“Protected” Wallstenting of Atheromatous Stenoses at the Carotid Bifurcation


1. Department of Neuroradiology and Interventional Radiology, Centre Hospitalier Universitaire, Caen, France
2. Neuroangiography Department, General Hospital of Catalunya, Sant Cugat Del Valles, Barcelona, Spain
3. Clinica Ntra Sra del Rosario, Madrid, Spain
4. Department of radiology, Hospices civils, Strasbourg, France
5. Section of Neuroradiology, Hospital of Geneva, HUG University, Geneva, Switzerland

Key words: atherosclerosis, carotid arteries, angioplast, stenting

Summary
Atheromatous stenoses at the carotid bifurcation were treated by angioplasty and Wallstenting with cerebral protection obtained in most cases by temporary occlusion of the internal carotid artery. 287 carotid stenoses were treated in 233 patients. The stenosis was symptomatic in 79% of cases. All patients presented either a stenosis of >70% with significant impairment of the cerebral circulation (281 cases) or a symptomatic ulcerated plaque (six cases). A self-mounted protection system was used in 177 cases, the Percusurge Guardwire protection device in 98 cases and an EPI filter in 12 cases. There was a contralateral internal carotid occlusion in 13% of cases. A combined stenting (vertebral, siphon, subclavian) was performed in 14% of cases. A Rolling membrane Wallstent was used in 84 patients, a first generation Easy Wallstent in 38 cases, a “Carotid” Easy Wallstent 35 in 55 cases and monorail 14 in 110 cases.

Full opening of the stenosis was obtained in 98% of patients with correction of the arterial curve and improvement of the cerebral vascular supply. There were 0.7% cases with transient symptomatic neurological complications and 2% with permanent sequelae mainly related to avoidable inadequacy in flushing or to the insufficient radial force of the first generation Easy Wallstent. There were no per and one post-procedural cardiac complication (0.6%) in the s165 cases performed with the “Carotid” Easy Wallstent. Follow-up angiograms showed 0.7% of restenoses. Still in evolution, endovascular treatment of atheromatous stenoses at the carotid bifurcation with cerebral protection and stenting is a promising alternative technique to surgery. The association of Carotid Easy Wallstent 14 monorail and Percusurge Guardwire appears to be currently satisfactory.

Introduction
Minimally invasive treatment options for atheromatously diseased carotid stenoses at the bifurcation, though still controversial, are becoming increasingly popular. Stenting and cerebral protection are two current techniques making significant progress. We present a new series of 287 Wallstenting of atheromatous stenoses at the carotid bifurcation using a cerebral protection provided in most cases (96%) by temporary occlusion of the internal carotid artery. This paper mainly emphasizes the evolution of Wallstent items and temporary occlusive protection devices.

Material and Methods
In 281 patients, the stenosis was >70% with a significant hemodynamic impairment on Digitized Parenchymography (see further). In six
cases, the stenosis was moderate but there was a significant symptomatic ulceration (ocular blindness one case, homolateral TIAs five cases).

The treatment was bilateral in 54 patients (19%) most often performed in two sessions (45 cases). There was a contralateral occlusion of the internal carotid in 37 cases (13%). In 40 cases (14%), there was a significant associated stenosis (carotid siphon six cases, subclavian artery seven cases, vertebral artery 27 cases) that were treated in the same session. The approach was femoral in 272 cases, right high brachial in three cases and, more recently, radial in 12 cases.

**Preparation of the patient**

The patients were given: 1) one week before the procedure Ticlopidine (Ticlid) 500 mg or currently Clopidogrel (Plavix) 75mg; 2) on the day of the procedure and for one month after the procedure Ticlopidine 500 mg or Clopidogrel 75mg and Aspirin 200mg every day (as
seen further we currently consider not using aspirin; 3) For the following five months either Ticlopidine or Clopidogrel.

General concept of “Protected Wallstenting” by temporary occlusion of the internal carotid artery (Figures 1,2).

“Protected Wallstenting” consists of: 1) protection of the brain by a temporary occlusion of the internal carotid distal to the site of the stenosis; 2) preangioplasty of the stenosis (in case of severe stenosis); 3) Wallstent placement; 4) post stent placement angioplasty to complete the opening of the stent; 5) aspiration of the potential detached debris followed by flushing the potential remaining debris towards the external carotid artery.

Evolution of the protection systems

At the beginning of this series, in 177 cases we used our self-mounted protection system. In 98 cases, the 14 Percusurge Guardwire system (Medtronic) developed on the same concept was used.

In 12 cases, an EPI Boston Scientific filter was used.

Description of the Percusurge Guardwire system:

– Distal orifice: the Guardwire temporary occlusion catheter currently used is a 0.014 angioplasty wire designed for the “monorail” technique and constructed with a hollow nitinol hypotube. Incorporated into the distal wire is an inflatable elastometric balloon capable of occluding vessel outflow. A marker shows the lo-
cation of the balloon. In the last generation, thanks to the profile of the wire and balloon, the system allows passage of very narrow stenoses and much better navigation in tortuous carotid arteries distal to the stenosis. By increasing the inflation of the same balloon mm by mm, the system also obtains adequate temporary occlusion checked on control angiographic series (see further).

- Proximal orifice: the hypotube wire incorporates a Microseal allowing inflation and deflation of the distal occlusion balloon utilizing a Microseal adapter. The Microseal keeps the elastometric balloon inflated while allowing catheter exchanges. In the last generation, the Microseal adapter has been much improved allowing easier elimination of the air in the wire.

