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Treatment of In-Stent Restenosis by Combining Cutting Balloon Angioplasty and Vascular Brachytherapy: A Report From the RENO Registry

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Background: The Reno Registry tracks all patients who are treated by Beta-Cath (Novoste, Brussels) coronary brachytherapy (CBT) in Europe not included in another trial. The theoretical advantage of cutting balloon angioplasty over conventional angioplasty prior to CBT is the potential to avoid balloon slipping which may induce geographic miss.

Methods: From April 1999 on, 1111 patients have been included in this Registry. In 166 patients with in-stent-restenosis a combined approach using cutting balloon angioplasty followed by CBT was performed (Group 1). In 712 patients with in-stent-restenosis conventional PTCA and CBT was performed (Group 2). The primary outcome measure was major adverse events (defined as a combination of death, myocardial infarction and target vessel revascularization) at 6 months.

Results: The clinical, angiographic and procedural characteristics of Group 1 were as follows: mean age was 62±10 years and 123 were male (74.1%); 44 patients (27.2%) had diabetes and 22 (13.8%) had unstable angina; 93.7% of lesions were located in native coronary arteries; reference vessel size was 3.25±0.39 mm and mean lesion length was 17.62±12.02 mm; radiation treatment was performed with a mean dwell time of 4.14±1.47 minutes (mean radiation dose: 20.35±3.18 Gy at a depth of 2 mm from the source); stents were implanted in 14.4% of cases. Procedures were successful in 97.7% of cases. During hospitalization, 1 patient died and 1 more patient experienced myocardial infarction (1.2% adverse events (death, myocardial infarction, target vessel revascularization) for Group 1 versus 1.8% for Group 2 (p=NS). At 6 months follow-up, there was a significant advantage in terms of target vessel revascularization for Group 1 (10.2% versus 16.6% for Group 2 (p=0.04) and in terms of the primary outcome measure (adverse events) for Group 1 (10.8% versus 19.2% for Group 2 (p=0.01)).

Conclusion: These results indicate the feasibility and safety of the strategy of combining cutting balloon angioplasty followed by CBT. They demonstrate additional clinical benefit at 6 months follow-up with this strategy compared to CBT and conventional PTCA.