

The Yukon-BTK: Final Results of the Randomized, Double Blind Study of Polymer-Free Sirolimus-Eluting Stents vs. Bare Metal Stents

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ClinicalTrials.gov number, NCT00664963

Study Endpoints




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Study Endpoints

Primary Endpoint:

 1-year primary patency rate, defined as freedom from in-stent-restenosis ($\geq 50\%$) detected with angiography or if appropriate with duplex ultrasound.

Major secondary endpoints:

 6-month primary patency rate

 secondary patency rates

 TLR rates







 Changes in Rutherford-Becker classification

 Ankle-brachial index

 MAE



Major Inclusion Criteria

-  At least 21 years old
-  PAOD Rutherford-Becker class of 2 to 5
-  Single de novo infrapopliteal lesion
-  Vessel diameter 2.0 mm to 3.5 mm
-  Lesion length 10 to 45 mm
-  Diameter stenosis of at least 70%



Study Design & Drug Regimen





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Study Design & Drug Regimen

Antiplatelet regimen:


-  Oral aspirin (100 mg daily) for life
-  Oral clopidogrel (a loading dose of 600 mg 24 hours before the procedure) 75 mg daily for six months



Study Design & Drug Regimen

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Stent dimensions:

 1 or 2 stents

 Length: 25mm

 Diameter: 2.5 / 3.0 / 3.5mm



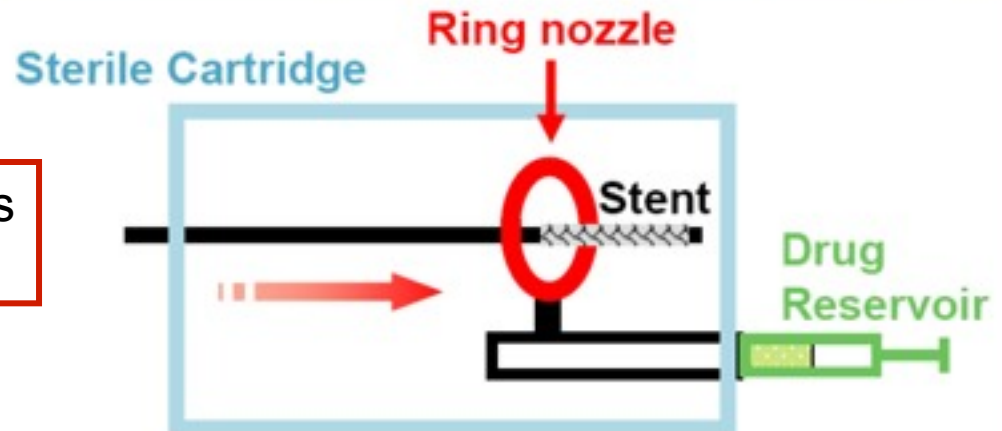
Study Device: Yukon Stent System

The Stent Coating Machines - inside



Current T-SCM2003

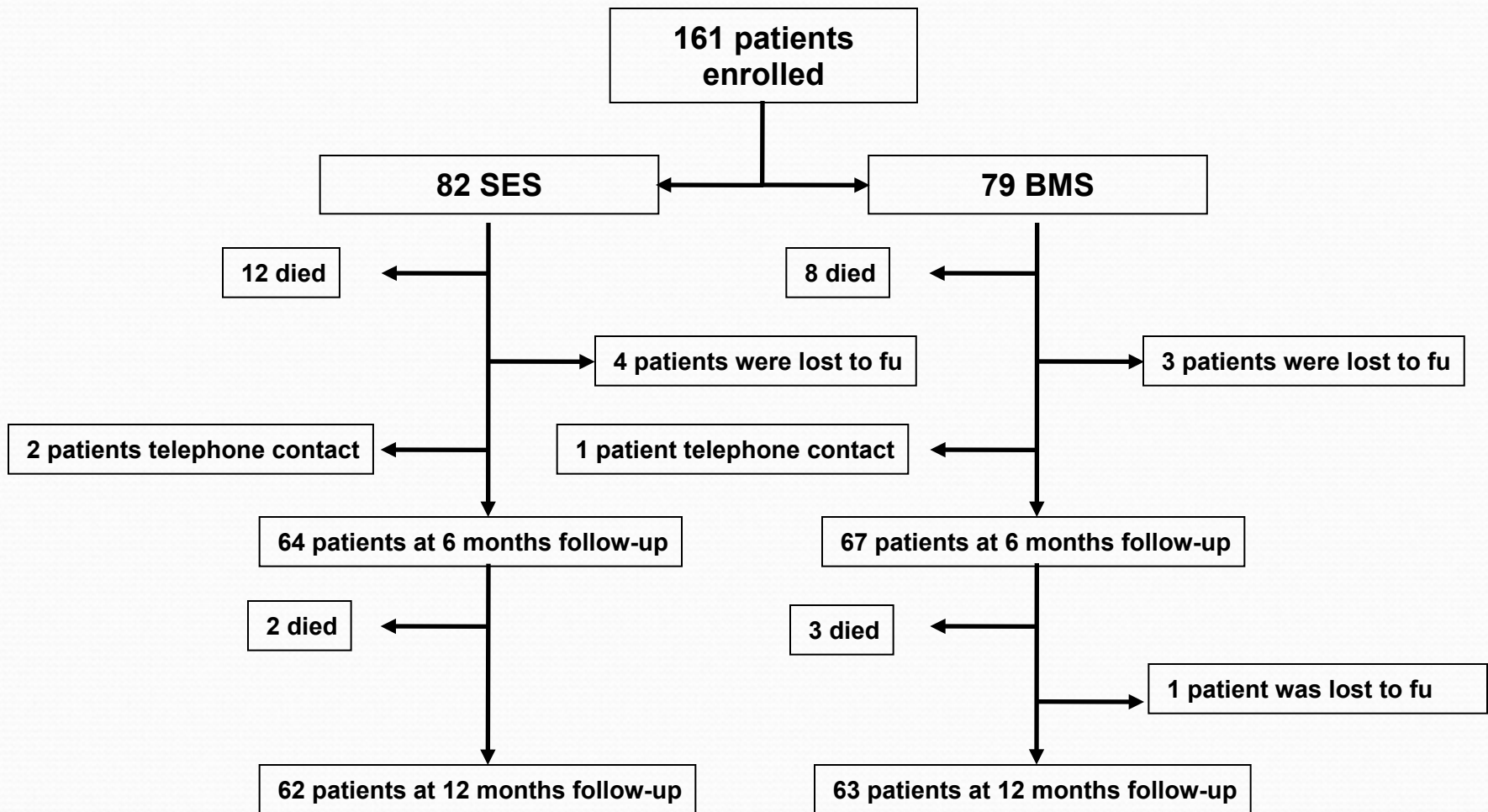
Warning: The Yukon stent device is not approved for peripheral use.



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Study Profile



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Baseline Patient Characteristics*

	All Patients (N=161)	Sirolimus Stent (N=82)	Bare Metal Stent (N=79)
Age (years)	72.9±9	73.4±8	72.3±9
Male sex (%)	66.5	67.9	64.9
Body-mass-Index	27±4	28±5	27±4
Diabetes mellitus (%)	53.8	56.8	50.6
Dyslipidemia (%)	76.6	76.5	76.6
Hypertension (%)	89.9	91.4	88.3
Current smoker (%)	28.5	28.4	28.6
Renal insufficiency (%)	35.4	35.8	35.1
Critical Limb ischemia (%) †	46.6	51.2	41.8
Target lesion (%)			
Anterior tibial artery	27	22	31
Tibioperoneal trunk	37	42	33
Peroneal artery	21	19	23
Posterior tibial artery	15	17	13

*Plus-minus values are means ±SD.

There were no significant differences between the treatment groups except for body-mass-index (P=0.044).

