

ENDOVASCULAR RECONSTRUCTION OF COMPLEX AORTO-ILIAC LESIONS:
BARE METAL STENTS VS. COVERED STENTS
5-YEARS FOLLOW-UP RESULT OF COBEST TRIAL

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Potential conflicts of interest

Speaker's name: B. Patrice Mwipatayi MMed, FCS, FRACS

I have the following potential conflicts of interest to report:

Consultant: Medtronic Australia

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Conflict of Interest

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- Medtronic Australia
- Atrium Australia – Pacific Rim

A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease

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Conclusion: COBEST demonstrates covered and bare-metal stents produce similar and acceptable results for TASC B lesions. However, covered stents perform better for TASC C and D lesions than bare stents in longer-term patency and clinical outcome. (J Vasc Surg 2011;54:1561-70.)

Outcomes of covered versus bare-metal balloon-expandable stents for aortoiliac occlusive disease

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Objective: Randomized trials and retrospective data suggest that covered balloon-expandable (CBE) stents have better short-term patency compared with balloon-expandable bare-metal stents (BMSs) in the treatment of iliac artery disease. This study evaluated midterm outcomes of BMSs vs CBE stents placed in the common iliac artery (CIA) for aortoiliac occlusive disease.

Conclusions: In this study, BMSs had significantly better patency compared with CBE stents for treatment of aortoiliac occlusive disease. A randomized trial comparing patency as well as restenosis rates with long-term follow-up is needed to determine if there is any benefit from use of covered stents in the aortoiliac segment. (J Vasc Surg 2014;60:337-44.)

DISCOVER: Dutch Iliac Stent trial: COVERed balloon-expandable versus uncovered balloon-expandable stents in the common iliac artery: study protocol for a randomized controlled trial

Study Design

Primary endpoint

- Freedom From Binary Restenosis at 12 and 18 months
- Freedom From Stent Occlusion at 12 and 18 months
- **Primary Patency Rate (12, 18 months and 5-Years)**

Secondary endpoint

- Ankle Brachial Pressure Index (ABPI) changes from baseline
- Any amputation above the ankle
- Primary outcomes analyzed by TASC grade (B,C,D)
- **Mortality Rate at 5-years follow-up**

