerebral protection by temporary occlusion of the internal carotid, presents a very mobile balloon of a diameter frequently too small, meaning the carotid closure may be incomplete. It is the reason the authors proposed to position the balloon in the carotid canal of the temporal bone.⁵ Due to the absence of collaterals, the verification of the efficiency of the temporary closure of the carotid artery by injection of contrast must show a stagnation of the contrast at its origin. The progression of the contrast up to the balloon is the sign of an incomplete, and therefore inefficient closure.
2. With auto-expandable stents, a pre-dilatation is rarely necessary (less than 5% of cases). The only moment of a real risk of embolic complication is the time of post-dilatation when the plaque is broken. The first series of 45 carotid stenting cases where protection was used, without complication, at the post-stenting phase has been reported.⁵ The authors' current experience is of more than 200 cases, and a more recent publication⁶ has confirmed these findings.
3. For haemodynamic reasons, the carotid bifurcation is a privileged site for endovascular therapeutics; significant restenosis is rare (less 5%) in comparison with other arteries. The Carotid Wallstent (Boston Scientific) has a very low restenosis rate at the carotid bifurcation but if placed at the level of the subclavian artery, the restenosis rate is much higher.
4. Tortuosity of the vessel is a consequence of vascular degeneration. It can have pathological consequences due to the turbulences and localised stagnations it produces. There is no interest to keep it and, consequently, the continuous frame stents that correct the tortuosity, seem to be better adapted to the treatment of the stenosis at carotid bifurcation.
5. In the carotid bifurcation, the use of long stents (4cm or more) are satisfactory for three reasons: a. they treat the whole diseased arterial segment by placing the stent from normal common carotid artery to normal internal carotid artery; b. they better correct the tortuosity of the vessels; and c. the rate of restenosis is lower.
6. The carotid bifurcation is a unique anatomical site because of the presence of the carotid sinus. This dilation at the origin of the internal carotid represents a protective natural filter for the cerebral supply. The turbulences produced by the division of the common carotid in two arteries are associated with the presence of the sinus. Consequently, the deposit of atherosclerotic particles are on the wall of the origin of the internal carotid and more specifically on its posterior face wall. The fundamental point is that this phenomenon is



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localised at the origin of the internal carotid, and the upper-lying internal carotid artery is usually free of these atherosclerotic deposits.

The new cerebral protection system (TwinOne®, Minvasys) is based on these different points. Its goal is to focus the problem on the carotid bifurcation and to concentrate, from the beginning to the end of the procedure, all manipulations on a very limited anatomical space.

The various phases of the technique are as follows:

- after having positioned the guiding catheter in the common carotid artery, the stenosis is passed with a 014 wire;
- when a predilatation is necessary, it is performed with a 2mm balloon without cerebral protection;
- the stenosis is passed with the stent without cerebral protection. The stent is auto-expandable and its length is of 4cm or more. It can be rapid-exchange or over-the-wire. Its diameter is from seven to nine mm according to the artery. It is a delicate moment and the manipulations must be extremely soft;
- the stent is deployed without cerebral protection. It is positioned covering the origin of the external carotid. To have more comfort in the manipulations, the segment above the external carotid origin will be slightly superior in length to the segment below this one;

*the guiding catheter is introduced in the stent.

- the delivery system of the stent and the wire are withdrawn; and
- the protection system is introduced (TwinOne) in the stent. It is a device combining a catheter loaded with an occlusion balloon with a rapid exchange angioplasty catheter.

Introduced as one tool, it is possible –after peeling away the sheath – to move each catheter separately to ensure best positioning of each item. There is no wire and the progression is especially fast and simple when continuous frame stents are used. For the open cell stents, a torquer facilitates the progression of the balloon.

- the system is positioned at the distal extremity of the stent;
- the occlusion balloon is inflated in the stent and the angioplasty balloon is positioned at the narrowing of the stent;
- an angiographic series is performed. Contrast should be gently injected to avoid forcing the contrast around the occlusive balloon and give a false impression of incomplete occlusion. The

contrast must remain at the origin of the internal carotid if the closure is efficient;

- the post-stenting dilatation is achieved. The patient is medicated, at least five minutes prior to post-dilatation, with one mg of atropine to limit the bradycardia secondary to the compression of the carotid glomus.
- the angioplasty balloon is pulled back and withdrawn from the femoral or radial introducer. The guiding catheter is repositioned, when necessary, on the site of the angioplasty and blood (one or two 20cc syringes) is aspirated through the guiding catheter. A flush is not performed.
- the occlusion balloon is deflated and retrieved. The mean occlusion time is less than five minutes in most cases and may reach only three minutes with some experience. The guiding catheter is positioned, again in the common carotid artery and control angiographic series are performed.

Conclusion

The combination of two instruments – an occlusion balloon and a post-stenting angioplasty balloon – in this new cerebral protection system permits the physician to focus the problem on the pathological zone and on the real risks of carotid stenting. It allows the physician to perform the treatment quickly and safely. The carotid closure time is very limited (three to five minutes). The cerebral tolerance to the temporary closure is good and to date there have been no cases of intolerance. As the inflation of the occlusion balloon is made in the stent, it does not provoke a spasm on the distal internal carotid, and this presumably increases the chances of a good cerebral response to the temporary closure of the carotid artery.

This technique permits the physician to concentrate the whole therapeutic problem on the stent and on a very reduced space that can be easily washed of all embolic particles after the dilatation. The verification of the efficiency of the closure of the carotid artery by an angiographic series is critical and permits the physician to have a guarantee of a total cerebral protection.

The system can be used via a femoral or radial approach with all types of stents, but it is clear that closed-cell stents permit an easier positioning of the occlusion balloon. Auto-expandable stents of at least four cm long facilitate the manipulation of the devices at the different times of the technique and do not increase the risk of restenosis. ■

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