RESEARCH LETTER

OCEANUS (PrOspective multiCentEr Study of cArotid Artery steNting Using mer Stent) Study: 30 Day and Two Year Results

Carotid artery stenting (CAS) with distal or proximal cerebral protection devices is an extensively developed method of endovascular treatment for atherosclerotic carotid stenosis, especially in high risk surgical candidates. Immediate and long term outcomes of CAS and carotid endarterectomy (CEA) have already been compared in CREST (Carotid Revascularization Endarterectomy *vs.* Stenting Trial), which included average risk patients. It should also be noted that CAS and CEA were only comparable regarding the composite end point; CEA proved to be superior to CAS regarding the incidence of ipsilateral stroke.[1]

Self expanding stents (open or closed cell) are the current gold standard for stenting of the internal carotid artery (ICA). The newest option is the use of mesh covered stents for the prevention of embolism. New types of stents and protection devices appear to contribute to better clinical outcomes and safety.[2]

The acceptable peri-procedural complication rates (death, stroke, and myocardial infarction [MI]) for CAS are 6% and 3% in symptomatic and asymptomatic patients, respectively. It is therefore believed that new devices should be tested and compared in high volume centres.[3]

From October 2016 to May 2017, 100 patients underwent CAS (according to current European Society of Cardiology guidelines) using a novel open cell carotid stent (MER). The prospective OCEANUS study (PrOspective multiCentEr study of cArotid artery steNting Using mer Stent) was performed in four Polish high volume cardiovascular centres (1 382 patients underwent CAS). The study was registered at ClinicalTrials.gov (NCT03133429). A self expandable, laser cut, open cell, nitinol MER stent dedicated to the carotid artery (Balton, Warsaw, Poland) was used in the study. The delivery system is manufactured as 5 F; the stents are tube like or tapered. The stent has four platinum markers on the proximal and distal ends.

The primary end point of the study was 30 day stroke rate; secondary end points were 30 day, and one and two year major adverse events, i.e., cumulative incidence of death, stroke, and MI, restenosis and repeat revascularisation rate. The OCEANUS protocol required the use of embolic protection devices.

The study population comprised 100 patients, including 61 males (61%); 44 (44%) patients were symptomatic. According to the protocol, symptomatic patients with $\geq$50% stenosis and asymptomatic patients with $\geq$75% stenosis of the ICA were enrolled. The mean $\pm$ standard deviation pre- and post-intervention maximum carotid artery stenosis in quantitative vascular analysis (QVA) was 81.98% $\pm$ 9.15% and 12.52% $\pm$ 8.70%, respectively ($p < .001$).

Size 5 F, 6 F, and 7 F introducers were used; the stent was delivered via a femoral approach. Distal and proximal protection was used in 81% and 19% of patients, respectively. Mild or moderate calcification was reported in 48% of the patients; those with severe calcification did not been qualified for the study. Pre-dilatation was performed in 45 (45%), and post-dilatation in all patients.

A major stroke was diagnosed on day four after the procedure in a high risk symptomatic patient with a history of contralateral ICA occlusion (i.e., 2.3% of the symptomatic group and 1% of the whole study population). Aphasia persisted over 24 h and resolved after neurological treatment; other neurological symptoms subsided five days after stroke. The patient recovered after conservative treatment with no neurological sequelae. No in hospital stroke, MI, or death was reported. There were also no deaths or MIs between discharge and day 30. During a two year follow up, seven patients developed $\geq$50% in stent restenosis confirmed by duplex examination; a repeat procedure was performed in two cases with $\geq$75% restenosis. Three deaths were reported: one was a suicide; one was due to MI related complications; and one was due to complications of treatment for acute leg ischaemia. Kaplan–Meier survival analysis at two years gave an overall survival of 97%. The stroke free and major adverse event free survival rates were 99% and 94%, respectively. No statistically significant differences between symptomatic and asymptomatic patients were seen (Fig. 1).

It is noteworthy that the cell size of the self expandable MER stent is approximately 6.2 mm^2, so it fits a lower mid-range cell free area of all currently used open cell stents. Hence, good apposition of the stent to the vessel wall and satisfactory plaque stabilisation are provided, which could have contributed to the good outcomes in the analysed group.[4]

The results from the multicentre OCEANUS study show that CAS using MER stents is safe and durable. The 30 day and two year complication rates were low.