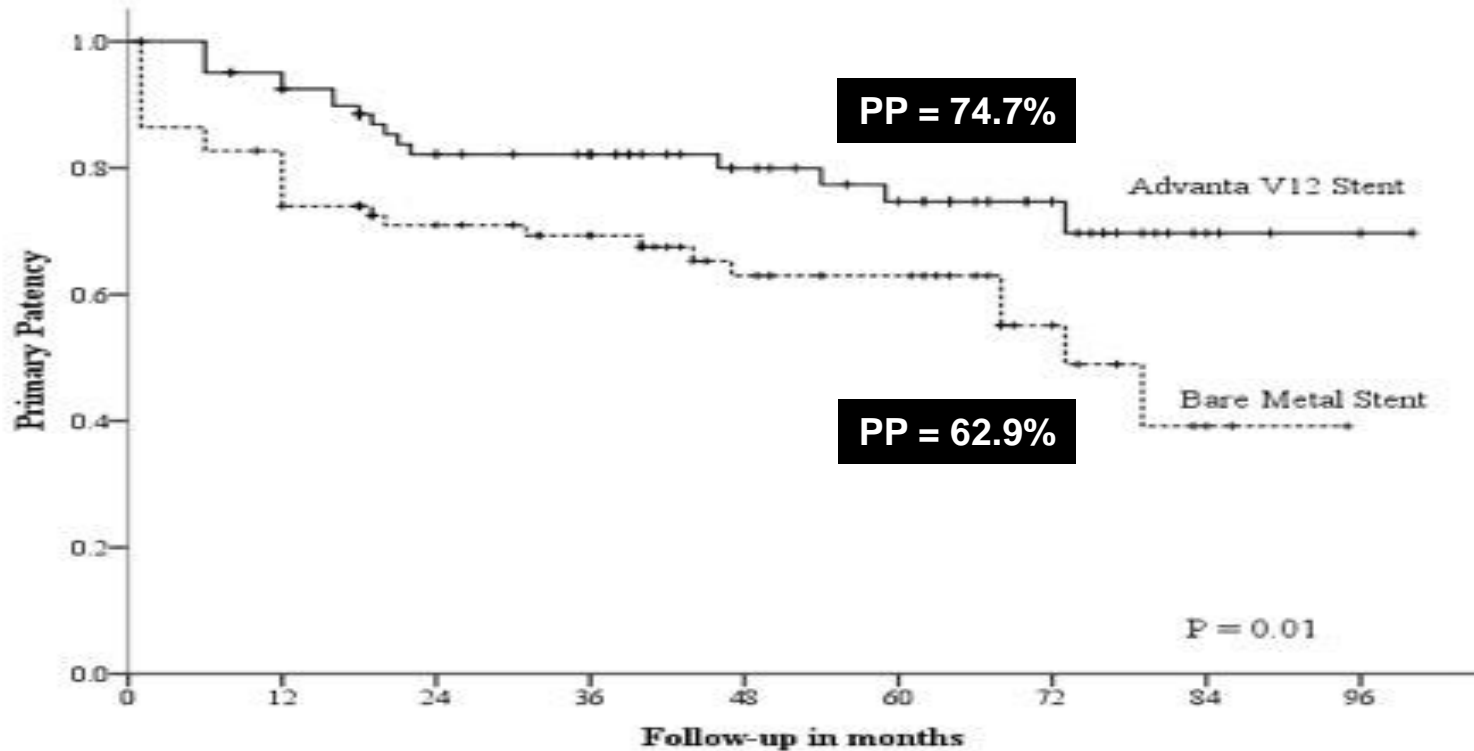
Baseline Demographics

	V12 stent (n=83)	Bare Stent (n=85)	P value
AGE (years) [Mean +/- S.D]	65.34 +/- 1.43	67.21 +/- 1.29	0.33
GENDER [%Male]	67.7	57.1	0.22
Rutherford Becker - %			
Category 1	3.2	4.8	
Category 2	27.4	30.2	
Category 3	40.3	50.8	
Category 4	24.2	12.7	
Category 5	4.8	1.6	
Risk Factors (n)			
Diabetes	24.2	28.6	0.58
HTN	56.5	71.4	0.08
Smoking	59.7	58.7	0.91
Hyperlipidemia	41.9	46.0	0.64
CRF	3.2	3.2	0.98
COAD	9.7	9.5	0.97
CAD	37.1	38.1	0.91
Hypercoagulable States	6.5	3.2	0.39

