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A novel bioresorbable magnesium-based stent: initial clinical results and 6-months follow-up by coronary computed tomography angiography scan

Authors:
C Ghafari¹, N Brassart², P Delmote¹, P Brunner², K Thayse¹, S G Carlier¹, ¹UMONS and CHU Ambroise Pare - Mons - Belgium, ²CHU Ambroise Paré - Mons - Belgium,

Topic(s):
Coronary Intervention: Stents

Citation:

Background: Drug-eluting stents (DES) are the gold standard in percutaneous coronary interventions (PCI), but leave a permanent metallic "caging" of the treated vessels limiting further assessment of in-stent lumen patency by coronary computed tomography angiography (CCTA) due to artifacts. Absorbable scaffolds were designed to overcome the caging limitation but the first generation made of poly-L-lactic acid demonstrated higher thrombosis rates. A novel bioresorbable magnesium-based (Mg-)stent coated with a biodegradable polymer eluting sirolimus has been developed, with promising results in the BIOSOLVEII-III studies.

Aim: We sought to characterize PCI results by CCTA at 6-mo follow-up of patients treated with at least one Mg-stent in our institution.

Methods: Prospective observational registry started since January 2017 of younger patients with de novo lesions preferably treated with Mg-stents after balloon pre-dilatation. Procedural data and major adverse clinical events (MACE) at hospital discharge and 6-mo follow-up were collected. Reference vessel and in-stent minimal lumen area were measured on a CCTA performed at 6-mo.

Results: 34 Mg-stents (mean diameter: 3.2±0.2 mm, length 21.3±4.1 mm) were successfully implanted in 29 patients (mean age 54±6 years with male:female ratio 3:1). Acute coronary syndrome was the presenting diagnosis in 76% (n=22) with STEMI in 31% (n=9). The left anterior descending artery was treated in 62% (n=21). Calcifications on angiography were found in 14 lesions (41%). Intravascular imaging was performed in 3 PCI. With CCTA at 7.1±3.5 months (n=15 up to date, ongoing further follow-up to be presented), proximal and distal stent markers were well visualized while scaffold struts were not discernible. Mean proximal and distal reference lumen area were respectively 8.5±4.2 mm² and 6.1±2.8 mm². Mean in-stent minimal lumen area (MLA) was 6.3±2.9 mm², with no statistical difference with the mean of the proximal and distal references (7.3±3.3 mm², p = 0.155, Wilcoxon rank test) demonstrating minimal instent hyperplasia at 6-mo: significant in-stent restenosis was noted in only one patient who remains so far asymptomatic (MLA 1.1 mm²; reference vessel lumen area 5.5 mm²). CCTA were non interpretable in 2 patients due to artifacts unrelated to the Mg-stents. One death secondary to a complicated cardiac tamponade was reported. No further MACE at 6-mo were noted.

Conclusion: 6-mo CCTA of patients treated with a Mg-stent are fully interpretable to detect in-stent restenosis, without blooming artifacts. Accurate non-invasive assessment of the late results of our monocentric observational registry demonstrated 1 asymptomatic instant restenosis in 34 Mg-stents (3%) and overall optimal stent deployment and late artery patency, achieved with only 1 MACE in 29 patients (3.4%). This highlights the potentials of this new Mg-bioresorbable stent and the use of CCTA for clinical follow-up of the treated patients.
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Figure 1: Cross sectional cut of proximal left anterior descending artery and in-stent minimal lumen area. The two radiopaque spots are the markers at the proximal and distal edges of the stent, without discernible struts in between.