†Critical limb ischemia was defined according to the Rutherford-Becker classification.

Target Lesion Characteristics and Acute Results*

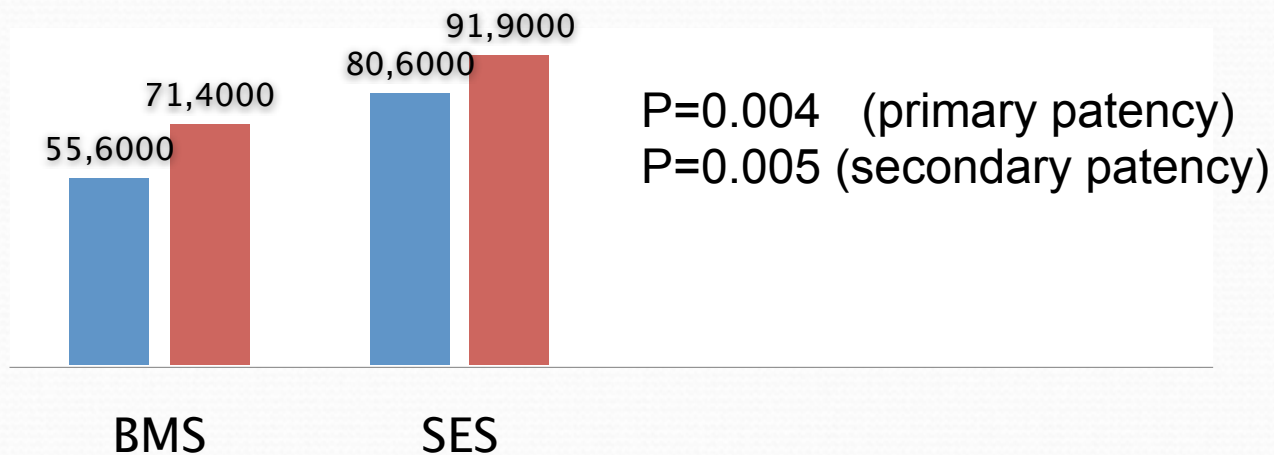
	All Patients	Sirolimus Stent	Bare Metal Stent
	(N=161)	(N=82)	(N=79)
Reference vessel diameter (mm)	3±0.4	3±0.4	3±0.4
Length of the lesion (mm)	30±9	30±8	31±9
Occlusion (%)	22.4	23.2	21.5
Target lesion diameter stenosis (%)			
Pre intervention	88±9	87±9	88±9
Post intervention	3±5	3±5	3±5
Number of stents/target lesion (%)			
1	69.6	52.7	47.3
2	28.5	48.9	51.1
3	1.9	1.2	2.6
Procedural success (%)	100	100	100
ABI pre intervention	0.48±0.16	0.47±0.18	0.49±0.14
ABI post intervention	0.84±0.17	0.86±0.15	0.83±0.19

*Plus-minus values are means ±SD. **There were no significant differences between the treatment groups**

Primary Endpoint Primary & Secondary 1-Year Patency

■ primary patency
■ secondary patency

1-Year Patency Rates



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Cox Regression Analysis



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Cox Regression Analysis

 Hazard ratio (HR) for restenosis for BMS vs. SES:
3.2 (95% CI 1.5 to 6.7; P = 0.003)