Baseline Lesion Characteristics

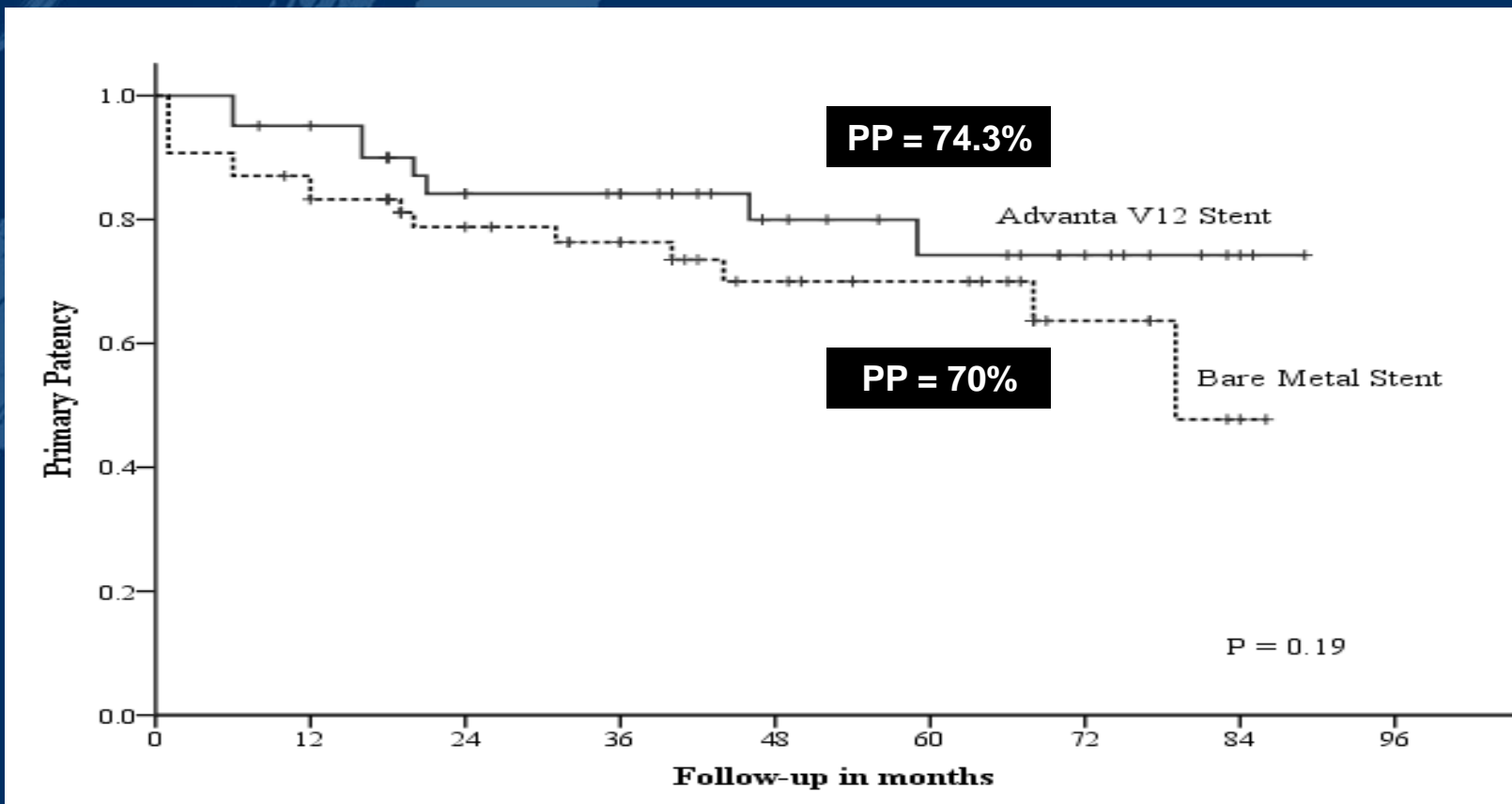
	V12 stent (n=83)	Bare Stent (n=85)	P value
Pre-Op Resting-ABI (side of lesion) – mean ± SEM	0.65±0.03	0.63±0.03	0.64
Pre-Op Duplex Scan			0.39
% Performed (n)	74.7 (62)	76.5 (65)	
>50% Stenosis	87.1	81.5	
Occlusion	12.9	18.5	
Pre-Op Angiogram			0.03
% Performed (n)	80.7 (67)	85.9 (73)	
TASC B	50.7	72.6	
TASC C	34.3	20.5	
TASC D	14.9	6.8	
Runoff			0.15
% Performed (n)	89.1 (74)	85.9 (73)	
0	0	1.4	
1	12.2	5.5	
2	20.3	21.9	
3	23.0	37.0	
4	44.6	34.2	

