Incidence, mechanisms and clinical impact of largely uncovered struts in current generation drug-eluting-stents: insight from the TRANSFORM-OCT Study

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Background: Thin-strut drug-eluting stents (DES) and optimal implantation technique reduce the rate of stent failure significantly. Nevertheless, uncovered struts (US) have been observed as a key factor for stent thrombosis regardless of stent generation and time of follow-up. Associated factors and temporal evolution are currently unknown.

Purpose: To evaluate the prevalence, mechanisms and long-term clinical impact of largely-US after state-of-the-art DES implantation in complex coronary clinical/lesion cohorts

Methods: The study was a pre-specified analysis of TRASFORM-OCT, a randomized controlled trial comparing bioabsorbable or durable polymer DES by serial optical coherence tomography (OCT), obtained at baseline, immediately after procedure, at 3 and 18 months follow-up. Methods and results were published previously. For the current analysis enrolled patients (n=90) were divided in 2 groups according to the amount of US identified by OCT at 3 months: a largely US (LUS $\geq$30%) group and the control group ($<$30% US), to evaluate factors associated to LUS, and the clinical impact at follow-up.

Results: Out of 90 patients, 31 (34.4%) were assigned to the LUS group, and 59 (65.6%) to the control group. At baseline, LUS patients had larger vessels (reference area 5.51±1.1 vs. 4.27±1.5 mm^2, p=0.001), a higher rate of plaque rupture (41.9 vs. 18.6%, p=0.02), thin-cap fibroatheroma (58.1% vs. 51.7% p=0.03) and thrombus (58.1% vs. 35.6%, p=0.001) as detected by OCT. 98% patients continued dual antiplatelet therapy up to 12 months, and 24% of them up to 18 months.

At stent implant, performed with high pressure dilation (21.18±3.8 vs 20.54±3.6 atm in LUS vs control group, p 0.48), the rate of apposed and embedded struts was high in both groups, although higher in controls (93.92±5.30% vs 96.46±3.68%, p 0.03 and 16.8±11.5% vs 21.7±15.8%, p=0.12, respectively for controls and LUS). At 3 months, US rate was 48.4±12% in the LUS group, and 13.3±7% in the control group ($p<0.001$). Global malapposition rate was 7.95±7.5% and 1.69±1.6% ($p<0.001$), respectively. 84.52±12.41% of the US in the LUS group and 86.49±19.98% in controls group were apposed to the wall (p 0.07). At 18 months, the rate of US dropped significantly to 8.4±10% in LUS group and 1.8±3% in control group ($p<0.001$), with malapposition rate being 1.4±3.3 and 0.16±0.43% (p 0.006). Of the US, 81.6±25.15 and 91.11±21.76% were apposed to the wall, respectively. At 5 years clinical follow-up, no differences were observed at the composite endpoint of major adverse cardiovascular events (detailed data will be presented).

Conclusions: In a setting of optimal PCI with modern DES and high-pressure inflation, LUS occur in 30% of patients at early follow-up, more frequently in large vessels with lipid-rich, complex plaques. The vast majority of US is apposed to the wall and near-complete coverage is observed at long-term follow-up, with no clinical impact compared to subjects with a low rate of US.