Strategic Transcatheter Evaluation of New Therapies

Drug-Eluting Stent Restenosis: First Multicenter Prospective Report of Treatment Strategies and Clinical Outcomes in the U.S.

Strategic Transcatheter Evaluation of New Therapies (STENT) Group

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For the STENT Group

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Presenter Disclosure Information

NAME: Charles Simonton, MD for The STENT Group

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement with the organization listed below.

Company Name	Relationships
Boston Scientific	Unrestricted Grant Funding
Cordis Corporation	Unrestricted Grant Funding
Possis Medical	Unrestricted Grant Funding
Medicines Company	Unrestricted Grant Funding

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Background

- **Paclitaxel (PES)** and **sirolimus-eluting (SES)** stents have each shown significant reductions in target lesion revascularization (TLR) vs bare metal stents and are applied widely in percutaneous coronary intervention
- However, **TLR continues to occur in approximately 3-5% of patients** receiving these stents and there is very little information from clinical studies concerning the outcomes of patients undergoing TLR for these lesions or the best method of treatment
- Clinical outcomes following TLR of DES restenosis lesions may differ significantly from what has been reported for bare-metal stent restenosis given the effects of sirolimus or paclitaxel on the vessel wall

Purpose

The purpose of the present study was to examine the treatment modalities and 9-month clinical outcomes of patients undergoing target lesion revascularization (TLR) for DES restenosis from a large prospective, multicenter registry of percutaneous coronary interventions (PCI)

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STENT Registry Methods

1. The Strategic Transcatheter Evaluation of New Therapies (STENT) Group represents a nine center prospective PCI registry beginning enrollment in May 2003.
2. A centralized database with dedicated personnel for database monitoring, quality control and statistical analysis
3. Data entry by each center locally into a secure, web-based database
4. Selection of nine coronary interventional centers representing a "real-world" range of centers, with a goal of prospectively consenting 8,000-10,000 consecutive cases per year
5. An Executive Steering Committee with representatives from each center to oversee data coordinators and data collection procedures, review periodic reports, and approve all requests for data analysis, abstracts and manuscripts
6. A working group of data coordinators from each center with regularly scheduled meetings for review of procedures, policies and progress

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STENT Registry Methods

7. **IRB approval** obtained at all sites.
8. **Consecutive enrollment** of all consenting patients. Consent includes consent to release of medical information during the follow-up period of 9 months and annually for five years
9. Database designed in full **adherence with HIPAA guidelines**
10. Complete in-hospital and 9 month data entry within 60 days of each time-point with **chart reviews for cardiac re-hospitalizations**
11. **Site audit of randomly selected records for validation of data quality** using source documents as gold standard comparison
12. **Physician adjudication** of key clinical events, specifically, TVR, MI, stent thrombosis and cardiac/non-cardiac death

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Participating Centers

Data Coordinating Center:

R. Stuart Dickson Institute for Health Studies, Charlotte, NC

Clinical Coordinating Center:

Carolinas Heart Institute, Charlotte, NC

Participating Centers:

Carolinas Heart Institute, Charlotte, NC
High Point Regional Hospital, High Point, NC
Holston Valley Medical Center, Kingsport, TN
Indiana Heart Institute, Indianapolis, IN
LeBauer Cardiovascular Research Foundation/
Moses Cone Health System, Greensboro, NC
McLeod Regional Medical Center, Florence, SC
Moore Regional Hospital, Pinehurst, NC
Sisters of Charity Providence Hospitals, Columbia, SC
Tennessee Cardiovascular Research Institute, Nashville, TN

Study Methods

1. All patients enrolled in the STENT Registry from inception in May 2003 through September 2005 and completing 9-month follow-up were included for study
2. Of these patients, those undergoing repeat PCI within the target lesion (TLR) for restenosis of a drug-eluting stent (either paclitaxel or sirolimus) constitute the patient group for this study
3. These DES restenosis patients were then described as either original paclitaxel or sirolimus-eluting stents, and examined for the type of repeat PCI procedure performed and the subsequent clinical outcomes at 9-months

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STENT Registry Consent and 9 Month Follow-Up Rates

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Eligible Procedures May 2003 – September 2005	18,067
Consented Procedures May 2003 – September 2005	16,440
Consent Rate	91%
Procedures with Completed 9m follow-up	15,072
9m Follow-Up Rate	92%

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Derivation of DES Restenosis Study Patients

Study patients must have the following:

1. *Two procedures with 9m follow-up in the Registry.*
2. *The first in-stent restenotic lesion for a patient must be matched with the same lesion segment on a prior procedure.*
3. *The lesion on the prior procedure was treated with DES.*

