

A New Modular Embolic Protection System: European Experience

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Background: Higher success rate of embolic protection in Carotid Artery Stenting (CAS) procedures has shown recently to reduce periprocedural rate of major adverse cardiac and cerebrovascular events (MACCE). We present the European experience in patients undergoing CAS using a novel modular guidewire-independent distal filter.

Methods and Results: The GARDEX Embolic Protection System (Gardia Medical Ltd., Israel) is a rapid exchange pre-crimped distal filter system used with 0.014" guide wire according to physician preference. It is a stent like system in form and operation. The GARDEX system is deployed after a 0.014" guidewire of choice was positioned across the lesion in a standard fashion. Then the GARDEX stand-alone filter unit can be delivered, positioned and locked anywhere along the guide wire, resulting in smooth crossing of the lesion and optimal protection position along the artery.

Thirty four (n=34) consecutive patients with a mean age of 70 years were enrolled. 6 patients were symptomatic and 28 were asymptomatic. The lesions treated (n=34) had an average stenosis of 83% and residual stenosis post CAS of 4%. There were no exclusion criteria based on lesion morphology or complexity. Despite complex anatomies device and angiographic success were achieved in all cases (100%), and the GARDEX performance was highly rated by multiple users.

Conclusions: Early clinical experience suggests that the use of the GARDEX EPD in CAS is simple, fast and shows high successful rates even in challenging anatomies. The ability to cross the lesion over the guide wire of choice and then deploy the filter in place creates a unique, natural and appealing advantage for all indications. Clinical outcomes appear to be favorable and the role of this new device in CAS needs to be further confirmed in a larger patient population.