



START 40

STents And Radiation Therapy 40

SUMMARY PRESENTATION

STents And Radiation Therapy 40 (START 40)

STUDY SCHEMA

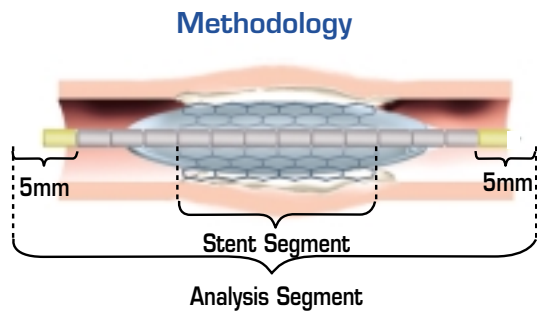
Purpose: To evaluate the safety and effectiveness of beta radiation using a $^{90}\text{Sr}/^{90}\text{Y}$ source with a wider therapeutic margin to the PTCA injury site than what was administered in the original START trial (START 30).

Design: Prospective, multi-center (22 sites in N. America & Europe), registry clinical trial.

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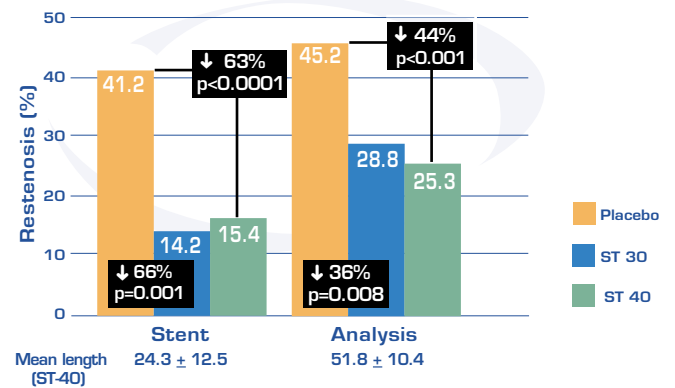
    graph TD
      S30[476 patients with in-stent restenosis] --> S30_Sr90[244 patients Sr-90]
      S30 --> S30_Placebo[232 patients Placebo]
      S30_Sr90 --> S30_Angio[8 month Angiogram Clinical Evaluation]
      S30_Placebo --> S30_Angio
      S40[207 patients with in-stent restenosis] --> S40_Sr90[207 patients Sr-90]
      S40_Sr90 --> S40_Angio[8 month Angiogram Clinical Evaluation]
  
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ANGIOGRAPHIC OUTCOMES

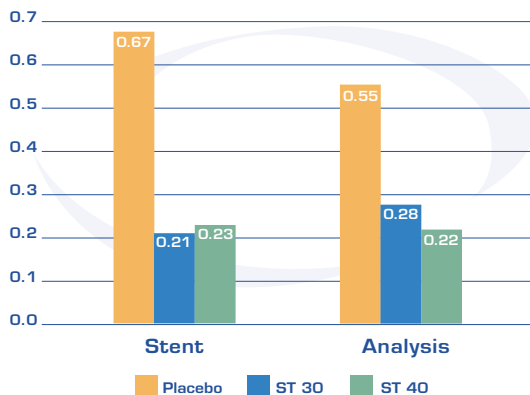


*30mm Source Train shown in illustration

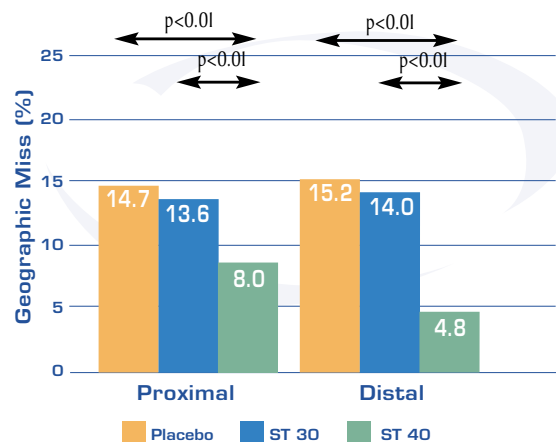
8 Month Angiographic GCA Analysis



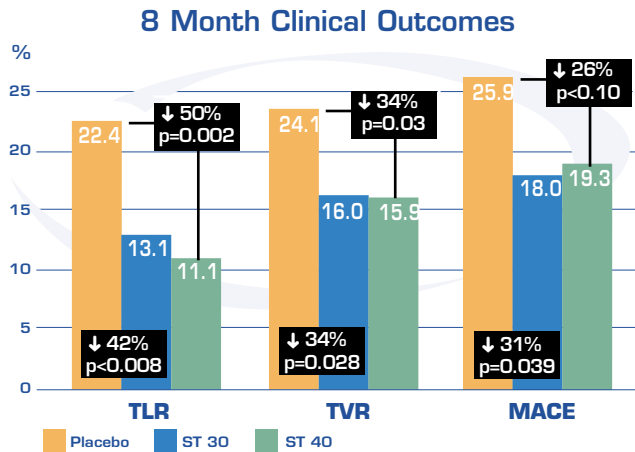
Late Loss Index



Frequency of Geographic Miss



CLINICAL OUTCOMES



8 Month Safety Results

PARAMETER	ST-30	PLACEBO	ST-40
Death	3 (1.2%)	1 (0.4%)	5 (2.4%) ¹
MI	4 (1.6%)	7 (3.0%)	9 (4.3%)
Q-wave	0	0	3
non-Q-wave	7	4	6
Aneurysm²	1 (0.5%) ²	0 (0%)	1 (0.7%) ²
Thrombosis			
In-hospital - 30 days	0 (0%)	1 (0.4%)	0 (0%)
31 - 240 days	0 (0%) ³	0 (0%)	2 (1.0%) ⁴
Angiographic			
Total Occlusions	8 (3.3%)	7 (3.0%)	5 (3.3%)