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Patients with completed 9m f/u for ≥ 2 procedures	1,549
# of Procedures for these Patients	3,314
# of Lesions for these Patients	4,705
# of Lesions without In Stent Restenosis	4,196
# of Lesions with In Stent Restenosis (ISR)	509
1st ISR (First Restenosis)	448
2nd+ ISR (Second+ Restenosis)	61

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Derivation of DES Restenosis Study Patients

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1st ISR Lesions	448
Lesions with no prior procedure in Registry	256
Lesions with matching non DES lesion	59
Lesions with matching de novo DES lesion	133 Lesions
Unique patients among matching lesions	125 Patients

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DES Restenotic Lesions: Target Vessel PCI Treatment (n=133)

	n	%
PES Restenotic Lesion (n=51)		
SES-Rx	23	45.1
PES-Rx	9	17.7
PTCA/Cutting Balloons-Rx only	17	33.3
Ablative/Debulking-Rx only	1	2.0
Brachytherapy	1	2.0
SES Restenotic Lesion (n=80)		
PES-Rx	32	40.0
SES-Rx	24	30.0
PTCA/Cutting Balloons-Rx only	15	18.8
Ablative/Debulking-Rx only	1	1.3
Brachytherapy	7	8.8
Bare Metal Stent	1	1.3
PES & SES Restenotic Lesion (n=2)		
PES-Rx	2	100.0

Note: SES approved May 2003; PES approved March 2004

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DES Restenosis Patients

	DES-Rx (n=86)		NON DES-Rx (n=39)		
	n	%	n	%	p
Age (mean yrs)	62.4		62.5		0.98
Gender (% male)	47	54.7	20	51.3	0.85
Race (% Caucasian)	77	89.5	22	71.8	0.02
Hypercholesterolemia	58	67.4	29	74.4	0.53
Diabetes Mellitus	36	41.9	18	46.2	0.70
Hypertension	66	76.7	33	84.6	0.35

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DES Restenosis Patients

	DES-Rx (n=86)		NON DES-Rx (n=39)		
	n	%	n	%	p
Smoking	50	58.1	25	64.1	0.56
Family History of CAD	30	34.9	15	38.5	0.69
History of MI	33	38.4	17	43.6	0.69
History of CABG	20	23.3	7	18.0	0.64

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DES Restenosis Patients

Clinical Status at Hospital Admission

	DES-Rx (n=86)		NON DES-Rx (n=39)		
	n	%	n	%	p
No Angina	8	9.3	2	5.1	
Atypical Chest Pain	0	0.0	1	2.6	
Stable Angina	9	10.5	3	7.7	
Unstable Angina	51	59.3	22	56.4	p = 0.68
Non-ST Elevation MI	10	11.6	6	15.4	
ST Elevation MI	7	8.1	5	12.8	

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DES Restenosis Patients

Clinical Status at Hospital Admission and Procedure Indications

	DES-Rx (n=86)		NON DES-Rx (n=39)		
	n	%	n	%	p
Left Ventricular EF (mean)	51.1 %		51.9 %		0.76
Acute CHF	4	4.7	2	5.1	0.99
Acute Evolving MI	7	8.1	4	10.3	0.74
Multi-Lesion Procedure	24	27.9	15	38.5	0.30
Multivessel Procedure	6	7.0	4	10.3	0.50

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DES Restenotic Lesion Characteristics

	DES-Rx (n=90 lesions)		NON DES-Rx (n=43 lesions)		
	n	%	n	%	p
SVG Lesion	7	7.8	0	0.0	0.10
Calcium Lesion	20	22.2	5	11.6	0.16
Ostial Lesion	13	14.4	6	14.0	0.99
Bifurcation Lesion	8	8.9	7	16.3	0.25
Vessel Diameter < 3mm	28	31.1	14	32.6	0.99
Avg Vessel Diameter	3.07mm		3.10mm		0.80
Avg Lesion Length	15.4mm		12.8mm		0.17

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DES Restenosis Patients

9-Month Clinical Outcomes (unadjusted)

	DES-Rx (n=86)		Non DES-Rx (n=39)		
	n	%	n	%	p
Death	7	8.1	2	5.1	0.72
MI	3	3.5	2	5.1	0.65
TVR	10	11.6	4	10.3	0.99
MACE	17	19.8	6	15.4	0.63
Subacute Stent Thrombosis	3	3.5	0	0.0	0.55

