

Results of the PROFI study reported at TCT 2011

November 12 2011

Results from the PROFI study indicate that the use of a proximal balloon occlusion in carotid artery stenting lead to fewer cerebral ischemic lesions – a predictor of stroke – than with the use of a filter. Trial results were presented today at the 23rd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

Previous randomized trials have revealed a higher rate of stroke following carotid artery stenting when compared to surgical removal of plaque from the carotid artery. One of the reasons for this may be that the use of filters in carotid artery stenting allows plaque particles to travel to the brain. PROFI is the first [randomized trial](#) comparing proximal balloon occlusion with filter protection in patients undergoing carotid artery stenting

In the PROFI (Prevention of Cerebral Embolization by PROximal Balloon Occlusion Compared to Filter Protection During Carotid Artery Stenting) trial, 62 patients undergoing carotid artery stenting with cerebral embolic protection for a $\geq 60\%$ symptomatic or $\geq 80\%$ asymptomatic internal carotid artery stenosis were randomly assigned to proximal balloon [occlusion](#) or filter protection. The primary endpoint was the incidence of new cerebral ischemic [lesions](#) as assessed by diffusion weighted magnetic resonance imaging (DW-MRI). Secondary endpoints were the number and volume of new ischemic lesions and major adverse cardiovascular and cerebral events (MACCE).

The incidence rate of new cerebral ischemic lesions was 87.1% in the filter group, and 45.2% in the balloon group. The mean number of new cerebral ischemic lesions was 3.5 in the filter group and 1.0 in the balloon group. There were no significant differences in MACCE at 30 days between the two groups.

"In this single center, randomized trial in patients undergoing [carotid artery](#) stenting, the incidence, number, and volume of new cerebral ischemic lesions were significantly lower under proximal [balloon](#) protection than under filter protection," said Joachim Schofer, MD, Professor of Medicine, at the Medical Care Center, Professor Mathey, Professor Schofer, Hamburg University Cardiovascular Center.

"A larger randomized trial with clinical endpoints is needed to investigate whether this benefit translates into a reduced periprocedural stroke rate," said Dr. Schofer.

Provided by Cardiovascular Research Foundation

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