- The Export aspiration catheter is placed over the shaft of the Guardwire to aspirate the debris generated by the procedure.

“Full protection” technique (figures 1, 2).

Protection at all the steps of the technique was used in 242 cases with predilatation in 63 cases. These numbers will be discussed further in relation to the technical evolution. The mean occlusion time of the carotid was 14 minutes in this group. In this paper, we describe in detail our current “monorail” technique with the protection balloon of the Percusurge Guardwire positioned in the carotid canal of the temporal bone in a case of severe stenosis necessitating a predilatation.

1) Puncture of femoral artery under local anesthesia and light sedation.
2) Use of a 8F introducer sheath (Terumo, Ref. RS B 80 K10 MQ).
3) The introducer is fastened to the skin with a suture (Seracap Ref. 49617) and connected to a continuous flush (pressurized infusion kit n°1).
4) A single bolus of Heparin is injected at a dose of 100 IU/Kg body weight and half of this
dose will be reinjected if the procedure turns out to be longer due to catheterization difficulties.

5) Catheterization of the common carotid artery with a regular 5F diagnostic catheter.

6) An exchange Cook THSCF 35 260 3 guide-wire or, depending on the difficulties of navigation, a Medi-tech Amplatz 46526 is positioned in the common carotid and the guiding catheter is introduced and positioned in the common carotid artery (Cordis-8F, vertebral curve 588-847 P). Prior to introduction of the guiding catheter, a hemostatic valve Nycomed Easycatch (Ref. 105 43 71) is fitted to the hub. A second continuous flush is used for the guiding catheter (pressurized infusion kit n° 2).

7) Diagnostic angiography is performed in this position (figure 1 A), and care is taken to evaluate the external carotid artery territory in order to eliminate potentially dangerous distal anastomoses to the ICA or vertebral artery territory (see further).

8) After orientation of the guiding catheter to fit the axis of the stenosis, the combined system including the predilatation catheter (Terumo DC RN2020PHM) and the prepared Percusurge Guardwire 14 (GR14-6.0-3.6-200) is advanced up to the tip of the guide catheter. The Guardwire is then gently advanced, under road-mapping, along and past the stenosis. It is positioned in the carotid canal of the temporal bone (figure 1 B).

9) The protecting occlusive balloon is inflated. Angiographic short series confirms the carotid occlusion (figures 1 C, 2 B). The patient is clinically tested and 1 mg of Atropine is administered i.v.

10) The preangioplasty catheter passes the stenosis. The stenosis is predilated (figure 1 D). There is usually no side effect at this step and particularly no bradycardia.

11) The predilatation catheter is retrieved (Retrieval #1). During retrieval, the occlusion balloon is maintained inflated.

12) The monorail Carotid Wallstent Boston scientific 9mm/4cm (SCH64713) or 7mm/5cm (SCH64709) for small arteries is introduced (figure 1 E) and positioned with its mid length in front of the ECA origin. The Wallstent is deployed (figure 1 F).

13) The delivery system of the Wallstent is retrieved (Retrieval #2). The guiding catheter is gently advanced into the stent.

14) The complementary monorail post-dilatation angioplasty balloon Guidant 6 mm / 1003010-20 “RX Via-Trac 14” or 7 mm /2 cm 1003012-20 “RX Via-Trac 14” is introduced in the stent.

15) Post-dilatation within the stent (Figures
1G) is performed. During this step, bradycardia and a slight decrease in alertness can occur markedly reduced if the injection of Atropine has been performed early enough in the course of the procedure. The patient may also complain of some pain in the neck at the site of the inflation.

16) Retrieval of the post-dilatation balloon catheter (Retrieval #3). The guiding catheter is again gently advanced in the stent. Introduction of the Export (Percusurge) aspiration catheter in the stent. Aspiration of the blood in the internal carotid from the occlusive balloon down to the site of the dilated stenosis (figure 1 H). The export catheter is retrieved (Retrieval #4).

17) Injection of 30 ml of saline flush at a rate of 1ml/second through the guiding catheter using a power injector. This flush release close to the occlusion balloon removes any potential remaining plaque debris flushed downstream and aspirated by the flow towards the ECA. This step is not performed if pretreatment angiographic series have shown dangerous anastomoses (see figures 11 B and C).

18) The occlusion balloon is now deflated. Control angiographic series centered on the bifurcation and on the intracranial vessels are performed (figure 1 I). After retrieval of the guide catheter, the introducer is either retrieved immediately using an occlusive device system such as Angioseal (Sherwood Davis & Geck, St. Louis, USA) (St Jude) or a few hours later using a Femostop II (Radi Medical Systems, Uppsala, Sweden). The patient is allowed...
to stand up and walk the following day and is discharged one day later.

“Simplified” technique (figures 3, 4).

This modified technique was used in 45 cases with a predilatation in 36 cases. It consists in using cerebral protection only at the post stent placement angioplasty step. This simplified technique was mainly used before the Carotid Easy Wallstent monorail was available and before the improvement of the Percusurge Guardwire navigability. The mean occlusion time of the internal carotid was nine minutes in this group. The stenosis was usually treated with an over-the-wire technique: the stenosis is passed with a 35 Termuno straight wire 4 meters long (RF GS 35 403 M) and the predilatation, when necessary, performed with a 3mm / 2cm Boston scientific Smash-SCH-5035 angioplasty catheter, the 9mm/4cm or 7mm / 5cm Wallstent mounted on 35 is then placed without protection. No complication was related to this simplified technique.