*p = NS for all Placebo versus ST-30 versus ST-40

1. 3 of 5 deaths were not related to the target vessel

2. No new aneurysm formation; present at baseline, without significant change at follow-up

3. One patient adjudicated by CEC had thrombosis at day 244

4. One patient had an event at day 31

Summary Comparison Start 30 versus Start 40

- Compared to the START 30 population, START 40:
 - patients were older and on an average had more unstable angina, and more prior treatments for in-stent restenosis
 - had similar RVD and lesion length
- Compared to START 30 placebo, START 40:
 - reduced restenosis in the analysis segment by 44% (vs 36% in ST 30)
 - reduced TLR by 50%, p=0.002 (vs 42% in ST 30)
 - reduced TVR by 34%, p=0.03 (vs 34% in ST 30)
 - reduced MACE by 26%, p=0.10 (vs 31% in ST 30)

Start 40 Conclusions

- Continues to support the efficacy of Sr-90 Beta radiation for the treatment of in-stent restenosis
- Shows no significant deleterious effects of adding 10mm of length to the source train
- Supports the lack of a relationship between Geographic Miss and clinical or angiographic outcome for in-stent restenosis

START 30 AND 40 COMPARISON

What's the Same...

- Patient selection criteria
- Indications including balloon injury ≤ 20 mm
- Endpoints
- Subset of same clinical centers
- Data Analysis Centers

What's Different...

- Registry
- 40mm Radiation Source Train used to treat all patients
- Expect a longer radiation margin (+ 10mm margin on each end)

DOSIMETRY METHODS

Dose Prescription

Dose prescribed at a point 2 mm from center of source axis based on visual assessment of reference vessel diameter (RVD):

- 18.4* Gy in RVD $\geq 2.7 - \leq 3.3$ mm
- 23* Gy in RVD $> 3.3 - \leq 4.0$ mm

*NIST dose, March 2000

PROCEDURE DETAILS

Adjunctive Devices

%	Placebo	ST 30	ST 40
DCA	0.9	0.0	0.5
RA	39.8	43.9	22.0*
ELCA	7.4	5.7	12.7**
New Stents***	19.8	20.9	15.3

* $p < 0.001$ ST 40 vs. ST 30 and Placebo

** $p = 0.01$ ST 40 vs. ST 30

*** "Bail-out" stent use reserved for severe residual stenoses or dissection after radiation delivery

INCLUSION/EXCLUSION CRITERIA

Major Inclusion Criteria

- Single lesion, single vessel intervention
- In-stent restenosis $> 50\%$ (by visual assessment)
- Target lesion in vessels between 2.7 and 4.0 mm RVD
- Target lesion length treatable with 20 mm balloon with the 40 mm Source Train

Major Exclusion Criteria

- Multi-vessel coronary intervention
- Target lesion residual stenosis $> 30\%$
- Unprotected left main disease
- Prior chest radiotherapy

BASELINE FINDINGS

	ST 30 n=244	Placebo n=232	ST 40 n=207
Clinical Characteristics			
Age (years) (1)	61.5	61.1	64.4
Men (%)	68.4	63.4	66.7
Diabetes (%)	30.7	32.3	26.3
Smoking (%)	12.5	8.1	9.0
Prior MI (%)	46.7	47.8	42.2
Prior CABG (%)	21.4	23.7	20.8
Unstable Angina (2)	73.8	78.9	85.0
Prior Tx for ISR (%)			
None (3)	52.5	57.0	38.8
One (4)	33.9	32.5	44.3
Two (5)	13.6	9.2	16.4
Angiographic Characteristics			
RVD, mm	2.76	2.77	2.77
Pre-MLD, mm	0.98	0.98	0.92
% Stenosis	64.2	64.2	66.6
Lesion Length, mm (6)	16.3	16.0	17.4
% LAD	43.2	41.3	44.7

(1) p-value 0.003 (placebo vs ST 40); 0.01 (ST 30 vs ST 40)

(2) p-value NS (placebo vs ST 40); 0.004 (ST 30 vs ST 40)

(3) p-value 0.0002 (placebo vs ST 40); 0.004 (ST 30 vs ST 40)

(4) p-value 0.012 (placebo vs ST 40); 0.03 (ST 30 vs ST 40)

(5) p-value 0.025 (placebo vs ST 40); NS (ST 30 vs ST 40)

(6) p-value 0.075 (placebo vs ST 40); 0.15 (ST 30 vs ST 40)

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