KM Curve of Primary Patency



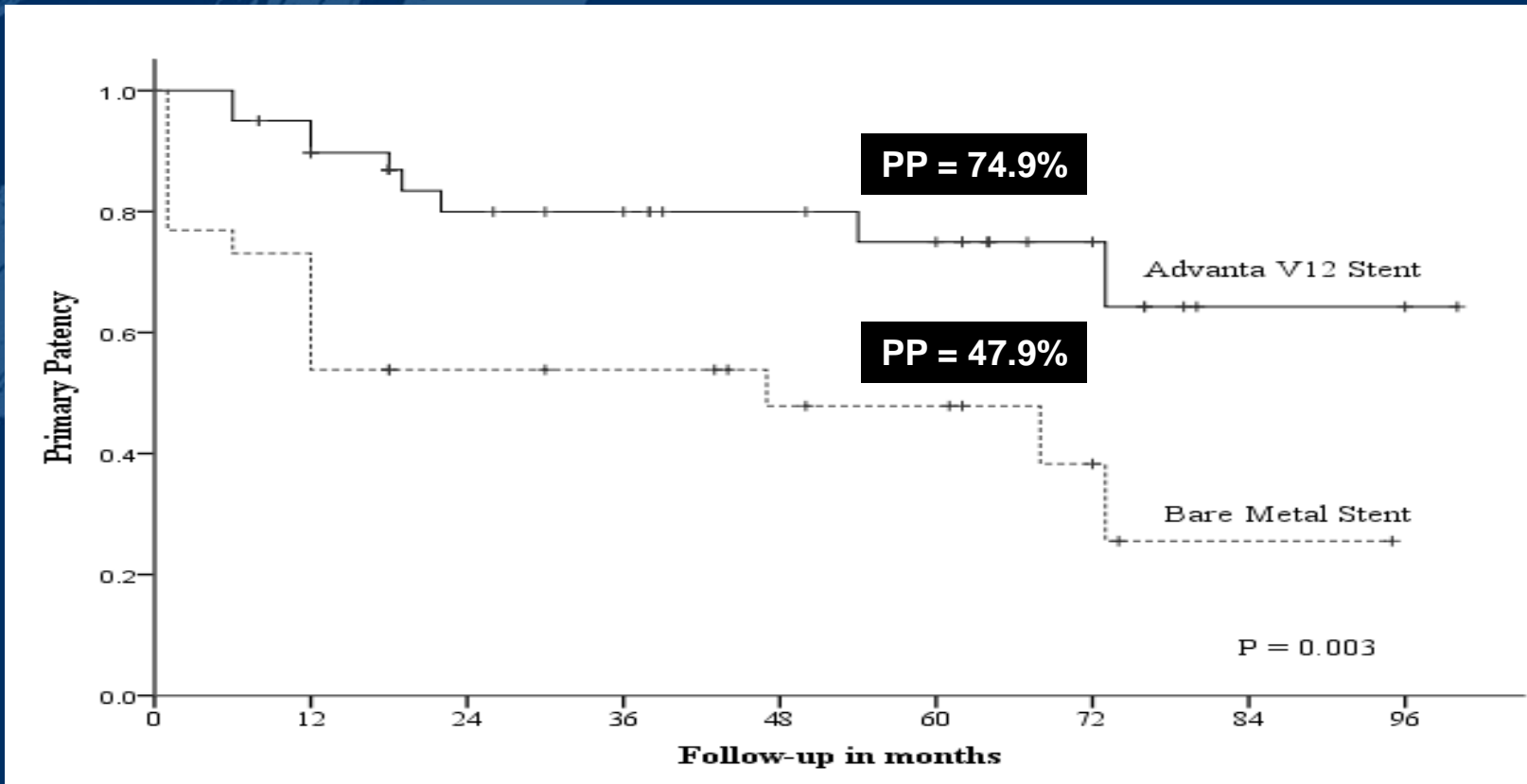
Time (Months)	0	12	24	36	48	60	72	84	96
Advanta V12 Stent (n. at risk)	83	74	52	47	35	28	17	5	2
Standard Error (%)	-	2.95	4.54	4.54	4.93	5.84	5.84	7.27	7.27
BMS (n. at risk)	85	66	46	40	28	23	10	3	1
Standard Error (%)	-	4.89	5.13	5.27	5.94	5.94	7.36	11.2	11.2

KM Curve of Primary Patency for TASC B lesion



Time (Months)	0	12	24	36	48	60	72	84	96
Advanta V12 Stent (n. at risk)	42	38	29	26	18	14	9	3	1
Standard Error (%)	-	3.36	5.96	5.96	6.99	8.51	8.51	8.51	8.51
BMS (n. at risk)	56	46	34	29	19	16	7	2	1
Standard Error (%)	-	5.10	5.72	6.04	7.03	7.03	8.81	15.3	15.3