Complementary techniques:

A) Treatment of arterial spasm: if, by mechanical irritation, the temporary balloon occlusion has produced a vasospasm of the ICA, as indicated by the presence of narrowing and flow disturbance (figure 5 A, B), then an injection of Nimodipine is prepared. Diluted Nimodipine is injected slowly as a bolus at a dose of 3 ml equal to 60 µg (Nimotop 10mg/50 ml is diluted by 10 with water, i.e. 20µg/ml). In our experience, the mobility of the Percusurge balloon induced more spasms than our original latex occlusive balloon and this led us to design a new balloon placement in the temporal bone.

B) In-stent clot formation may occur when the procedure has been prolonged by catheterization difficulties and when the anticoagulation has not been renewed. Protected arterial thrombolysis usually solves these problems (figure 5 C, D).

C) Autoblood infusion distal to a temporary occlusion of the internal carotid (Figure 6 E) used in rare cases where the temporary occlusion of the carotid artery is not well tolerated because of a poor circle of Willis, other multiple occlusive lesions of the neck vessels or an antecedent of stroke. This technique was successfully used in three cases but the current availability of filters makes it less useful.

1) Both femoral arteries are punctured.
2) An introducer 8 F Terumo Ref RS B 80 N 10 MQ (Intro n°1) on one side and an introducer 6 F or 7F Termuno Ref .RS B 60 N 10 MQ on the other side (Intro n°2).
3) Injection of 200 IU/kg of Heparin.
4) A regular 5F diagnostic catheter is positioned in the common carotid artery.
5) A Cook Microferret MFHS 021 135 HC is
Figure 5  Two cases illustrating asymptomatic technical incidents. A) Asymptomatic spasm distal to the stent that was treated by intra-arterial injection of Nimodipine. B) Control angiogram performed the following day showing the spasm clearance and a better expansion of the stent on the arterial wall. C) Control angiogram after a protected angioplasty showing a thrombus formation. The procedure had been lengthy due to catheterization difficulties. Anticoagulation had not been repeated. The protection balloon was repositioned, local intra-arterial thrombolysis was performed and the clot was aspirated. D) Control angiogram after the procedure.
Figure 6 Temporary occlusion of the internal carotid. Illustration and comments: thanks to the circle of Willis, this occlusion is very well tolerated in most cases. We estimate the absolute intolerance not to be superior to 1 or 2%. When tolerance is not satisfactory, the following can be used: a) filters; b) a fast simplified technique as seen previously; c) a better oxygenation of the patient; d) a better prevention of bradycardia by atropine; e) an autoblood infusion technique (see E). A) Patient presenting a symptomatic stenosis of the left internal carotid artery. Aortic angiogram shows that he also presented with a right internal carotid and vertebral occlusion. B) Left internal carotid stenosis. C) Treatment by protected Wall-stenting. D) Post-stenting complementary angioplasty step. During the temporary occlusion of the internal carotid using the Percusurge Guardwire the brain was only supplied by the left vertebral artery. Excellent clinical tolerance. D) Post-treatment angiogram. E) Diagram of the principle of autoblood infusion. The blood supplied by contralateral femoral introducer is infused in the internal carotid artery distal to the occlusion balloon. The infusion microcatheter (arrow) is positioned at the beginning of the procedure and the completely protected technique of balloon occlusion, angioplasty and stenting is performed from the contralateral approach over the infusion microcatheter which is slowly withdrawn by sliding smoothly underneath the stent at the end of the procedure.
introduced into the catheter. The stenosis is passed with a thin wire.
6) The tip of the microferret is positioned in the internal carotid in front of C1-C2.
7) The diagnostic catheter is pulled down in the common carotid artery leaving the microferret in the same place.
8) From the other femoral artery, a 8 or 9F guiding catheter is advanced into the common carotid artery.
9) The whole procedure of protected angioplasty and stenting is performed as seen before over the microferret and proximal to its tip which infuses the blood of the femoral artery (double male connector Vygon Ref. R 89300).
10) At the end of the procedure, the microferret is gently pulled under the stent.

Immediate post-procedural period

Better handling of antiagregant drugs and improvement of the Wallstent have markedly simplified the patient follow-up. An intensive care unit (ICU) surveillance is safer in the immediate post treatment period, this being typically overnight for a period of about 12-24 hours. The mainly feared complications in the early post-treatment period involve thrombus formation with occlusion or thromboembolic events and delayed onset of bradycardia with a threat of critical decrease of the mean arterial pressure. We currently also fear hemorrhagic complications (see further). The critical period, mostly at risk for thromboembolic events in the hours following the procedure, is during the decrease of the heparin blood level. The post-treatment surveillance involves frequent neurological checks evaluating deficits related to thromboembolic events.

Long term surveillance and treatment

After the first month, either Ticlopidine or Clopidogrel are given permanently. To avoid events of thromboembolism, strict compliance with the prescribed intake of antiagreggants is mandatory. Restenosis related to myo-intimal hyperplasia is the most feared long-term complication of endovascular recanalization. Sonographic control at three and nine months, and every year thereafter is suggested. Follow-up angiograms were performed in this series at six months and one year but less extensive control will presumably be warranted in the future if the present good results of the Carotid Wallstents are confirmed.