The main limitation of the study is the fact that it was a one arm, non-blinded, non-randomised study, and therefore a head to head comparison of different carotid stents was not possible. Another limitation is that the MER stent was only tested in a small heterogeneous population; this novel device needs to be tested in recently symptomatic patients when they are at the highest risk of recurrent stroke. Also, the study protocol did not include pre- and post-procedural

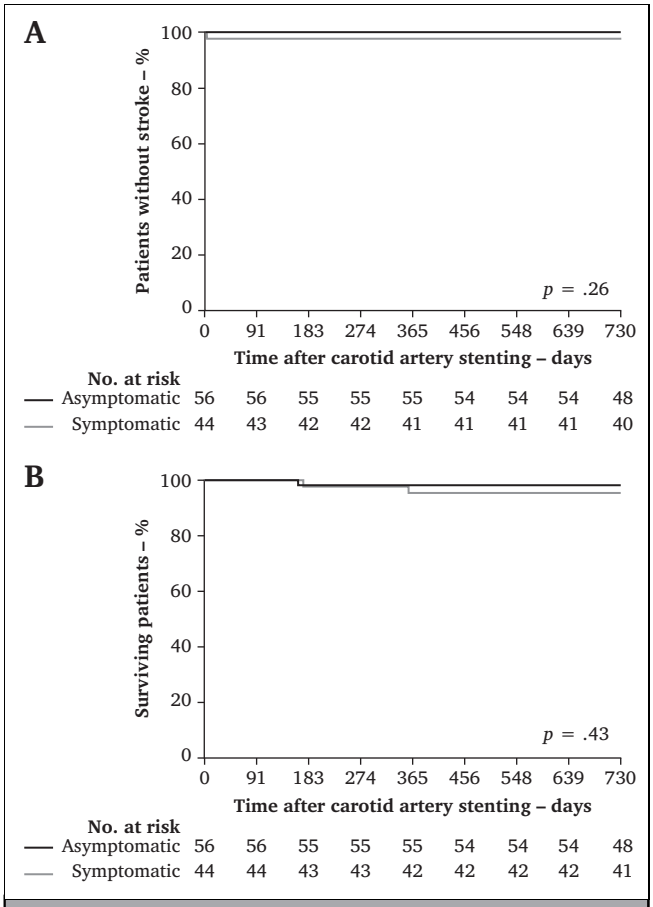

Figure 1. Cumulative Kaplan–Meier estimate of (A) patients without stroke and (B) surviving patients after treatment of symptomatic or asymptomatic carotid artery stenosis with self expandable, laser cut, open cell, nitinol MER stents (Balton, Warsaw, Poland).

diffusion weighted (DW) magnetic resonance cerebral imaging; therefore, the short term effects of CAS procedures on post-procedural cerebral embolism could not be evaluated. Future studies should incorporate DW magnetic resonance imaging assessment of subclinical procedure related events.[5]

CONFLICT OF INTEREST

None.

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REFERENCES

1 Brott TG, Hobson 2nd RW, Howard G, Roubin GS, Clark WM, Brooks W, et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. *N Engl J Med* 2010;**1**:11–23.
2 Musialek P, Mazurek A, Trystula M, Borratynska A, Lesniak-Sobelga A, Urbanczyk M, et al. Novel PARADIGM in carotid revascularisation: prospective evaluation of All-comer peRcutaneous cArotiD revascularisation in symptomatic and Increased-risk asymptomatic carotid artery stenosis using CGuard™ MicroNet-covered embolic prevention stent system. *Eurointervention* 2016;**12**:e658–70.
3 Bosiers M, Deloose K, Verbist J, Peeters P. What practical factors guide the choice of stent and protection device during carotid angioplasty? *Eur J Vasc Endovasc Surg* 2008;**35**:637–43.
4 Muller-Hulsbeck S, Preus H, Elhoft H. CAS: which stent for which lesion. *J Cardiovasc Surg* 2009;**6**:767–72.
5 Schofer J, Arendt M, Tübler T, Sandstede J, Schlüter M. Late cerebral embolization after emboli-protected carotid artery stenting assessed by sequential diffusion-weighted magnetic resonance imaging. *JACC Cardiovasc Interv* 2008;**1**:571–7.

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