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Short Communication

The micromesh stent: A superior design?

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1. Introduction

Stroke represents the third leading cause of death in US and a carotid stenosis is responsible for about 30% of the cases. Carotid endarterectomy (CEA) was considered as the gold standard treatment of a carotid stenosis. However, this operation is not without drawbacks and always at risks.

Carotid angioplasty and stenting (CAS) has been proposed as an alternative to surgery, and a large number of registries, randomized studies for high risk or standard risk patients (SAPPHIRE Study,¹ CREST Study²) showed that CAS is at least non-inferior to CEA and gives good immediate and long-term results similar to surgery.

However, in brain embolic events, neurological complications remain the major problem of the procedure and we have to try to reduce these brain embolic events with a better neuroprotection.

2. How to reduce the risks of neurological complications

2.1. Good patient and lesion selection

Following the CREST study, FDA in 2011 approved expanded indications for CAS for:

- Symptomatic patients with a stenosis $\geq 50\%$ or
- Asymptomatic patients with a stenosis $\geq 60\%$ by angiography or $\geq 70\%$ by duplex

Some patients are at a higher medical risk, for example, patients with crescendo TIA, stroke in evolution symptomatic patients, diabetics, and octogenarians. Some other patients are at higher anatomical risks: patients with long diffuse lesions, ulcerated plaques, patients with diffusely diseased atheromatous aortic arch, type III aortic arch, and tortuous

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arteries. A good study of the aortic arch of the lesion must be done before the procedure with good CT scan/MRI, good duplex scan to have a good imaging of the plaque and of the aortic arch to detect high-risk patients for CAS.

2.2. Correct technique with experienced operators

- Choose carefully guide wires, catheters, guiding catheters, or sheaths
- Choose the approach way (40% of all strokes are related to access site)
 - o Femoral most of the time
 - o Radial/brachial
 - o Direct puncture in case of high-risk aortic arch with severe atheromatous lesions
 - o Direct carotid access by minisurgical incision in some specific indications
 - o Keep the procedure short

2.3. Pharmacological agents

Antiplatelet agents are given before and after procedure, and heparin during the procedure.

2.4. Embolic protection devices (EPD)

EPDs are mandatory for each case of CAS. 2 types are currently used:

- o Filters: most often used
- o Proximal protection
- Is it efficient?
 - o Yes, as demonstrated by Garg et al.³ in a metaanalysis of 134 reports, and in the CREST study.² Without EPD, death, stroke, MI rate within 30 days was 20.8% and with EPD, it was 5.3%.
- What is the best protection?
 - o If we look at the clinical results, there is no significant difference between filters and proximal protection. With filters, the 30 days MAE varied between 1% and 4.4%⁴⁻⁶ and with proximal protection, 2.25% as reported in the metaanalysis by BERSIN.⁷
 - o If we consider the silent brain infarcts, the new cerebral ischemic lesions detected by DW-MRI, we can say that in most of the published series, we have a greater number of DW-MRI lesions after CAS than after CEA and a greater number of new ischemic lesions after CAS under filters.⁸

But in fact, we do not know the clinical significance of the new DW-MRI lesions. The majority do not cause neurological deficit and have no prognostic impact.

However, several studies showed that patients with silent brain infarcts have 5 times higher stroke incidence, cognitive dysfunction, and higher risk of Parkinson's disease and Alzheimer's disease.

The size of the lesions and not just the lesion count is an important consideration. The data from ICSS study⁹ have shown fewer, larger lesions after CEA, a greater number but smaller lesions after CAS, such that CAS and CEA have equal

volume of DW-MRI abnormalities and the same risk of neurological events.

The neurological events rate depends on DW-MRI lesion volumes.

It is crucial to choose carefully the best protection device suited for the patient depending on the lesion and the arch and other arteries.

2.5. Stents

The stent design plays an important role in preventing distal embolization and thus reducing the incidence of procedure-related strokes.

3 types of stents are currently on the market:

- Closed cell design stent
- Open cell design stent
- Hybrid stent

BOSIERS's study¹⁰ and the SPACE trial¹¹ showed less embolic risk with closed cell design than with open cell stents and in particular delayed embolic events. With open cell stents, we have more plaque protrusion with the risk of late embolic events. We have to point out that the majority of strokes occur post procedure and before discharge.

New stent design to reduce plaque prolapse through the stent struts should improve the results of CAS and reduce the risk of brain embolism.

3. The Micromesh stent

The Micromesh stent is a new stent designed and developed to trap thrombus and debris (that can dislodge and travel downstream after traditional stenting) against the wall of the artery and prevents plaque prolapse and embolic events.

The stent is coated with a micromesh net. The micromesh technology is a flexible, single fiber, knitted mesh wrapped on an open cell stent platform.

The first stent developed was the M GUARD (INSPIRE MD Israel) for coronary procedures. The metallic frame was 316 stainless steel, the crossing profile 1.1-1.3 mm, the mesh sleeve in PET, the fiber width 20 microns, and maybe the most important the mesh aperture size only 150-180 microns (the pores created by stent struts are 10-40 fold larger in diameter).

This microfibrer net has minimal effects (<0.1 mm) on the stent's crossing profile and deliverability. During stent deployment, the net stretches and slides over the expanding stent struts.

A first study with this stent, The MASTER Study was reported by Stone et al.¹² 443 STEMI patients were randomized to M GUARD VS Bare metal stent (BMS) or drug eluting stent (DES).

3.1. Results

- Complete ST resolution significantly improved in patients treated with M GUARD compared to control (57.8% vs 44.7%)
- M GUARD stent resulted in superior rates of TIMI 3 flow (91.7% vs 82.9% P = 0.006)

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