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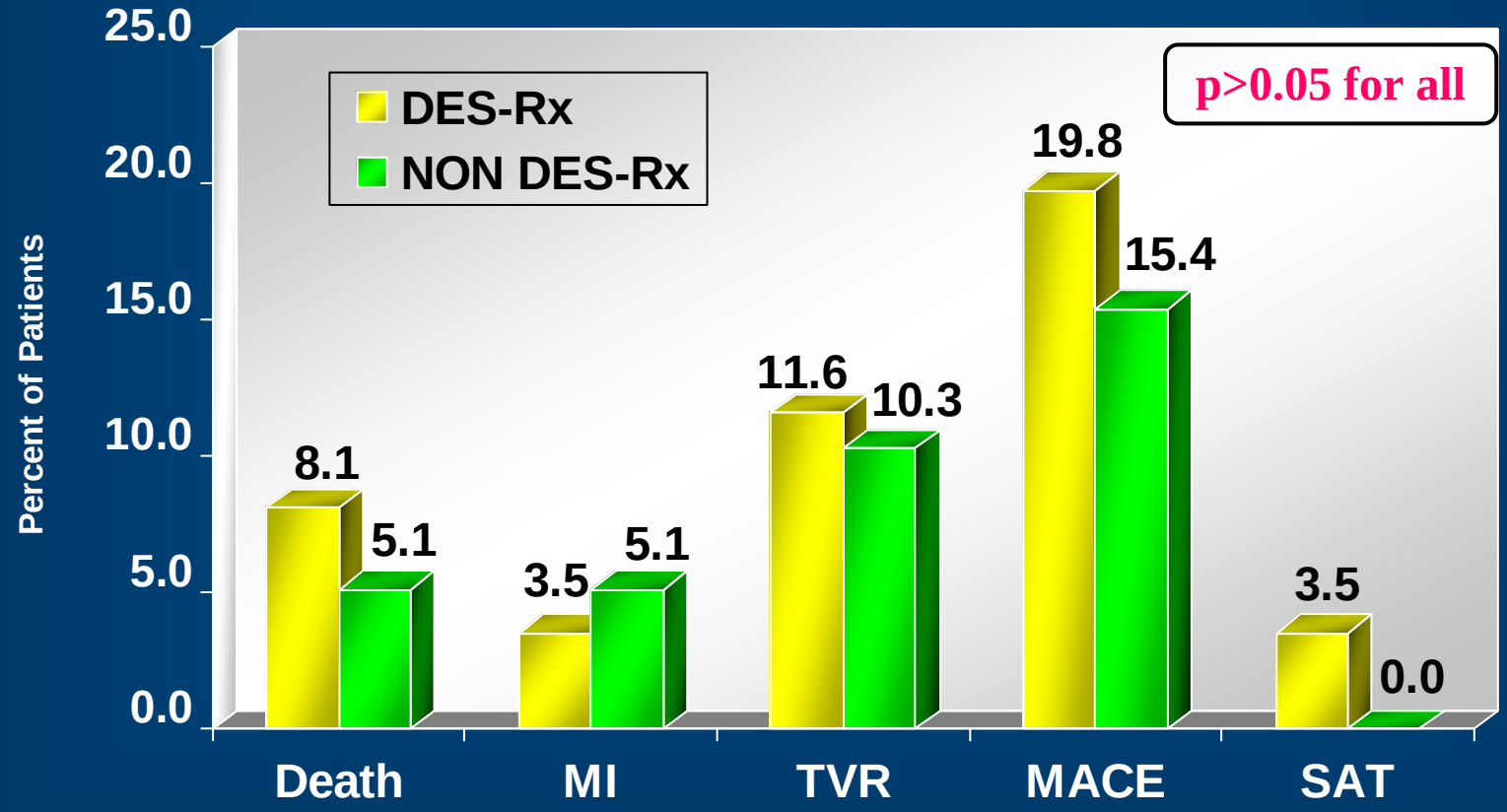
DES Restenosis Patients
9-Month Clinical Outcomes (unadjusted)



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Conclusions

1. **DES restenosis** continues to occur in a small but significant number of patients in real-world practice (approximately 3-5% of DES patients)
2. Treatment consists of a mixture of **repeat DES (60-70%)** and **non-DES modalities (PTCA, cutting balloon, other) (30-40%)**
3. Regardless of treatment strategy, **TVR and all MACE events at 9 months** following PCI for DES restenosis appear **much higher** than for de novo lesions from previous reports.
4. Of note, stent thrombosis in this population occurred only when another DES was placed to treat DES restenosis.
5. Further prospective trials of available treatment options with clinical follow-up are needed to define the optimal strategy for this complex patient population