

A prospective randomized trial of the use of drug-eluting balloon catheters for the treatment of a lateral branch in patients with true bifurcation lesions

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Background. Endovascular interventions for bifurcation lesions of the coronary arteries account for approximately 15–20% of all coronary interventions. Despite the use of drug-eluting stents, the management of bifurcation lesions remains challenging, especially in the setting of lateral branch involvement. Although the Provisional stenting strategy is the preferred method for most patients, several studies have shown that dual-stent techniques may be advantageous in this patient population. However, as a general approach, the European Bifurcation Club recommends that percutaneous coronary interventions be performed with a minimum number of stents.

Aim. To evaluate the safety and efficacy of using a paclitaxel-coated balloon in the treatment of a lateral branch in patients with true bifurcation coronary disease.

Methods. This work was performed as a result of a clinical analysis and evaluation of the results of treatment of 80 patients with coronary artery disease, who underwent stenting of a true bifurcation lesion in the period from 2020 to 2021. All patients were randomized in a 1:1 ratio to main branch stenting followed by lateral branch dilatation with drug-eluting balloons and provisional stenting. A direct angiographic analysis was carried out before and after the intervention, and control coronary angiography was performed 12 months later with an assessment of the results obtained. All patients underwent a comprehensive clinical, laboratory and instrumental examination.

Results. Pre-procedure reference main branch diameters were 2.97 ± 0.41 mm and 3.12 ± 0.38 mm in the Provisional and drug-eluting balloons groups, respectively. The degree of stenosis of the main branch before percutaneous coronary interventions was $65.2 \pm 14.1\%$ and decreased to $13.3 \pm 6.6\%$ after intervention in the Provisional stenting group. This was comparable to the results of percutaneous coronary interventions in the group of patients who used drug-eluting balloons $63.8 \pm 12.3\%$ and $12.9 \pm 5.8\%$, respectively. The minimum diameter of the main branch after percutaneous coronary interventions increased from 1.04 ± 0.34 mm to 2.72 ± 0.44 mm in the Provisional stenting group and subsequently decreased to 2.18 ± 0.33 mm, according to control coronary angiography after 12 months. At the same time, patients who underwent intervention using drug-eluting balloons had a smaller loss of the lumen of the main branch 0.41 ± 0.33 mm versus 0.63 ± 0.32 mm ($p = 0.003$). In addition, late loss of lumen both in the lateral branch (0.51 ± 0.22 mm versus 0.33 ± 0.24 mm) and total in both branches of the bifurcation (1.06 ± 0.29 mm versus 0.79 ± 0.27 mm) was statistically greater with Provisional stenting.

Conclusion. Treatment of bifurcation lesions using the Provisional technique with drug-eluting lateral branch dilatation has shown better results than with conventional balloons.

Keywords: drug-eluting stent; follow-up studies; percutaneous coronary intervention

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