

A New Modular Embolic Protection System; First In Man Experience

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Aims: The use of Embolic Protection Devices (EPD) in CAS procedures has shown to lower the periprocedural rate of 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 marketed guide wires.

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

Nine (9) patients (out of the 20 designed for this trial) with a mean age of 72.2 years, were enrolled in the study. Three patients were symptomatic and 6 were asymptomatic. The lesions treated (9) had average stenosis of 84.4% and residual stenosis post treatment of 7.8%. Device and angiographic success were achieved in all cases. No major adverse cardiac or neurologic events were recorded until hospital discharge.

Conclusions: The new EPD use in CAS is encouraging. Early clinical experience suggests that the device is easy to use and functions well in challenging anatomies. The modular EPD is able to lock on commercially available guide wires, 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 and other clinical applications needs to be further confirmed in a larger patient population.