**Introduction**

There is a growing body of evidence for the treatment of coronary lesions with paclitaxel-coated balloon (PCB) catheters. Currently, most of the published data for PCBs were generated with the original Paccathe® Technology in patients with in-stent restenosis of drug eluting stents (DES-ISR), in-stent restenosis of bare metal stents (BMS-ISR) and de-novo lesions.

Most of these trials had angiographic endpoints. Relative to their angiographic findings, late lumen loss (LLL) indicative for the suppression of intimal hyperplasia was consistently low in patients treated with PCB catheters. In addition, LLL after PCB angioplasty was significantly reduced as compared to their controls (uncoated balloon, paclitaxel eluting stent). There are sustained angiographic and clinical benefits with the Paccathe® coating technology to treat BMS-ISR (1-4) as well as DES-ISR (5-7). However, there are only four studies on de novo lesions treated with PCB’s. One study was conducted in diabetics (8), small vessel disease (9,10) and bifurcations (11).

**Methods**

The SeQuent® Please small vessel ‘PCB only’ Registry was an international, prospective, multicenter registry enrolling patients with de novo lesion of small reference diameters (≥ 2.00 mm, ≤ 2.75 mm). The primary endpoint was clinically driven target-lesion revascularization (TLR) at 9 months. Secondary endpoints were technical success, in-hospital outcomes 9-month major adverse cardiac events (death, myocardial infarction, or TLR), and the occurrence of definite stent thrombosis.

**Results**

A total of 479 patients (66.1±10.9 years, 36.7% diabetics) were enrolled, 105 (23.3%) with an acute coronary syndrome, 41 STEMI (9.2%) and 64 NSTEMI (14.3%) patients (Table 1). The initial procedural success rate was 99%. 27% (91) patients needed additional BMS implantation. Follow-up after 9.4 ± 1.7 months revealed a PCB-only TLR rate of 3.6% (Table 3, Figure 1) in the absence of target lesion thrombosis. The 9-month ‘PCB-only’ MACE rate was 4.7%.

**Conclusions**

In this so far largest prospective small vessel de novo PCB registry, TLR and MACE rates were low. Our 9-month TLR rate of 3.6% compares very favorably to other published data (Figure 2). Therefore, the ‘PCB-only’ strategy without stenting seems to be an attractive alternative to DES implantations in small vessels.

**References**