Results

A full opening of the stenosis was obtained in 281 cases (98%) in all types of stenoses (figures 7, 8). Partial dilatation was obtained on six cases when a protected post dilatation could not be performed due to difficulties in catheterization that made the positioning of the protection system unsafe. Spontaneous improvement in the opening of the artery, however, was documented in the follow-up angiograms in four cases. A complementaty protected angioplasty using another approach was performed in two cases one month later.

Complications

In the complete series of 287 cases, there were transient symptomatic complications in 0.7% of cases and 2% permanent complications, more or less severe, including four deaths (1.4%).

In the group of 165 cases performed with the “Carotid” Wallstent, there were no periprocedural complications and one immediate post procedural death related to cardiac failure (0.6%). More detailed listing of transient and permanent complications is as follows.

During the procedure.

1) Transient neurologically asymptomatic:

a) some degree of vasospasm (figure 5 A) was observed on the site of the occlusive balloon in the distal internal carotid in 12% of the 177 cases performed with the handcraft protection system and in 55% of the 79 cases performed with the Percusurge Guardwire balloon (67 cases) or the EPI filter (12 cases) positioned in the distal cervical artery. All the cases remained neurologically asymptomatic and responded well to local Nimodipine. There was no vasospasm in the 31 cases performed with the Percusurge Guardwire balloon positioned in the temporal carotid canal (see further).
b) intrastent clotting was observed in a patient at the end of the procedure and was successfully treated by protected intra-arterial thrombolysis followed by aspiration of the clot (figure 5 B).
Figure 7 Treatment of stenosis and ulcerae illustrated on two selected cases with immediate closure of the ulcerations and correction of the arterial curve. Case 1. A) Symptomatic ulceration. B) Control angiography immediately after treatment. Case 2. C) Narrow stenosis with significant ulceration of the plaque. D) Control angiography immediately after treatment.
Figure 8 Rolling membrane Wallstent. Characteristics of the stent followed by illustration of three selected cases. A) Angle of the stent framework (same angle in the Carotid Easy Wallstent). Case 1. B) Ulcerated plaque involving both the internal and common carotid arteries before treatment. Case 2. C) Control angiography after treatment. Case 2. D) Delayed auto-expansion of the stent. In this case, due to catheterization difficulties, no complementary post-dilatation was performed on this symptomatic ulcerated plaque. Immediate post-stent placement angiogram. E) 6
c) one patient presented an asymptomatic occlusion of the internal carotid artery due to erroneous placement of the stent in a false lumen underneath the intima.
d) one patient (figure 10) presenting a very tortuous and calcified stenosis was treated using a first generation Easy Wallstent and the complementary angioplasty led to tearing of the arterial wall by the calcified plaque. The Easy Wallstent did not have a sufficient radial force to stop the resulting bleeding that was successfully treated by the placement of a Palmaz stent in the Wallstent.

2) **Transient neurologically symptomatic:**
   - One patient treated for a stenosis of the right internal carotid presented a transient posterior fossa stroke due to reflux from the carotid artery towards the right vertebral artery during flushing (4ml/s flush).

3) **Permanent:**
   - One patient presented an anatomical variant with an ophthalmic artery arising from the middle meningeal artery. Although the opening of the carotid artery had been successful with a good intracerebral result, flushing of the remaining particles in the external carotid led to monocular blindness (figure 11 B, C).

**After the procedure**

1) **Transient neurologically asymptomatic:**
   - a) In 30 cases (11%) a significant hypotension was observed in the 24 hours following the procedure. All the patients remained asymptomatic and more severe hypotension was controlled by Dopamine. All these patients had been treated with a classic rolling membrane Wallstent. No patient treated with a first generation Wallstent presented a significant hypotension after the procedure. With the “Carotid” easy Wallstent, a moderate hypotension is regularly observed but does not usually necessitate an injection of Dopamine.
   - b) One patient presented an aneurysm of the femoral artery that was successfully treated by surgery.

2) **Transient neurologically symptomatic:**
   - One patient presented a moderate hemorrhagic suffusion of a recent infarction visualized on the CT performed after the procedure for some alteration of consciousness. The patient was neurologically intact at the follow-up examination.

3) **Permanent:**
   - a) One patient with a recent infarction presented a bleeding of the infarcted area after the procedure with reappearance of language problems that cleared only partially.
   - b) One patient presenting with a silent infarction on the pretherapeutic MRI presented bleeding of the infarcted area in the hours following the successful procedure (figure 16).
   - c) One patient treated with a first generation Easy Wallstent incompletely deployed due to calcification of the plaque presented a motor deficit three hours after the procedure (figure 9). No occluded vessels were demonstrated on the repeated angiogram.

   This complication, interpreted as a distal vasospasm or a very distal embolism was not treated by thrombolysis. The patient improved markedly in the following hours on heparin but died from haemorrhage of an unknown gastric ulceration five days later.
   - d) One patient treated with a first generation “Carotid” Easy Wallstent presented hemiplegia related to the occlusion of the stent three days after the procedure. This occlusion was successfully treated by thrombolysis but the patient died two days later due to an intracerebral haemorrhage contralateral to the treated side.
   - e) One patient treated with a “Carotid” Easy Wallstent died two days after the procedure due to decompensated ischemic cardiac failure.