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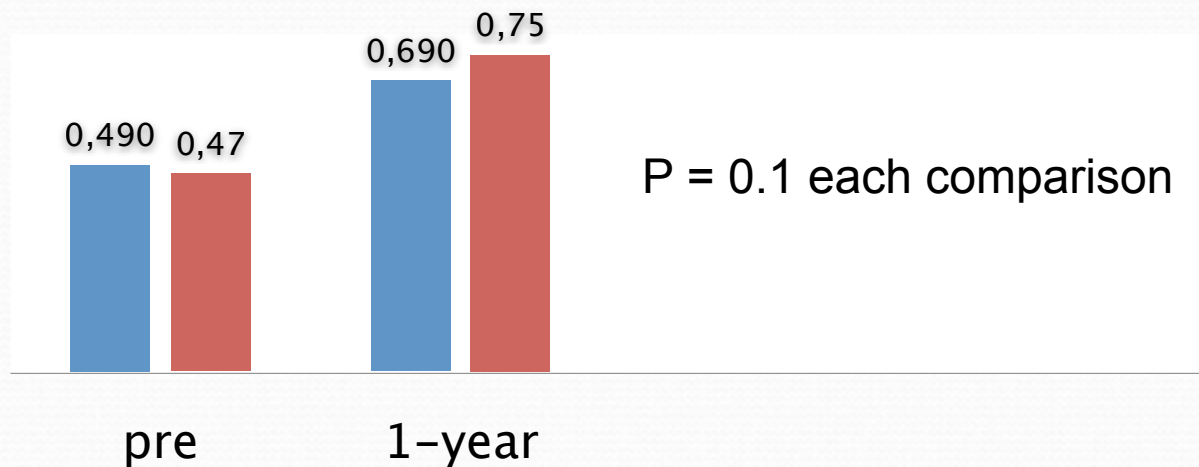
 Adjusted HR (diabetes mellitus, smoking status and body-mass-index) for BMS vs. SES:
3.0 (95% CI 1.4 to 6.4; P = 0.005)



Secondary Endpoint Ankle Brachial Index Baseline & 1-Year

■ BMS
■ SES

Ankle Brachial Index



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Secondary Clinical Endpoint

Rutherford-Becker Classification at 6 Months & 1 Year

6 months

	N=131	N=64 (SES)	N=67 (BMS)	P-Value
Median (IQR)*	2 (1 to 3)	1 (1 to 3)	2 (1 to 3)	0.3
Improvement by ≥1 Class	93 (70.9%)	49 (76.5%)	44 (65.7%)	
No Change	35 (26.9%)	14 (21.9%)	21 (31.3%)	
Worse by ≥ 1 Class	3 (2.3%)	1 (1.6%)	2 (3.0%)	
Median Change (IQR)*	-1.5 (-3 to 0)	-2 (-3 to -1)	-1 (-2 to 0)	0.09

12 months

	N=125	N=62 (SES)	N=63 (BMS)	P-Value
Median (IQR)*	2 (1 to 3)	2 (0.75 to 3)	2 (1 to 3)	0.01
Improvement by ≥1 Class	91 (72.8%)	52 (83.9%)	39 (61.9%)	
No Change	30 (24%)	8 (12.9%)	21 (34.9%)	
Worse by ≥ 1 Class	4 (3.2%)	2 (3.2%)	2 (3.2%)	
Median Change (IQR)*	-2 (-3 to 0)	-2 (-3 to -1)	-1 (-2 to 0)	0.004