KM Curve of Primary Patency for TASC C/D lesion



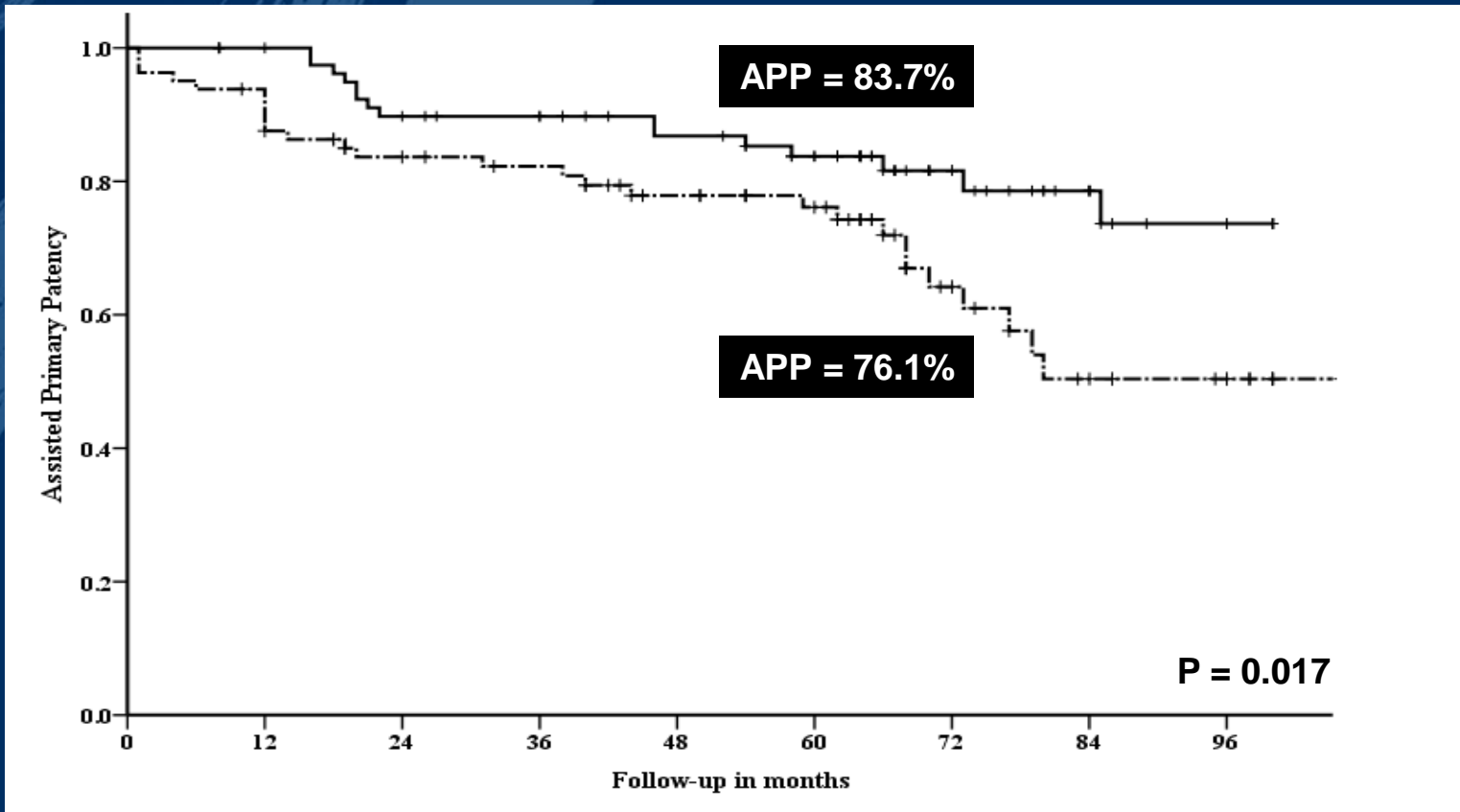
Time (Months)	0	12	24	36	48	60	72	84	96
Advanta V12 Stent (n. at risk)	41	36	24	21	18	15	8	3	2
Standard Error (%)	-	4.87	6.90	6.90	6.98	8.08	8.08	12.1	12.1
BMS (n. at risk)	29	19	13	12	9	8	4	2	1
Standard Error (%)	-	9.78	9.78	9.78	10.4	10.4	11.9	13.1	13.1

Factors independently affecting primary patency of different types of stent based on multivariate logistic regression models

Variable	Coefficients B	SE	Wald test	HR (95% CI)	P value
Type of stent used (Advanta V12 vs. BMS)	1.028	0.328	9.838	2.797 (1.471–5.318)	.002
Rutherford stratification	9.122	80.786	11.044	2.019 (1.278–3.191)	.026

