

Late Results from the PAINT trial

Percutaneous Intervention with biodegradable-polymer based paclitaxel-eluting, sirolimus-eluting, or bare stents for the treatment of de novo coronary lesions

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on behalf of the PAINT trial
investigators

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University of Sao Paulo, Brazil

Potential conflicts of interests

- **Advisory Board:** Cordis, Boston Scientific, Scitech
- **Speakers Board:** Boston Scientific, Lilly, Scitech, Abbott
- **Institutional Research Grants:** SMT, Boston Scientific, Scitech

LATE-PAINT trial

Main Objective

To evaluate the late safety and efficacy of 2 novel formulations of DES with paclitaxel or sirolimus, eluted in biodegradable polymers, in comparison to bare stents

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Study Design

274 patients treated with coronary stenting for:

- De novo coronary lesion in a native vessel
- Vessel size 2.5-3.5 mm
- Single stent per lesion up to 29-mm stent length

Randomization (1:2:2)

Infinium PES
(n=111 pts)

Supralimus SES
(n=106 pts)

Matrix BMS
(n=57 pts)

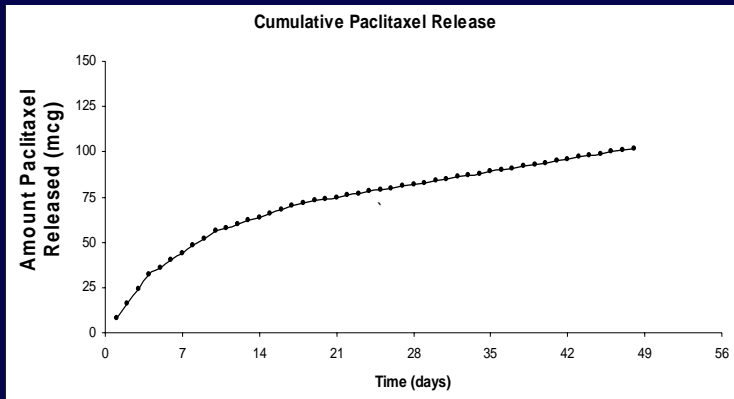
9-month angiographic follow-up (96%)

Clopidogrel for 1 year

36-month clinical follow-up

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Infinnium™ Paclitaxel-Eluting Stent & Supralimus™ Sirolimus-Eluting Stent



- Slow drug release profile
 - 50% release within 9 days
 - 100% within 48 days
- Drug released from the porous surface by diffusion
- Polymers breaks into CO₂ & H₂O.
- No residual polymer after 7 m.

Total drug content (µg)

	19-mm	23-mm	29-mm
Infinnium	122	147	185
Supralimus	125	151	191

Drug dose (µg)

Infinnium 2.5-3.5 x 19 mm	122
Taxus 2.5-3.0 x 20 mm	135
Supralimus 2.5-3.5 x 19 mm	125
Cypher 2.5-3.0 x 18 mm	153

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Study Coordination

Steering Committee

- Pedro A. Lemos , Princ. Investigator
- Expedito E. Ribeiro
- Bruno M. Machado
- Maurício de Rezende Barbosa
- César R. Medeiros
- Itamar Ribeiro Oliveira
- Eulógio E. Martinez
- Valter C. Lima
- J. Airton Arruda
- Fábio S. de Brito Jr.
- Paulo R. A. Caramori

Data Safety and Adjudication Committee

- Antonio Carlos Carvalho, President
- Luciano Drager
- Carlos Augusto Campos

Contract Research Organization

Fundação Zerbini, São Paulo,
Brazil

Database management

Coreware, São Paulo,
Brazil

Angiographic core lab

Cardialysis BV, Rotterdam,
The Netherlands

Partial Corporate Sponsoring

Sahajanand MT, Surat, India
CMS Medical, Goiânia, Brazil

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Multicenter in Brazil

Enrollment by Center

Pedro A. Lemos InCor	103 pts
Bruno Moulin HUCAM	39 pts
Marco Perin Hosp. Sta Marcelina	32 pts
Ludmilla de Oliveira Natal Hospital Center	21 pts
Valter C. Lima UNIFESP	18 pts
J. Airton de Arruda Intercath Meridional	18 pts
Antonio A. G. Lima HU Walter Cantidio	15 pts
Paulo R. A. Caramori PUCRS	14 pts
Cesar R. Medeiros Rede D'Or de Hospitais	8 pts
Mauricio R. Barbosa Biocor	4 pts
Fabio S. Brito Jr. Hospital São Camilo	2 pts

