

Mount Sinai Hospital Experience

with the Beta-Cath™ System for the Treatment of In-Stent Restenosis



Presented June, 2002 at "A Live Symposium of Complex Coronary and Vascular Cases" by: S.K. Sharma, MD; A.S. Kini, MD; et al.

From February 2001 to April 2002, 113 patients with ISR (119 vessels, 128 lesions) underwent cutting balloon PTCA or rotational atherectomy followed by Beta radiation using the Novoste™ Beta-Cath™ System with a mean follow up of 6 months (±3)

Baseline Characteristics		Procedural Characteristics & QCA			
Age (yrs)	66±11	Lesion Length (mm)	17.5±8.9	Ref vessel size (mm)	2.91±0.04
Male (%)	66	Total Occlusion (%)	7.2	MLD-Pre (mm)	0.72±0.31
CCS class III-IV(%)	27	ACC/AHA type C (%)	33	MLD-Post (mm)	2.21±0.42
Prior restenosis >1(%)	58	LAD/LCX/RCA/SVG (%)	43/29/21/7	MLD-Post ICBT (mm)	2.12±0.32
ISR interval (days)	182±62	CB PTCA+Rota (%)	76	Re-dilatation post ICBT (%)	7
LVEF (%)	51.4±9.1	Rotablator (%)	20	Vasospasm (%)	5
GP IIb/IIIa use (%)	67	Re-stent (%)	0	Dissection/perforation/embolization (%)	0

In Hospital Results:

- One patient died in hospital of non-cardiac cause
- No other in-hospital adverse events
- Average length of stay was 2.5 days (±3.1)
- Periprocedural CK-MB elevation occurred in 16.4% of cases

Anti-platelet Therapy: ASA and Plavix was prescribed for one month

Long-term Follow-up: Target Lesion Revascularization (TLR): 7.0%
 (n=8, 2 edge effects, 6 true treatment failures)
 Delayed acute closure/subacute thrombosis: 0%
 Death: 2.6% (3 pts)

Conclusion:

Debulking combined with ICBT provides sustained long-term, acceptable restenosis in single digits without need for re-stenting or delayed thrombosis. These favorable results (compared to reports of randomized trials) may be attributed to full lesion coverage by long source trains and no repeat stenting.

*For additional information about these results, please contact Dr. Sharma.

To view Beta-Cath™ System cases presented during the Live Symposium, please visit www.mssmtv.org.



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 U.S. Patent Numbers 5,403,345; 5,995,882; 6,013,020; and 6,261,279. Other patents pending.
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