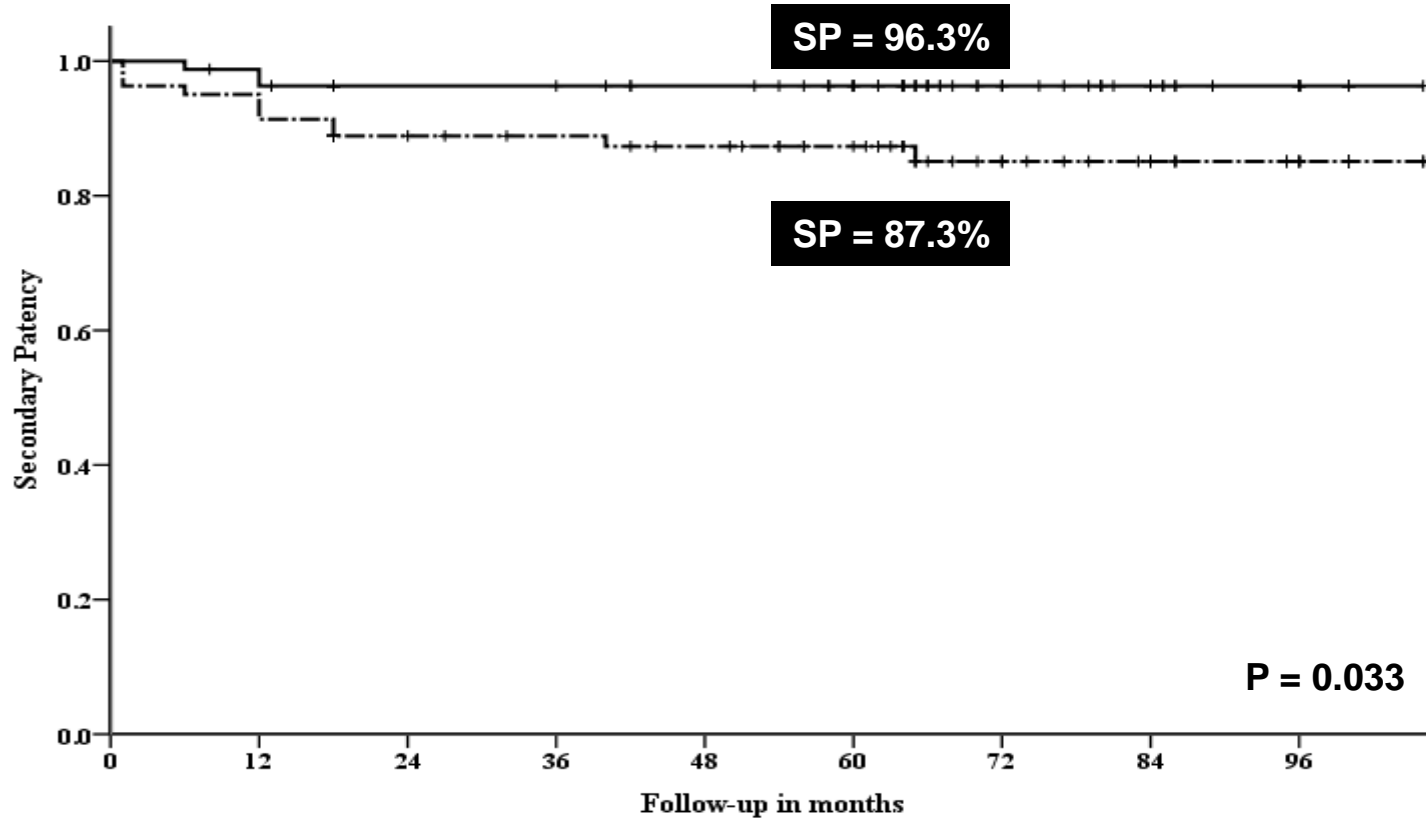


KM Curve of Assisted Primary Patency



Time (Months)	0	12	24	36	48	60	72	84	96
Advanta V12 Stent (n. at risk)	83	79	20	67	61	52	30	19	11
Standard Error (%)	-	1.79	3.44	3.44	3.90	4.32	4.71	5.42	6.96
BMS (n. at risk)	85	75	62	59	50	43	22	13	9
Standard Error (%)	-	3.68	4.15	4.31	4.76	4.97	6.50	7.98	7.98

