Ovalum CiTopTM: A Novel Guidewire for crossing Chronic Total Occlusion in Coronary Artery Disease patients – First-in-Man Experience

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Aims: To evaluate the safety and efficacy of the CiTop™ Guidewire in attempting to cross through chronic total occlusion in CAD patients with various coronary dimensions and morphology. Although chronic total occlusions are encountered frequently in patients with coronary artery disease, an effective strategy to deal with them has yet to be devised. Various new guidewires have been designed in an attempt to negotiate chronic occlusions successfully. The aim of the CiTop™ guidewire is to improve the success rate of CTO recanalization.

Methods: Ten consecutive male or female patients between 21 and 80 years of age, with no significant co-morbidities and with angiographic documented Chronic Total Occlusion (> 1 month) showing distal TIMI flow 0, or a prior failed guidewire attempted CTO were included in the study. The end points analyzed were technical success (crossing of CTO by placement of CiTop™ distal to occlusion with no device related major complications), angiographic success (<20% residual stenosis and TIMI flow grade 3), and clinical success. The basic features of the novel guidewire and its assessment of compatibility with other cathlab equipments were also recorded.

Results: The mean (± SD) age of the all male patient group was 53.6±9 years. The mean (±SD) lesion diameter and length was 3.1±0.4 mm and 20.4±7.9 mm, respectively, while the mean (±SD) age of occlusion was 25.5±26.8 months. Technical and angiographic successes were obtained in 7 patients (70%). The dissection of the coronary artery was observed in 2 (20%) patients using other guidewire. No events were recorded within seven days and 30-days follow up after discharge.

Conclusion: The CiTop™ guide-wire was found to be efficacious and safe for use in recanalization of chronically occluded coronary arteries in this initial experience.