*IQR = interquartile range

Rutherford-Becker Classification at 6 Months & 1 Year

6 months

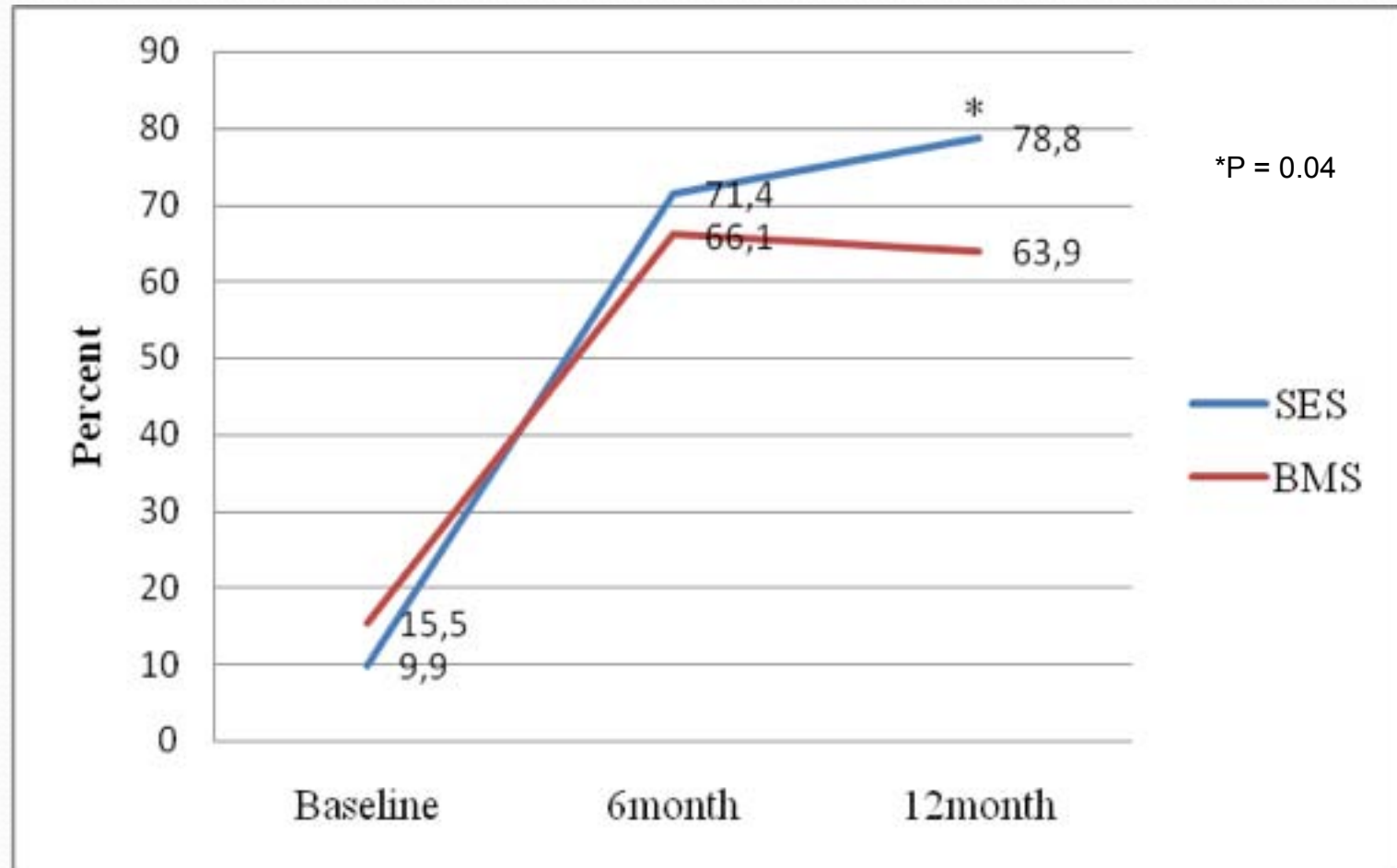
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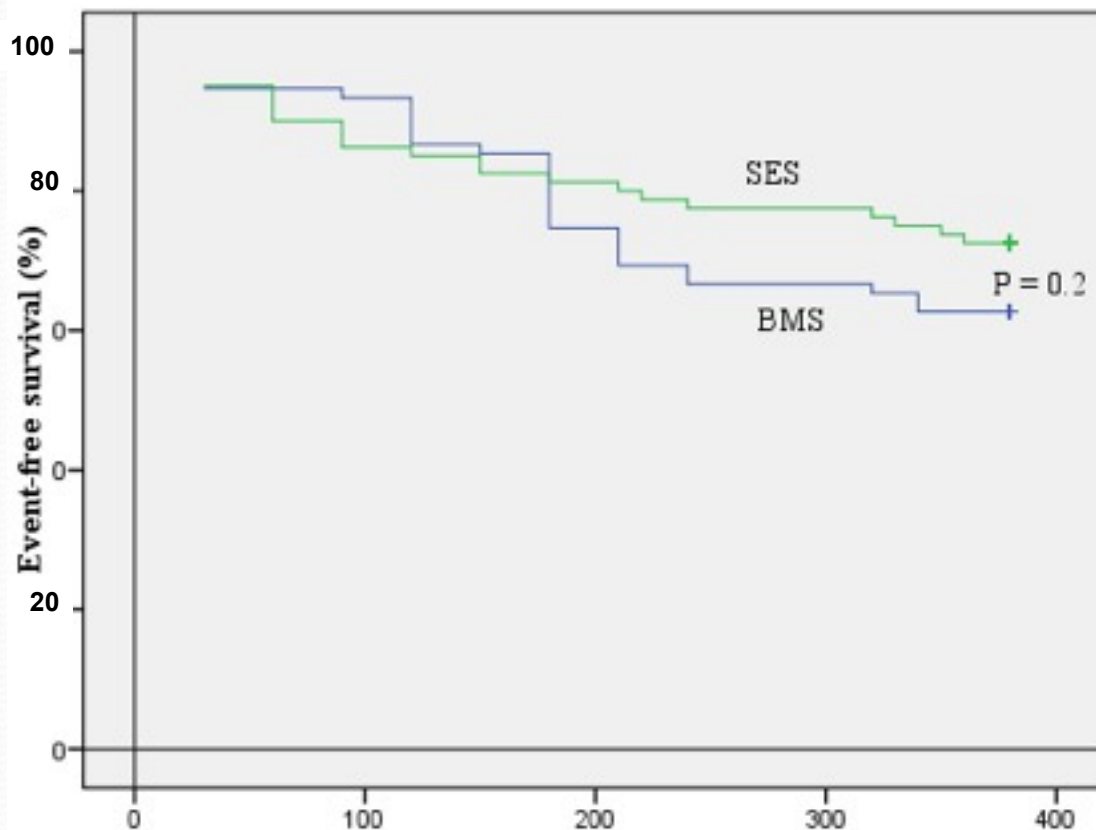
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PROPORTION OF PATIENTS WITH RUTHERFORD CLASS ≤ 2 AT BASELINE AND 6 AND 12 MONTHS OF EACH TREATMENT GROUP