KM Curve of Secondary Patency

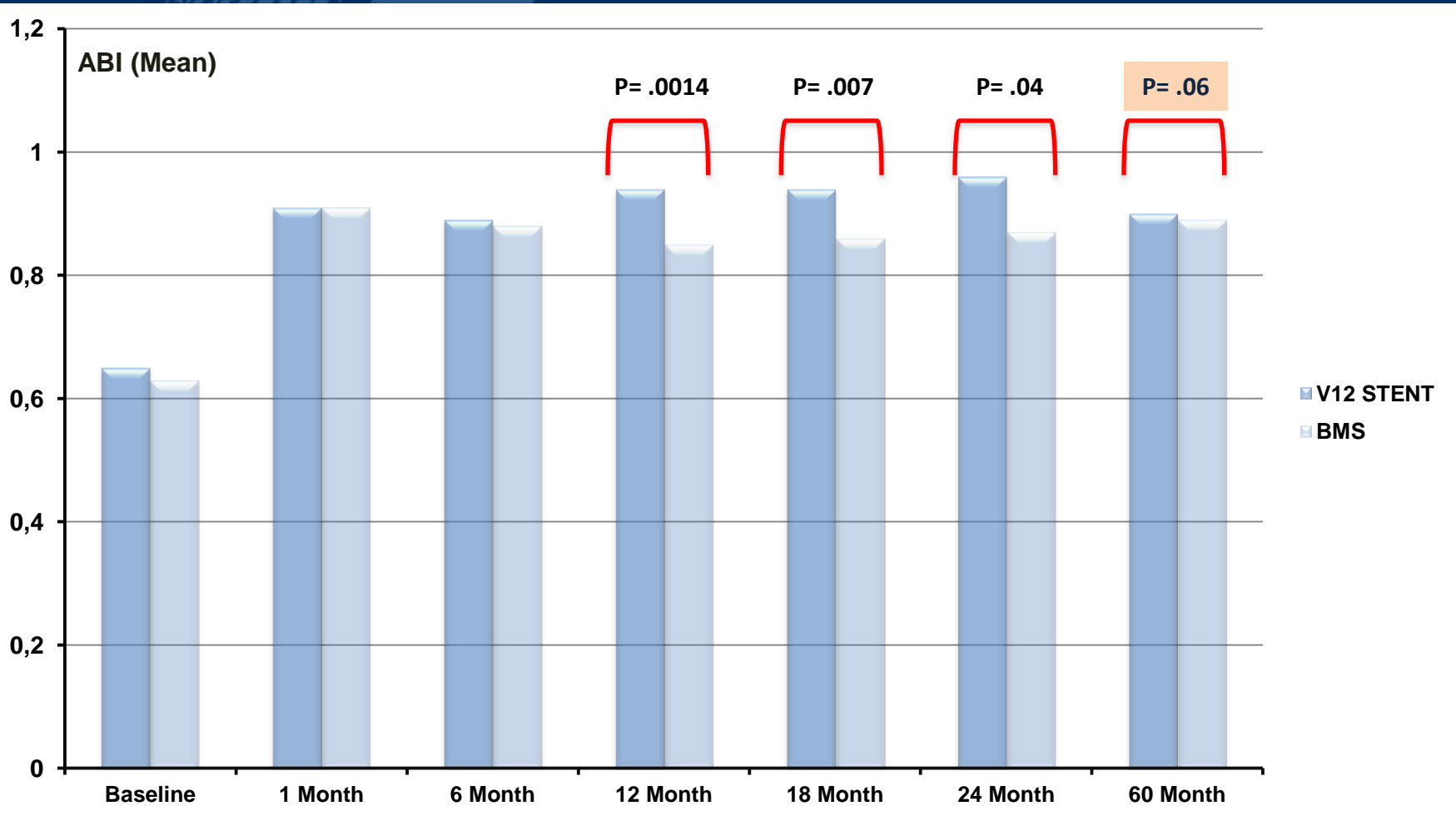


Time (Months)	0	12	24	36	48	60	72	84	96
Advanta V12 Stent (n. at risk)	83	80	77	68	64	58	33	23	14
Standard Error (%)	-	2.09	2.09	2.09	2.09	2.09	2.09	2.09	6.91
BMS (n. at risk)	85	77	60	58	55	48	32	25	16
Standard Error (%)	-	3.12	3.49	3.49	3.76	3.76	4.28	4.28	4.28

