

IASIS CE STUDY

Aims: To study the focal effect of Paclitaxel, eluted by a PTCA balloon, on the process of in-stent restenosis.

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Materials and methods: 102 patients with documented coronary in-stent restenosis are divided into two groups. Experimental group which consists of 51 patients (age 60.4 ± 9.3) treated with Paclitaxel eluting balloon catheter and control group which consist of 51 patients (59.1 ± 9.8) treated with usual balloon catheter. They are compared together in terms of immediate angiographic result, size of the coronary lumen of the target zone after 12 months and MACE during this period.

Results: Both groups are identical in terms of initial angiographic data- length of the restenosis, referent lumen diameter, minimal lumen diameter of the diseased coronary vessel and final post-procedure minimal lumen diameter. After 12 months for the patients treated with Paclitaxel eluting balloon, the degree of the binary in-stent restenosis is $15.46\% \pm 10.50\%$ vs. $41.86\% \pm 13.71\%$ for those treated with usual balloon catheter ($t= 10.91$, $P < 0.001$). Average minimal lumen diameter in the zone of restenosis is 2.52 ± 0.43 mm vs. 1.70 ± 0.36 mm for the control group ($t= 10.44$, $P < 0.001$). The decreasing of the lumen diameter is respectively 0.46 ± 0.31 mm vs. 1.26 ± 0.46 mm., ($t= 10.30$, $P < 0.001$). Second revascularization was performed in 8 patients (15.67% , Sp 12.85) from the experimental group vs. 33 (66.67% , Sp 8.21) from the control group, $t= 3.34$, $P < 0.01$.

Conclusion: Use of Paclitaxel eluting balloon catheter for treatment of in-stent coronary stenosis helps to keep down the process of binary restenosis as it preserves a larger coronary lumen in comparison with the use of usual balloon catheter. This corresponds to the smaller percent of manifested clinical adverse events in these patients.

