Endpoints

The primary endpoint is primary patency at 6, 12-month follow-up. Secondary endpoints are technical success rate, and the occurrence of major adverse events, defined as stent thrombosis and all causes of death through 1 month. MAE, major amputation of the target limb through 12 months, or target lesion revascularisation through 12 months. Primary vessel patency was defined as duplex ultrasound peak systolic velocity ratio ≥ 2.4, without clinically driven target lesion revascularisation (TLR) or bypass of the target lesion.

Results

Thirty-two patients were enrolled from February 2019 to December 2019 (Table 2). We didn’t reach the target number, therefore the enrollment will be extend by March 2020. Full baseline and procedural characteristics are summarized in Table 3. Technical success was 98.8% (31 of 36) of ISR lesions. Stent thrombosis occurred in one patient (2.8%) at 2 weeks postoperative. This case seemed to be associated with clopidogrel resistance. Because VerifyNow showed PRU (P2Y12 reaction units) was 235 on emergency re-admission. No death occurred in any patients.

At 6 months, the primary patency rate was 95.6% (23/24). The Kaplan-Meier estimate of primary patency was 94.6% at 6 months (Figure 1).

Discussion

Zeller et al. (2) reported 108 patients and 119 lesion who were enrolled in the ZILVER-PTX single-arm study which is Paclitaxel-coated stent. The mean lesion length was 13.3 cm. Primary patency was 78.8% at 1 year. Primary patency in this study was better than conventional POBA (1).

On the other hand, Gray et al. (3) reported 465 patients who were randomly assigned to Eluvia (n=308) or to Zilver PTX (n=156). The mean lesion length was 8.65 cm. Primary patency at 1 year was significantly higher in the Eluvia group (86.8%) than in the Zilver PTX group (81.5%). Therefore, the present study regarding ISR also is expected to show that the primary patency is better in Eluvia than in Zilver PTX.

However there is one biggest concern about Eluvia stent. Katasano et al. reported that there is increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs (4). Eluvia was not included in these meta-analyses. Plus, there were quite different regarding the total volume of the drug and the duration of the drug release between these stents. Therefore Eluvia stent will be expected not to be associated with increased risk of death, because there was no evidence to prove increased risk of death following application of paclitaxel-coated stents in coronary field. That is why the total volume of drug and the duration of the drug release may be too low with increased risk of death following application of paclitaxel-coated balloon and stents.