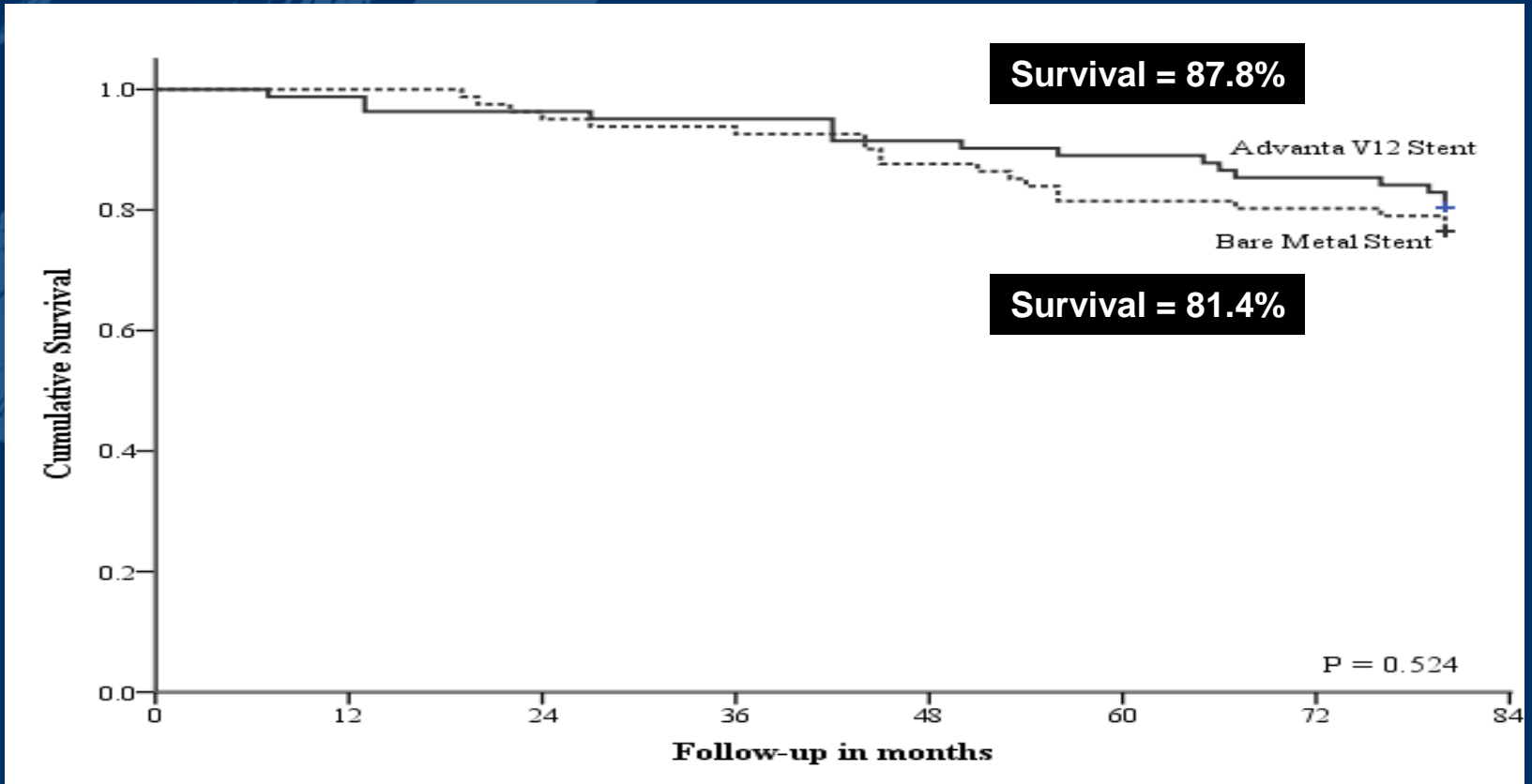
Factors independently affecting secondary patency of different types of stent based on multivariate logistic regression models

Variable	Coefficient (B)	SE	Wald test	HR (95% CI)	P value
Type of stent used (Advanta V12 vs. BMS)	1.176	0.406	8.368	3.240 (1.461–7.187)	.004
Number of stents used	-1.708	0.845	4.083	0.181(0.035–0.950)	.043
Rutherford stratification	9.611	75.881	10.025	1.934 (1.200–3.118)	.040
Hypertension	-1.033	0.443	5.442	0.356 (0.150–0.848)	.020
Smoking	1.210	0.495	5.964	2.747 (1.105–6.828)	.015

Improvement in ABI



Long-term Survival Rate



Time (Months)	0	12	24	36	48	60	72	84	96
Advanta V12 Stent (n. at risk)	83	82	79	78	74	72	56	51	41
Standard Error (%)	-	2.05	2.61	2.61	3.43	3.60	4.18	4.73	4.73
BMS (n. at risk)	85	82	79	77	70	65	52	46	35
Standard Error (%)	-	1.21	2.38	2.88	3.80	4.33	4.51	4.71	5.32

CONCLUSION

The COBEST Trial demonstrate:

- For TASC B lesions, both Covered and Bare Metal Stents give acceptable results.
- For extensive lesions (TASC C and D lesions), covered stents perform better than bare stents in terms of patency and clinical outcome results at 12 and 18 months follow-up.
- These results appears to be durable and sustainable at 5-years follow-up with better patency For Covered Stent compared to Bare Metal stent (paper submitted to JVS).

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