Event-free Survival at 12 months

Survival free from target lesion revascularisation, major and minor amputation, myocardial infarction and death was compared by Kaplan-Meier analysis with the use of the Mantel-Cox log-rank test.



No. at risk

	0	100	200	300	400
Sirolimus Stent	82	71	64	63	62
Bare-metal Stent	79	72	67	64	63



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Table 4 a Major adverse events in patients with critical limb ischemia at baseline

	Sirolimus Stent (N=42)	Bare Metal Stent (N=33)	P
Death	9 (21.4%)	8 (24.3%)	0.9
Minor Amputation	1 (3.4%)	1 (4.3%)	1
Major Amputation	1 (3.4%)	1 (4.3%)	1
TLR	4 (13.8%)	3 (13%)	1

Table 4 b Major adverse events in patients with intermittent claudication at baseline

	Sirolimus Stent (N=40)	Bare Metal Stent (N=46)	P
Death	5 (12.5%)	3 (6.5%)	0.46
Myocardial infraction	0	3 (6.5%)	0.25
TLR	2 (5.9%)	8 (20%)	0.09

TLR, target lesion revascularisation


Summary



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Summary



 SES achieve significantly higher primary and secondary patency rates at 1 year as compared with BMS in the treatment of infrapopliteal lesions.



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Summary

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-  The improvement in Rutherford-Becker class at 1 year was significantly better in the SES group.



Summary

-  SES achieve significantly higher primary and secondary patency rates at 1 year as compared with BMS in the treatment of infrapopliteal lesions.
-  The improvement in Rutherford-Becker class at 1 year was significantly better in the SES group.
-  In the long run, the superior patency of SES may also improve limb salvage rates in patients with CLI Rutherford class 5 & 6 and an appropriate life expectancy.

