TCTAP A-098
Outcomes Following Endovascular Therapy with a Drug-eluting Stent (Zilver PTX) in the Femoropopliteal Artery
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Background: Although a drug-eluting stent (Zilver PTX) has become available for endovascular therapy (EVT) for peripheral artery disease in Japan, outcomes following EVT using Zilver PTX for patients presenting with femoropopliteal (FP) artery lesions remain to be elucidated. This study focuses on midterm outcomes.

Methods: Between July 2012 and March 2013, FP lesions in 106 limbs from 89 patients were treated with Zilver PTX. Primary outcome including primary patency and freedom from clinically driven target lesion revascularization (TLR) were analyzed by Kaplan-Meier estimation. Restenosis (diameter stenosis >50%) was assessed with angiography at 12 months. Furthermore, we compared patency of TASC (A/B and C/D) by log-rank test.

Results: At 1-year, primary patency and TLR rate were 71% and 85%, respectively. There were no significant differences between patency of TASC A/B and C/D (P = 0.28).

Conclusion: Midterm outcome was acceptable after Zilver PTX stent implantation in FP lesions.

TCTAP A-100
The Restenosis Pattern and Predictor of In-stent-restenosis Ater Zilver PTX Stenting for Superficial Femoral Artery Disease
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Background: The first drug eluting peripheral stent of Zilver PTX (COOK Medical) showed higher primary patency rate over plain old balloon and/or bare Zilver stent in TASC (A) and (B) lesions in superficial femoral artery (SFA) disease from the Zilver PTX Randomized Trial. This study led to the approval Zilver PTX in Japan. But, in real world clinical practice, we have to deal with more complex SFA disease and previously implanted SFA in-stent restenosis. We need to clarify restenosis rate, target lesion revascularization rate (TLR) and restenosis pattern of Zilver PTX in real clinical cases. The purpose of this study was to investigate restenosis rate, target lesion revascularization rate (TLR) and angiographic patterns of in-stent restenosis (ISR) after Zilver PTX stenting in real world SFA disease.

Methods: The study was prospective maintained database, retrospective analyzed by two centers. Between July 2012 and March 2013, 65 consecutive patients (pts) with 65 lesions (mean age 72 years, 68% male) underwent successful Zilver PTX stenting for SFA disease or de novo or in-stent restenosis (ISR). The following parameters were documented before the intervention, immediately afterward, 6, 9 and 12 months later: clinical stage, ankle-brachial index, peak systolic velocity ratio (PSVR) and TLR. Restenosis was defined as >2.5 of PSVR. In TLR cases, restenotic pattern was classified into three Classes. Class I is the focal (<50 mm in length) ISR group, included lesions positioned at the stent body, the stent edge, or a combination of these sites. Class II is the diffuse (>50 mm in length) ISR group, includes not only stent body lesions, but also stent edge lesions and Class III is the totally occluded ISR group.

Results: 71% of the 65 pts were in claudicant and 29% in critical limb ischemia. 40% were on hemodialysis. Mean lesion length was 174.9±11.7mm and the number of stented Zilver PTX were 1.9±0.8. Mean follow up period was 8.7±3.1 months. 65% of TASC (C) and (D), 32% of pre ISR patients were included. Primary patency rate was 75%, 62%, 57% and freedom from TLR was 92%, 74%, 63% at 6, 9, 12 months, respectively. In 20 cases of TLR analysis, restenotic pattern were 15% (3 cases) in Class I, 25% (5 pts) were Class II 60% (12 pts) were in Class III. Multivariate analysis for ISR by prespecified risk factors, the lesion which was pre ISR (HR 2.5, 95%CI 0.6–9.7; p=0.032), for 2 stents use (HR 4.5, 95%CI 1.3–13.4, p=0.019), and the pts on Clodiazol (HR 5.4, 95%CI 1.0–35.0, p=0.045) were an independent negative predictor for restenosis. And pre ISR (HR 11.4, 95%CI 2.1–87.7, p=0.003), chronic total occlusion (HR 9.2, 95%CI 1.5–90.4 =p=0.014), over 3 stents use (HR 2.1 95%CI 1.5–13.9, p=0.046) were significant negative predictor of class III.

Conclusion: The most commonly seen restenotic pattern of first drug eluting stent, Zilver PTX was class III (in-stent-re-occlusion). And its negative predictors of Zilver PTX patency were pre ISR, chronic total occlusion and over 3 stents use. These results were consistent with previously mentioned results of those bare metal Nitinol stents.

TCTAP A-101
Efficacy of the Preoperative Assessment with Ultrasonography “Vascular Elastograph” in Endovascular Therapy
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Background: The success rate of endovascular therapy (EVT) for long chronic total occlusion (CTO) of femoropopliteal arteries has improved because of devices

Methods: Between April 2007 and April 2012, 179 patients (217 limbs) with CLI classified to Rutherford 5 or 6 were treated with EVT in our institute. Out of 161 individual wounds (128 patients, 146 limbs) were successfully treated. Successful EVT was defined as revascularization of achievement of direct blood flow to the wounds evaluated by digital subtraction angiography just after EVT. Each variables were analyzed using the univariate Cox proportional hazards model for wound healing. All variables analyzed in univariate analysis with p < 0.25 were included in multivariate Cox hazards model.

Results: The mean follow-up period was 21.8±17 months. Wound healing rates were 41%, 58%, 71%, and 72%, at 3, 6, 12, and 18 months, respectively. Multivariate Cox proportional hazard analysis revealed that insulin use (HR 3.18-0.766, p=0.002), dependence on hemodialysis (HR 0.40, 95%CI 0.257-0.623, p<0.001), low ejection fraction (HR 0.438, 95%CI 0.205-0.935, p=0.033), and not toe wounds (HR 0.388, 95%CI 0.253-0.594, p<0.001) were independent adverse predictors of wound healing following successful EVT.

Conclusion: Achievement of direct blood flow to the wounds is important factor for wound healing, but that is not enough. Insulin use, dependence on hemodialysis, low ejection fraction, and not toe wounds were adverse independent predictors of wound healing.