Effectiveness of the Misago stent for the treatment of super TCT-530 infrainguinal CTO, primary crossing success is higher with crossing device use.
Takao Ohki1, John F. Angle2, Hiroyoshi Yokoi3, Michael Jaff4, Jeffrey Popma5

Trial (OSPREY)

lower ankle-brachial indices (0.63 vs. 0.27 vs. 0.74
69.1 mm; p < 0.003), and in patients with critical femoral artery (SFA)
Claudication and critical limb ischemia. However, in-stent restenosis (ISR) after femoropopliteal artery stenting remains a challenging therapeutic problem due to procedural complications and repeat restenosis of up to 50%.
Methods: EXCITE ISR is a multi-center, prospective, randomized, controlled trial comparing Excimer Laser Atherectomy (ELA; Spectranetics, Inc.) with adjunctive PTA to PTA alone for the treatment of femoropopliteal ISR. A total of 335 patients were planned for enrollment utilizing a 2:1 randomization structure (ELA +PTA: PTA) at 40 centers in the United States. Primary inclusion criteria were Rutherford class 1 to 4, target treatment length ≥ 4 cm, vessel diameter 5-7 mm, and lesion entirely crossable by an intraluminal guidewire. Primary endpoint was freedom from major adverse event (MAE) through 30 days post-procedure and freedom from target lesion revascularization (TLR) through 6 month follow up.
Results: Both groups were similar in baseline demographics and lesion characteristics. Patients were predominantly male (63%) while nearly half were diabetic (47%) and had a history of ISR (30%). Lesion length averaged 19 cm with 30% total occlusion. The trial was stopped at 250 enrolled patients after successful primary endpoint analysis. ELA + PTA demonstrated better procedural success with a significant reduction in procedural complications and post-treatment stenosis as compared to PTA alone. The primary safety and efficacy endpoints established superiority of ELA + PTA as compared to PTA alone.
Conclusions: The EXCITE ISR study is the first trial conducted under an IDE to support an FDA indication for femoropopliteal ISR. The complete 6 month results will be provided to show that ELA + PTA is superior to PTA alone in the treatment of femoropopliteal ISR.

TCT Abstracts/Iliac and SFA

Background: Successful crossing of superficial femoral artery (SFA) and below the knee (BTK) chronic total occlusions (CTO) often involves careful selection of a primary crossing strategy. We compared CTO crossing success rates with a primary wire-catheter or crossing device use.

Methods: We analyzed a total of 439 SFA and BTK CTO interventions in 316 patients enrolled in the multicenter Excellence in Peripheral Artery Disease (XLPAD) registry (NCT01904851) between July 2005 and May 2014.

Results: A total of 295 (67.4%) procedures utilized a primary wire-catheter and 143 primary crossing strategy. We compared CTO crossing success rates with a primary wire-catheter and had a history of ISR (30%). Lesion length averaged 19 cm with 30% total occlusion. In patients with lower ankle-brachial indices (0.63 ± 0.27 vs. 0.74 ± 0.32; p = 0.011).

Conclusions: Although most operators select a primary wire-catheter strategy to cross infranigual CTO, primary crossing success is higher with crossing device use.

TCT-530

Effectiveness of the Misago stent for the treatment of superficial femoral artery disease: 12-month Results of the First Japan and the United States Collaboration Trial (OSPREY)
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Background: The safety and efficacy of the Misago superficial femoral artery (SFA) stent was evaluated prospectively in this initial collaboration trial between Japan (JP) and the United States (US) (Misago, Terumo corp., Tokyo, Japan). Since this trial enrolled patients mainly from JP and US, and since there is question as to whether race difference exists in SFA stent performance, the race-difference on outcome was also analyzed. In addition, results were compared with a prior SFA stent trial.

Results: The Misago stent was implanted in 261 subjects with TASC A/B SFA lesions (201 subjects in US, 50 in JP, 9 in Taiwan, 1 in South Korea). The mean patient age was 69.3±10.0 and mean lesion length was 8.3±4.1 cm. The overall 12 months primary patency rate and clinically driven TLR were 82.9% and 13.0%, respectively. When these results were compared with the Zilver PTX trial, there were no difference in primary patency rate (OSPREY 82.9% vs Zilver PTX 89.9%; P = 0.206), non-TLR (87.0% vs 90.5%; P = 0.252) and stent fracture rate (1.3% vs 0.9%; P = 0.694), however, stent thrombosis rate was statistically less common in OSPREY (0.4% vs 2.7%; P < 0.05) (Zilver PTX, Cook Medical, Bloomington, IN). As far as race difference within OSPREY trial, outcome between US and non-US patients were similar including primary patency (82.9% versus 83.0%; P = 0.489), clinically driven TLR (13.4% versus 11.7%; P = 0.829), stent fracture rate (1.5% versus 0.0%; P = 1.000) and stent thrombosis rate (0.5% versus 0.0%; P = 1.000).

Conclusions: OSPREY 12 months data showed satisfactory outcome of the Misago stent for the treatment of TASC A/B SFA lesions and appears to be comparable to drug eluting stent experience. In addition, the lack of difference in outcome among race supports the value of international trials.

TCT-531

EXCITE ISR: A Prospective, Randomized Controlled Trial of Excimer Laser Atherectomy vs Balloon Angioplasty for the Treatment of Femoropopliteal In-Stent Restenosis
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Background: Femoropopliteal stenting for treatment of peripheral arterial disease has shown superiority to balloon angioplasty (PTA) for the treatment of lifestyle limiting claudication and critical limb ischemia. However, in-stent restenosis (ISR) after femoropopliteal artery stenting remains a challenging therapeutic problem due to procedural complications and repeat restenosis of up to 50%.
Methods: EXCITE ISR is a multi-center, prospective, randomized, controlled trial comparing Excimer Laser Atherectomy (ELA; Spectranetics, Inc.) with adjunctive PTA to PTA alone for the treatment of femoropopliteal ISR. A total of 335 patients were planned for enrollment utilizing a 2:1 randomization structure (ELA +PTA: PTA) at 40 centers in the United States. Primary inclusion criteria were Rutherford class 1 to 4, target treatment length ≥ 4 cm, vessel diameter 5-7 mm, and lesion entirely crossable by an intraluminal guidewire. Primary endpoint was freedom from major adverse event (MAE) through 30 days post-procedure and freedom from target lesion revascularization (TLR) through 6 month follow up.
Results: Both groups were similar in baseline demographics and lesion characteristics. Patients were predominantly male (63%) while nearly half were diabetic (47%) and had a history of ISR (30%). Lesion length averaged 19 cm with 30% total occlusion. The trial was stopped at 250 enrolled patients after successful primary endpoint analysis. ELA + PTA demonstrated better procedural success with a significant reduction in procedural complications and post-treatment stenosis as compared to PTA alone. The primary safety and efficacy endpoints established superiority of ELA + PTA as compared to PTA alone.
Conclusions: The EXCITE ISR study is the first trial conducted under an IDE to support an FDA indication for femoropopliteal ISR. The complete 6 month results will be provided to show that ELA + PTA is superior to PTA alone in the treatment of femoropopliteal ISR.