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Baseline Characteristics

	PES <i>(n=111 pts)</i>	SES <i>(n=106 pts)</i>	BMS <i>(n=57 pts)</i>	P
Age, y	60±10	60±11	59±10	0.6
Male	61	67	67	0.6
Diabetes	29	35	26	0.5
ACS	30	32	27	0.9
MVD	37	35	42	0.9
LAD treated	44	57	58	0.1
St. diam., mm	3.1±0.4	3.1±0.4	3.1±0.3	0.8
St. length, mm	21.6±3.7	21.9±4.0	21.5±3.5	0.6

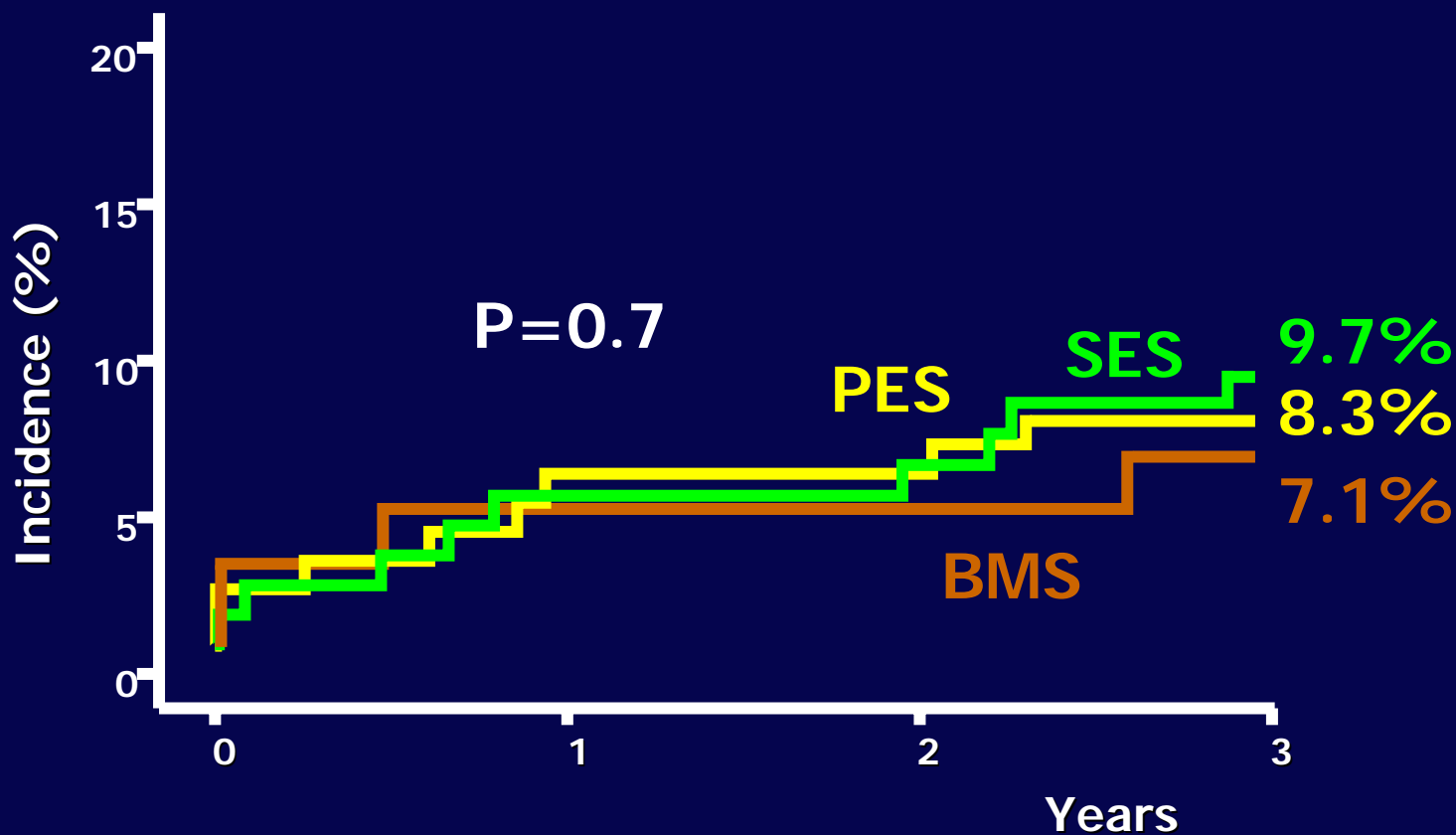
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12-Month Clinical Outcomes

