Abstract: 
P973

Intravascular lithotripsy for lesion preparation in calcified coronary lesions: a prospective, observational, two-center registry

Authors:
A Aksoy, C Salazar, UM Becher, F Jansen, V Tiyerli, S Zimmer, E Grube, JM Sinning, G Nickenig, N Gonzalo, J Escaned, N Werner, University Hospital Bonn, Dept. of Internal Medicine II; Cardiology, Pulmonology, Angiology - Bonn - Germany, Hospital Clinic San Carlos, Universidad Complutense - Madrid - Spain,

Topic(s):
Coronary Intervention: Technique

Citation:
Background: Intravascular coronary lithotripsy (IVL) is a novel alternative treatment for heavily calcified lesions. This study sought to determine the strategy success and safety of IVL on calcified lesions in an all-comers cohort of patients. Methods: Patients with moderate and severely calcified coronary lesions were screened in two centers in Spain and Germany starting April 2018. Until February 2019, 61 patients with 67 lesions were eligible for IVL. Patients were assigned to the following groups: A) Primary IVL therapy for patients with circumferential calcified de-novo coronary lesions (n=32), B) Secondary IVL therapy for patients with moderate or severe calcified coronary lesions in which conventional non-compliant balloon dilatation failed (n=18) and C) Tertiary IVL therapy in patients with in-stent stenosis due to stent underexpansion after previous stenting (n=17). Primary endpoint was strategy success and safety outcome. Strategy success was defined as successful stent delivery and expansion with attainment of < 20% in-stent residual stenosis of the target lesion. Safety outcome were procedural complication, defined as coronary dissection, slow or no-reflow phenomenon, new coronary thrombus formation during PCI, abrupt vessel closure and device failure (inability to place the balloon, malfunction, or burst) and in hospital MACE. Results: 61 patients with 67 calcified lesions were treated with IVL. Mean diameter of calcified stenosis on quantitative coronary angiography was 72.02 ± 13.8 % at baseline and decreased to 17.7 ± 15.84 % (p-value: < 0.01) after IVL with an acute gain of 1.9 ± 0.63 mm. Mean minimal lumen diameter was 1.0 ± 0.5 mm at baseline and increased after IVL to 2.9 ± 0.6 mm. The overall average of applied pulses was 63 ± 22. The primary endpoint of strategy success was reached overall in 85.2 % of patients. 4 type b dissections (3 in group A, 1 in group B) were observed without further sequelae. There were no in-hospital MACE. In one patient (1.6 %) non-ischemia driven target lesion failure was observed in routine follow up coronary angiography and was in need for revascularization. According to the subgroups, strategy success in primary IVL treatment (group A) and secondary IVL treatment (group B) was reached in 81.3 % and 83.3 % of cases, respectively. In tertiary IVL therapy (group C), the primary study endpoint was reached in 64.7 % of cases. Device delivery and IVL treatment of target lesion could be performed in all lesions without vessel complications. 7 IVL balloons ruptured during treatment without any sequelae. Rupture was observed in most cases after repositioning of the balloon within the calcified lesion. Conclusions: IVL provides a valid strategy for lesion preparation in severely calcified coronary lesions, with high success rate, and low procedural complication and MACE rates. Longitudinal studies will confirm if these favourable initial results of IVL-supported PCI are followed by good long-term results.