**Late results**

- a) There was no case of stent deformation.
   - b) There was no case of occlusion of the covered external carotid.
   - c) No patient presented a recurrent neurological symptom in the treated territory.
   - d) The layer of myointimal hyperplasia was usually minimal on the follow-up angiograms (figure 13), but was more accentuated in the cases treated with first generation easy Wallstents.
   - e) There were two cases of significant restenosis (0.7%). One case was an Easy Wallstent first generation. The second case was a restenosis of the proximal segment of a “Carotid” Easy Wallstent 35. This case was redilated without protection and this led to a transient embolic complication successfully treated by thrombolysis.
Figure 9  Easy Wallstent first generation. Characteristics of the stent followed by an illustrative case with an embolic complication that occurred 5 hours after the procedure. This complication was directly related to the insufficient radial force of this type of stent that was incompletely expanded. This presumably led to aggregation in the stent followed by intracerebral migration when the level of the anticoagulant decreased. A) Angle of the stent framework originally designed to reduce the shortening of the stent (see text). B) Embolic complication case. Pattern of the stent after deployment and complementary postangioplasty. AP projection. Insufficiently expanded stent surrounded by the calcified plaque. C) Same procedure. Left oblique angiogram. Insufficient expansion.
Discussion

The application of percutaneous transluminal angioplasty\textsuperscript{[1,2]} in cervical arteries has lagged behind application in other anatomical regions because of the risk of a central nervous system complication. Since October 1984, after the pioneering work by Mathias\textsuperscript{3}, we have performed 679 carotid out of 1008 supra-aortic endovascular treatments. We proposed the concept of “protected” carotid angioplasty\textsuperscript{[4,5]}. We showed the feasibility of stenting the carotid artery\textsuperscript{6} and reported a first series of balloon expandable stents at the carotid bifurcation\textsuperscript{7}. Carotid angioplasty and stenting has been used by several other teams that reported an acceptable complication rate although the procedures were performed without cerebral protection\textsuperscript{8-12}. From our series of 488 atherosclerotic stenoses at the carotid bifurcation, we selected a more recent group of 287 cases to present in this paper where auto-expandable Wallstents were first used in association with our self-mounted cerebral protection system in 177 cases and currently, in 98 cases, with the Percusurge GuardWire system based on the same technical concept and with the EPI Boston scientific filter in 12 cases.

Stent characteristics (figures 8, 9)

Compared to the balloon expandable stents that we have previously used\textsuperscript{7}, the placement of the Wallstent is less traumatic because the auto-expandable stent is deployed without breaking the plaque. By compression of the carotid glomus, the continuous radial force is responsible for frequent hypotension and bradycardia in the following hours for at least 24 hours when a classic “rolling membrane” Wallstent was used. In our experience, these symptoms, well compensated when necessary by Dopamine, have never had any clinical consequence and actually represented a kind of “security sign” showing that the stent expansion was satisfactory in the critical hours following the procedure. These signs were not observed with
Figure 10  Easy Carotid Wallstent first generation. Transient hemorrhagic local complication. A) Symptomatic (transient stroke) right carotid stenosis. Pre-treatment angiogram. Very tortuous right internal carotid artery with a stenosis at its origin. B) Pattern of the stent framework before complementary angioplasty with incomplete expansion of the stent at the level of the calcified stenosis. C) Angiogram after complementary angioplasty. Late phase. Demonstration of a hemorrhage in and around the stent caused by a tear at the level of the calcifications that complementary angioplasty with a larger balloon was unable to stop. D) A Palmaz stent was placed in the Wallstent at the site of the bleeding, allowing for compression of the injured vessel wall structures thanks to the stronger radial force of this stent. E) Immediate control angiogram. Bleeding arrest and satisfactory pattern of the dilated vessel with correction of the vessel tortuosity.
Figure 11 Embolic complications. Illustration of the anatomical and technical causes of residual embolic complications in the technique of protection with temporary occlusion of the internal carotid. As long as these causes are known they currently can easily be avoided.

A) Example of the embolic material retrieved after cleaning of the working site. B) Schematic drawing illustrating two anatomical and two technical causes of unsatisfactory cerebral protection. **Technical causes:** 1 - the stent is advanced in a narrow stenosis of the internal carotid before checking the efficacy of the balloon temporary occlusion without stent (see Figures 1C and 2B). This would give a wrong impression of occlusion on the pretreatment angiogram but after deployment of the stent a new angiogram, not always repeated, would show that the occlusion was related to the stent in narrow stenoses and not to the balloon, whose inflation might be insufficient to occlude the artery. 2 - The Percusurge balloon does not occlude the distal internal carotid efficiently.

**Anatomical causes:** normal anatomical variations of large anastomoses between the external carotid and the vertebral and internal carotid arteries: 1- meningo-ophthalmic artery; 2- muscular branches of the occipital and vertebral arteries. The absence of these large anastomoses should be checked before flushing the working site at the end of the procedure. C) Example of a complicated case: monocular blindness in a case of protected angioplasty in relation to flushing of particles in a meningo-ophthalmic artery.