	PES <i>(n=111 pts)</i>	SES <i>(n=106 pts)</i>	BMS <i>(n=57 pts)</i>	P
Cardiac Death	0.9	0.9	0	0.5
Myocardial infarction	6.4	5.7	5.3	0.8
Target lesion revasc.	5.6	4.8	15.9	<0.01
Target vessel revasc.	5.6	5.8	17.6	<0.01
Any event	10.9	8.6	21.1	<0.05

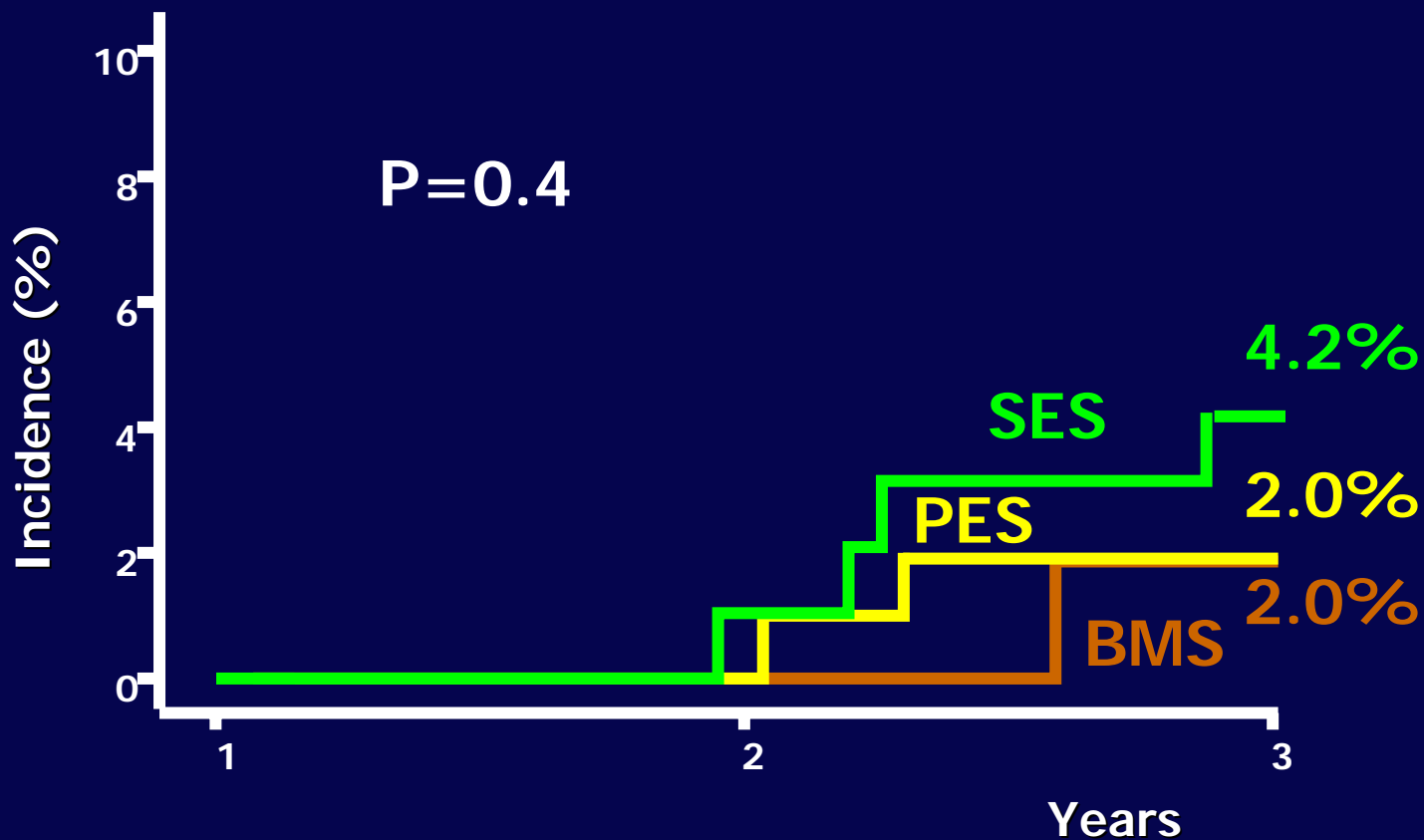
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3-Year Death or Non-Fatal MI



