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Efficacy of Long Radiation Treatment in Native In-Stent Restenosis: A Subanalysis From the RENO Registry

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Background: The effectiveness of intracoronary radiation therapy of diffuse in-stent restenosis (ISR) with Strontium-90 Beta sources is unknown.

Methods: The RENO registry is a post market prospective surveillance study enrolling consecutive patients with ISR at 46 European centers using the Novoste Beta-Cath™ system. Patients were treated with approved interventional devices, followed by Strontium-90 Beta-radiation treatment. Of the 1098 patients enrolled in the trial, 139 had diffuse native coronary ISR treated with a stepping technique using a 30, 40, or 60mm source train or a single 60mm source train. The historical control group was the placebo arm of the WRIST and LONG WRIST studies (N=94).

Results: Baseline characteristics were similar between two groups except for more diabetics in placebo. Brachytherapy success (<50% residual stenosis and successful delivery of the radiation device) was 99.3% in the RENO group. Clinical follow-up at 6 months was available in >96%. The results are shown in the table.

Conclusion: Beta-radiation with Sr-90 using either a stepping (pullback) technique or a single 60mm source train to treat patients with diffuse, long native ISR lesions is effective and results in significant reductions in TVR by 75% and MACE by 72% without any increase in the late thrombosis rates compared to historical controls .

	RENO Long Radiation (N=139)	WRIST Placebo (N=94)	p-Value
Diabetes (%)	21.9%	37.2%	0.02
Lesion length (mm)	35.33 ± 17.89	27.97 ± 11.84	0.0003
TVR at 6 months	14.9%	60.6%	<0.0001
MACE at 6 months	17.9%	64.9%	<0.0001
Total occlusion at 6 months	12.2%	9.9%	NS