D) Unsatisfactory occlusions of the internal carotid artery with the Percusurge system that led us to develop another site of placement of the occlusive balloon (see figures 1 and 2) in the temporal carotid canal. Example 1: the occlusive balloon inflated at its maximum diameter was not able to occlude the internal carotid. E) Example 2: late phase of a control angiogram performed after protected stenting of a carotid stenosis. This shows a filling of the internal carotid up to the occlusive balloon. This means that the occlusion is incomplete and that the potential risk of embolic migration remains around the very mobile Percusurge balloon when placed at this site.
the first generation of “Easy Wallstent” that we no longer recommend for carotid treatments because of its weaker radial force leading to an incomplete stent expansion in heavily calcified stenoses. This was responsible in our series for: a) difficulties in controlling bleeding in the arterial wall during the procedure; b) a risk of platelet aggregation with secondary embolism after the procedure. Four complications of this series were, in our opinion, definitely related to this weakness. The “Carotid” Easy Wallstent represents an advance because the radial force in relation to the framework angle and the metal characteristics has been changed. This radial force remains, in our opinion, slightly inferior to that of the “rolling membrane” Wallstent and this fact is confirmed by the less significant hypotensive reaction observed in the hours following the procedure. It is why we currently feel more comfortable using a 9 mm diameter stent to secure the deployment of the stent.

The classic shortening at deployment of the wallstent, for which the framework angle had been originally changed from 140° for the “rolling membrane” Wallstent to 120° for the first generation Easy Wallstent, does not actually represent a real problem at the level of the carotid bifurcation. This because in our technique the diameter of the chosen stent was that of the common carotid artery: the covered arterial segment including both the common and internal carotid arteries is not cylindrical but conic and this consequently neutralizes the stent shortening.

Other complementary advantages of the Wallstent are:
1) There is no secondary deformation compared to that described at the level of the bifurcation with balloon expandable stents.
2) The continuous frame of the Wallstent is responsible for the correction of the tortuous curve of the carotid artery which is presumably beneficial and is regularly obtained as long as the stent is properly positioned as seen further.
3) The rate of restenoses is very low (0.7%) compared to that observed with Strecker stents (6%) . This low rate of restenoses in carotid endovascular treatments in general (to be confirmed) is presumably related to the very high flow in the carotid artery which is a large diameter artery supplied in a straight line from the heart. This rate of restenosis is far from the one encountered after carotid endarterectomy and in the endovascular treatment of other smaller arteries such as coronary arteries but also, in our experience, in another main supra-aortic artery, the subclavian artery, when the same type of stent is used. The carotid bifurcation might be recognized in the future as being a privileged arterial site for endovascular treatments.

Placement position, length and diameter of the stent.

From the very first time we placed a Strecker stent in a carotid bifurcation in 1990 we have always intuitively considered it necessary to cover the whole plaque that for hemodynamic reasons involves both the common and internal carotid. In this Wallstent series, we chose a stent length between 4 and 5 centimetres for the following reasons:
1) The arterial disease is determined by the conjunction of the carotid bifurcation and the carotid sinus enlargement. We strongly believe that it is safer to place the stent from a normal arterial segment of the common carotid artery to another normal arterial segment of the internal carotid artery instead of having the extremities of the stent in a pathological area that might potentially induce other turbulences and platelet aggregations.
2) There was no secondary occlusion of the external carotid in this series of follow-up angiograms.
3) The stent placement and its length modify the tortuous curve of the artery. They actually induce not only a straightening of the artery that certainly not only consists in a distal displacement of the degenerative curve but in a kind of “absorption” of the curve with recovery of the “genuine” arterial shape that we assume to be beneficial to the patient’s brain supply. This phenomenon is more significant with the Wallstent, whose framework is continuous than with other segmented stents.

The ideal length of the stent remains to be discussed in relation to the potential carotid kinks because the distal extremity of the stent might injure the arterial intima if it remains implanted in a sharp curve.

We also currently assume that the large distal diameter of the stent might be responsible, along with the mobile occlusive balloon, for a moderate but rather frequent spasm of the distal internal carotid artery. As seen further, an-
other positioning of the occlusive balloon and the use of conic stents might solve these problems.

4) There was no evidence in this series, on the follow-up angiograms, that a longer stent was more responsible for significant restenosis than a shorter one.

Prevention of cerebral artery embolism (figure 11).

The technical concept of cerebral protection in the course of a simple balloon angioplasty consists of a triple coaxial catheter that, from a single femoral approach, enables angioplasty with distal temporary internal carotid occlu-
sion, aspiration of potential plaque debris and flushing of the working site. This technique has practically eliminated the risk of embolic complications seen during the procedures using angioplasty alone. It is interesting to note that the early results of primary stenting without protection have shown approximately the same percentage of major and minor embolic complications (between 5 to 10%) as in our very first series using simple angioplasty without protection. This has consequently confirmed that the stent alone does not protect against embolic plaque debris migration. Two studies have demonstrated the frequent existence of

Figure 13 Long term follow-up. Excellent results to be confirmed illustrated by three selected patients. A) Ulcerated symptomatic stenosis with marked tortuosity of the internal carotid artery. B) One year follow-up angiogram. The patient has remained asymptomatic. Note the occlusion of the ulceration and the correction of the arterial tortuosity; by the stenting this is not a distal displacement and its mechanism could be explained by a kind of "regeneration" of the original tonicity of the arterial wall. C) Another patient. Bilateral carotid stenting. Two year follow-up angiogram. Right side. D) Same patient. Left side. Note a minor layer of myointimal hyperplasia. E) One year follow-up angiogram in a patient also presenting an associated fibromuscular dysplasia distal to the stent, more significant asymptomatic myointimal hyperplasia, (unfrequent case).
such plaque debris during endovascular procedures. They favourably contributed to the interest of companies in the research and development of protection devices. The Percusurge Guardwire Cerebral Protection system, based on the same cerebral protection concept, currently appears to be satisfactory especially after the improvement of both proximal and terminal extremities appearing in the last generation device.