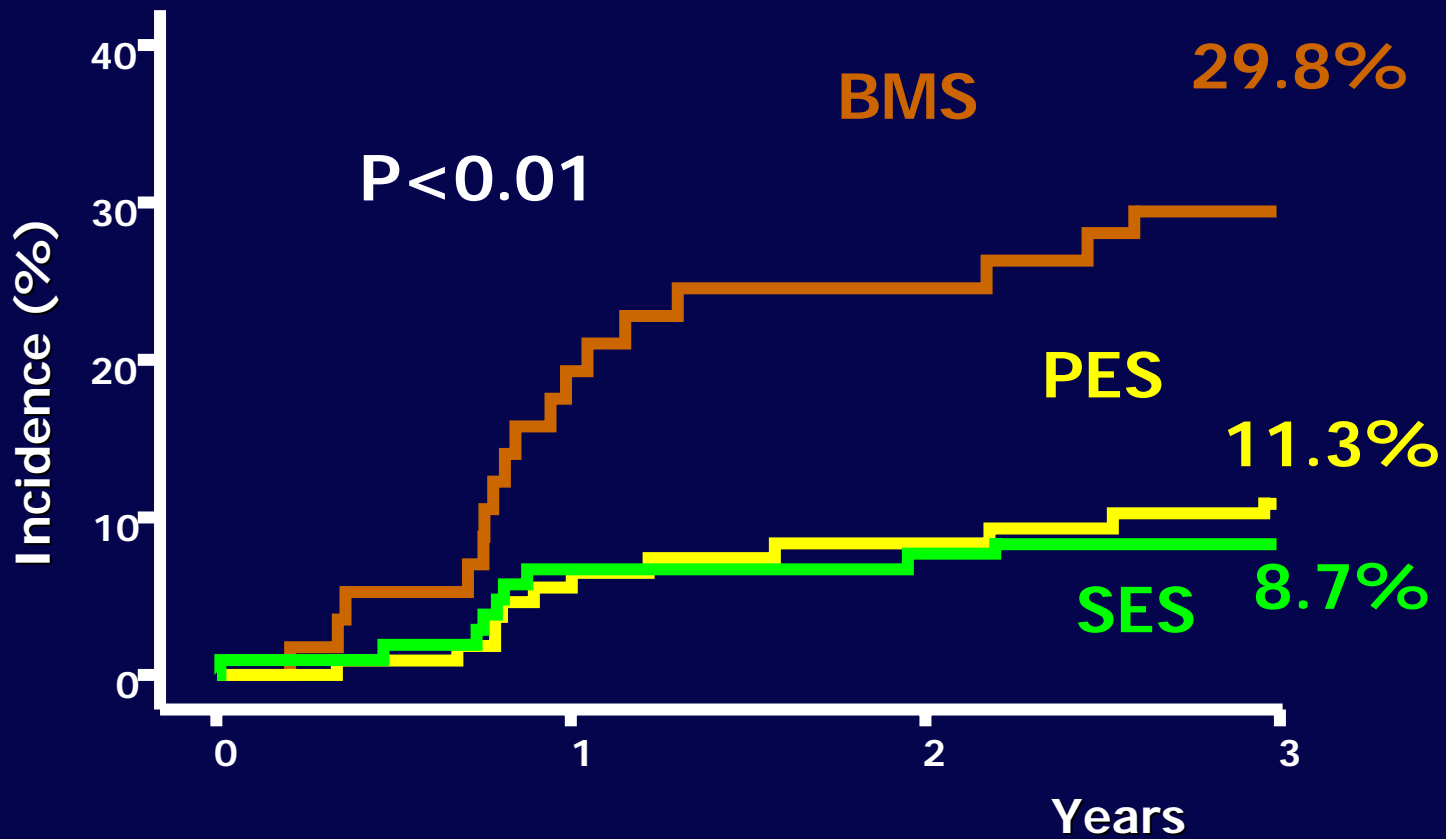
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1-3 Years Death or Non-Fatal MI



