

A New Modular Embolic Protection System; First In Man Experience

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Background: The use of Embolic Protection Devices (EPD) in Carotid Artery Stenting (CAS) procedures has shown to lower the periprocedural rate of major adverse cardiac and cerebrovascular events (MACCE). We present a preliminary report of a First In Man study in patients undergoing CAS to evaluate the safety and performance of a new modular distal filter protection device that can be delivered, locked and deployed on commercially available 0.014" guidewires.

Methods and Results: The new EPD (Gardia Medical Ltd., Israel) is a rapid exchange pre-crimped distal filter system used with 0.014" guide wire according to physician preference. Its modular stand-alone filter unit may be positioned and locked anywhere along the guide wire without compromising wire performance.

Twenty (n=20) consecutive patients with a mean age of 69 yrs were enrolled. Four patients were symptomatic and 16 were asymptomatic. The lesions treated (n=20) had average stenosis of 83.8% and residual stenosis post CAS of 6.0%. Device and Angiographic Success were achieved in all cases (100%). After guidewire was positioned across the lesion all Gardia EPDs were passed across the lesion and positioned in a pre determined location, regardless of lesion severity or vessel tortuosity.

One patient had neurological deficiencies which resolved within 48hrs. No other MACCE were recorded up to 30 days follow up.

Conclusions: The new EPD use in CAS is encouraging. Early clinical experience suggests that the device is easy to use and functions well in a variety of challenging lesions and vessel's anatomies. The modular EPD is able to lock on commercially available guidewires and can be positioned anywhere distal to the treated lesion. 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 study.