The first papers reporting early results using this device are very encouraging. However we emphasize the embolic events reported in one of the series that we did not have in our later group of 98 Percusurge cases. These complications were related, in our opinion, to two reasons:

1) In most cases, we keep the flushing step of the working site towards the external carotid after the aspiration with the Export catheter. Experiments in vitro have shown that this final flushing is important to complete the cleansing of the site although it requires, as seen further, safe anatomical conditions.

2) We strongly believe that the regular Percusurge occlusive balloon is frequently not totally occlusive when positioned at the regular site of the internal carotid artery in front of C1-C2 even when it is inflated at the maximum 6 mm diameter.

For this reason, we have developed a technical variant where the positioning site of the occlusive balloon was the carotid canal of the temporal bone. This allows:

a) a perfect temporary occlusion of the internal carotid artery. Mandatory check by an angiographic series should be done before advancing the stent in a narrow stenosis that might give the misleading impression of a correct occlusion and consequently of a good cerebral protection;

b) an elimination of the frequent arterial spasm at the C1-C2 arterial segment in relation to its normal hyperspasticity and the hypermobility.
of the Percusurge occlusive balloon compared to our original latex occlusive balloon.

The possibility of currently using a monorail Carotid Wallstent has become our standard technique and we chose to describe it in detail. It has significantly changed the technique in two ways:

1) The three meter long microcatheter or wire holding the occlusive balloon is no longer necessary for catheter exchange while the balloon remains inflated.

2) The “simplified” technique can be performed with smaller 14 wires and 2 mm pre-angioplasty balloon minimizing even further the potential embolic risk of the non protected steps. We intuitively considered that the risk of producing plaque debris was highest during the post-dilatation after stent deployment. This is because the plaque is broken at this step with a risk of cutting off fragments with the stent struts and that the risk of producing embolic debris was small during a small diameter 3 mm, or currently 2 mm with the monorail technique, gentle predilatation and autoexpandable stent deployment. This allowed us to take advantage of the better guiding capacity of a hydrophilic coated guidewire to negotiate difficult vascular geometry and to shorten the occlusion time (average nine minutes in this group). Because this simplified technique was started in difficult cases, it explains, in this series, the greater percentage of predilatations in the “simplified” group (currently significantly decreasing due to the better profile of the monorail carotid wallstent) compared to the percentage (34%) in the “full protection” group. The clinical results observed suggest that this simplified technique might keep the complication rate related to embolic events as low as procedures performed under full protection. This further supports the notion of post-dilatation being most at risk of producing embolic events.

The remaining embolic complications that occurred during the procedure in this series were only related to the cleaning procedure, both occurring during flush application into the freshly stented and post-dilated bifurcation area:

1) After aspiration, remaining plaque debris was flushed towards an external carotid artery territory with “dangerous” anastomoses and we observed monocular blindness in one patient, where the presence of an anatomical variant with supply to the ophthalmic artery territory coming from the middle meningeal artery was overlooked. It is mandatory to perform and evaluate preliminary diagnostic angiography with visualization of the external carotid artery branches prior to treatment to avoid such events. Other dangerous connections include anastomotic channels going from the internal maxillary artery to the ICA or more frequently from the occipital to the vertebral artery. The technique should then rule out the flushing step and be limited to a thorough aspiration of the working site.

2) Flushing too vigorously during the cleansing procedure may lead to reflux down to the origin of the carotid artery that in one case provoked reflux from the right carotid artery towards the right vertebral artery with a transiently symptomatic embolization to the vertebrobasilar system. As experimental studies on a model have shown, for cleansing with large amounts of fluid, the flush should not exceed 2 ml/second to allow acceptance of the fluid amount injected by the external carotid artery territory. This is more critical on the right side, since the average length of the right common carotid artery is shorter than on the left side.

Temporary distal occlusion of the internal carotid is well tolerated in most cases and even in cases with other occlusions of supra-aortic arteries and in our series 12% of the patients presented a contralateral carotid occlusion. In a few cases, usually presenting a poor circle of Willis, the occlusion was not well tolerated. There are five potential solutions to this problem:

1) The procedure should be performed on a well oxygenated patient keeping a high systemic arterial pressure.

2) The “simplified” technique significantly reduces the occlusion time by limiting the occlusion to the angioplasty post-stent placement.

3) The placement of the stent without post dilatation in cases without major calcifications anticipating a secondary satisfactory auto expansion that can only be expected with a Wallstent presenting a sufficient radial force and when the plaque is moderately calcified.

4) The experimental technique of auto-blood perfusion.

5) The distal filter which does not interrupt the flow towards the brain. We used EPI filter in 12 cases of this series in only three cases for a non
tolerance of temporary internal carotid occlusion on patients who had presented a transient stroke. In the other ten cases, the filter was chosen because of the tortuosity of the distal internal carotid artery that precluded the temporary positioning of the Percusurge balloon.

In our opinion, the only currently remaining significant technical difficulties of endovascular carotid treatments are mainly related to the catheterization of supra-aortic tortuous vessels and the impossibility of positioning the cerebral protection system safely.