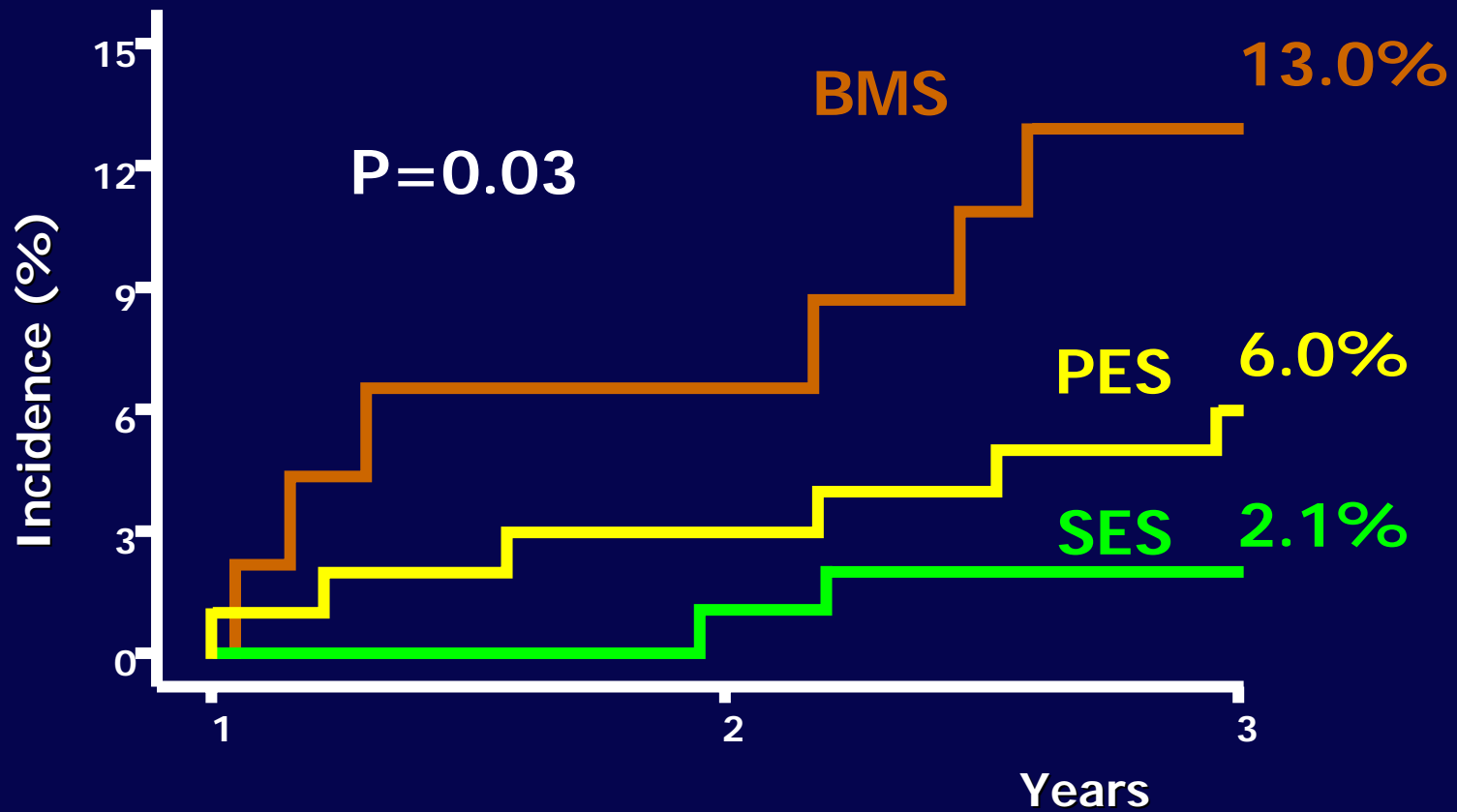
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3-Year Target Vessel Revascularization



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1-3 Years Target Vessel Revascularization



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36-Month Clinical Outcomes

	PES <i>(n=111 pts)</i>	SES <i>(n=106 pts)</i>	BMS <i>(n=57 pts)</i>	P
Cardiac Death	1.9	2.9	0	0.4
Myocardial infarction	7.3	9.7	7.1	0.7
Target lesion revasc.	8.5	7.8	28.3	<0.01
Target vessel revasc.	8.7	11.3	29.8	<0.01
Any event	12.5	16.6	33.3	<0.01

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Stent Thrombosis*

	PES <i>(n=111 pts)</i>	SES <i>(n=106 pts)</i>	BMS <i>(n=57 pts)</i>	P
1 year				
Definite	1.9	1.0	0	0.6
Definite/probable	1.9	1.9	0	0.6
1 – 2 years				
Definite	0	1.0	0	0.5
Definite/probable	0	1.0	0	-
2 – 3 years				
Definite	0	0	0	-
Definite/probable	0	0	0	-

*Academic Research Consortium Criteria

Conclusions

Compared to bare stents, implantation of biodegradable-polymer Infinnium paclitaxel- and Supralimus sirolimus-eluting stents resulted in:

- No late increase in hard events, with zero stent thrombosis after 24 months
- No loss in efficacy up to 36 months of follow-up
- Persistence of significantly better 36-m MACE rates