Figure 15 Symptomatic ulceration without significant stenosis. Delayed closure. A) Angiogram before stenting, early phase: irregular posterior margin of the carotid bifurcation without significant stenosis. B) Same angiogram, late phase: the ulceration remains opacified. C) Angiogram immediately after stenting, early phase: the posterior margin of the carotid artery is slightly less irregular. D) Same angiogram, late phase: the ulceration appears slightly smaller. E) Six month follow-up angiogram, the patient has remained asymptomatic, early phase: the carotid margin appears smooth. There is some degree of circumferential myointimal hyperplasia or a special flow phenomenon on the proximal segment of the stent. The external carotid stenosis is unchanged. F) Same angiogram, late phase: the ulceration is no longer opacified.

Prevention of dissection by stenting

This series confirms that the stent practically ruled out dissections as long as the stent was placed in the true lumen of the vessel after a careful check on two orthogonal projections. When this is inadvertently overlooked, angioplasty and stenting will lead to immediate occlusion of the artery (one case in our series).

Prevention of thrombotic and hemorrhagic complications

Most of the patients treated in this series were prepared with Ticlopidine or Clopidogrel that were given along with Aspirin on the day and for one month after the procedure. Subsequently, either Ticlopidine, Clopidogrel or Aspirin were given for at least three months fol-
following this procedure. This protocol, familiar to cardiologists, appears quite simple and efficient. It eliminates the fluctuations in the anticoagulation that had been responsible for complications at the beginning of our experience. The tolerance of Ticlopidine is irregular and necessitates thorough laboratory analyses but Clopidogrel is expected to improve both tolerance and comfort during follow-up. Carotid treatments performed immediately before another surgical cardiac procedure implies that a more delicate handling of classic anticoagulation is done if the procedure has to be performed in the first month after stenting. This type of complication has already been reported and remains a potential risk of any kind of surgical or endovascular revascularization technique. Since the last hemorrhagic complication (figure 16), we currently consider not giving aspirin any longer but only Clopidogrel: the carotid artery is not comparable to the coronary artery and the risk of aggregation in the stent after the procedure is limited considering its high flow.

**Indications, Selection of patients**

In our opinion, the treatment of cerebral ischemia should not only be focused on the percentage of stenosis of one of the arteries supplying the brain, but on a more general concept of intermittent or chronic cerebral ischemia that necessitates information on the actual supply of the cerebral parenchyma. Endovascular treatment will then provide possibilities of treating, in the same or in a limited number of sessions, the stenoses of the other arteries such as subclavian, vertebral, siphon (figure 13) or contralateral carotid supplying the brain. Consequently, the cerebral vascular supply will be significantly improved.

The information provided by NASCET and ACAS studies are of strong statistical value but do not allow for evaluation of the hemodynamic effect on the intracranial circulation on an individual basis. The hemodynamic impact of carotid stenoses is difficult to evaluate in the presence of multiple stenotic lesions. The variable conditions given by the circle of Willis...
make this analysis even more complex. For these reasons, we decided to evaluate the arterial supply to the brain starting with the small vessels of the brain parenchyma and from there working backwards to the aortic arch. We employ Digitized Parenchymography as a routine technique to obtain a direct visualization and physiological information on cerebral perfusion in the course of the diagnostic angiographic pretherapeutic evaluation. It can be considered a physiological technique since the contrast is injected against the flow in the ascending aorta. This technique can yield much information (competitive with Perfusion MRI) that will be developed more extensively elsewhere. For the purpose of this paper we shall only stress two points:

1) A patient presenting a carotid stenosis and a normal parenchymography has only a small risk of an accident of hemodynamic origin. If the patient presented with a transient ischemic accident, its mechanism was embolic and not hemodynamic regardless of the narrowness of the stenosis. Endovascular or surgical treatment could nevertheless be considered to modify the turbulences on the carotid plaque and prevent recurrent embolic events.

2) Hemodynamic repercussion distal to a stenosis is particularly important when demonstrated in “asymptomatic” patients (figure 14). The observation on Digitized Parenchymography of a unilateral delay in the filling of the intracranial carotid artery- a distal parenchymal hypovascularisation - a unilateral venous stasis on the side of the stenosis - a longer unilateral or bilateral transit time - are the basic signs of potential hemodynamic complications. Such an observation supports the need for a revascularisation for hemodynamic reasons. Re-establishment of normal parenchymal supply after the procedure can be demonstrated by using the same technique and will usually show transient signs of hypervascularization that correspond to the opacification of the cortical vessels previously dilated but not filled because of the decreased flow distal to the stenosis. Indications for endovascular treatment when there is a moderate stenosis and a significant ulceration are intended to prevent a neurological complication related to embolization. Protected stenting efficiently cures the ulceration by changing the turbulences responsible for its development. The occlusion of the ulceration is either immediately or secondarily obtained (figure 15).

Conclusion

Because endovascular techniques are performed without general anaesthesia and, in the process, eliminate embolic complications by cerebral protection and dissections by a systematic stenting, there is no absolute contraindication against using them in any type of atherosclerotic stenosis at the carotid bifurcation. The only remaining limitations are the difficulties that can still be encountered in positioning the protection devices due to difficult catheterization of tortuous supra-aortic arteries. Protected stenting is currently satisfactory when using autoexpandable stents such as monorail 14 Carotid Easy Wallstents and a cerebral protection device such as Percusurge Guardwire. Still in evolution, they represent a promising alternative technique to surgery.
References


Dr J.G. Théron
Department of Neuroradiology and Interventional Radiology
Centre Hospitalier Universitaire, Caen, France.
Fax 33.2.31.06.46.86