Leipzig Interventional Course
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Self-expanding vs. balloon-expandable stents for iliac artery disease: Is either superior?

Hans Krankenberg

Department of Angiology, Asklepios Klinikum Harburg
Hamburg, Germany

Disclosure

Speaker name: Hans Krankenberg

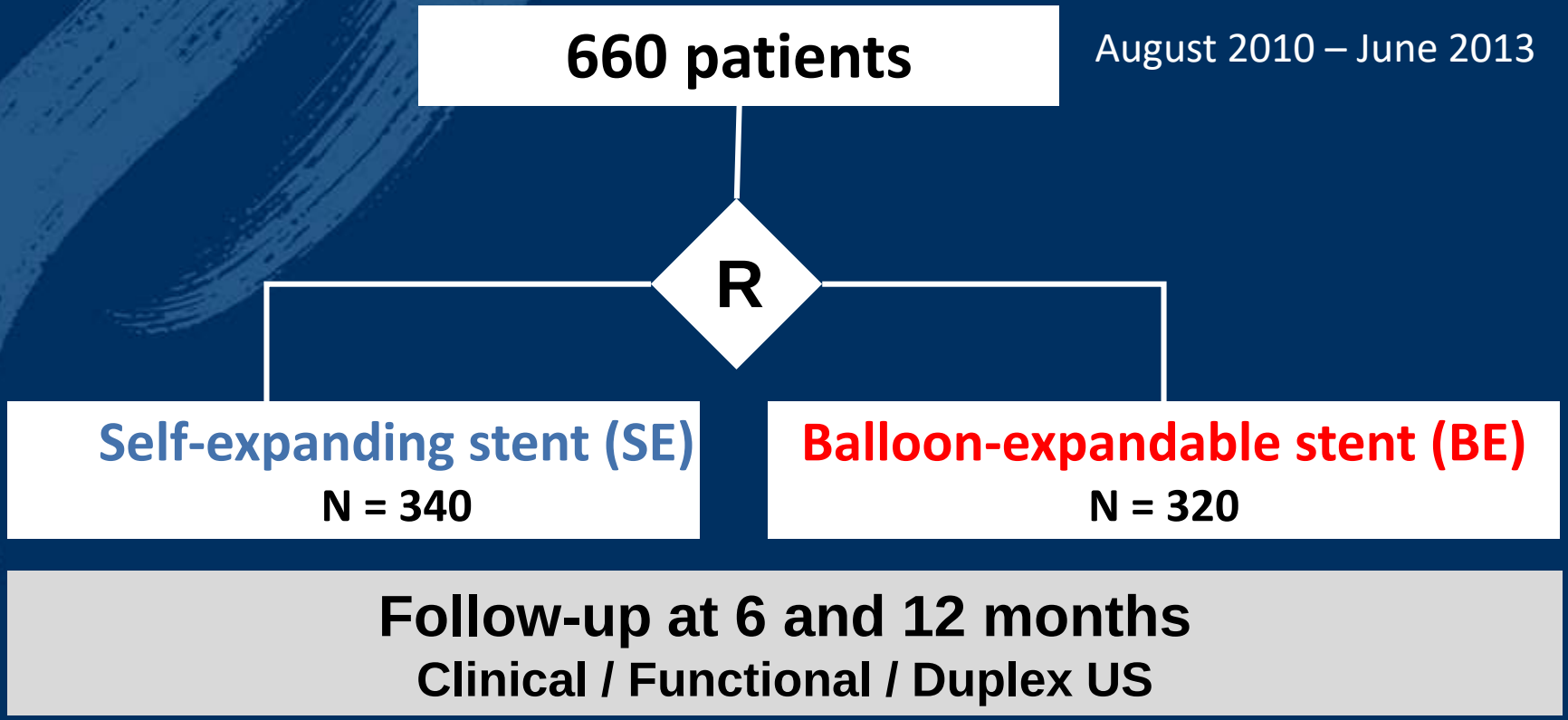
I do not have any potential conflict of interest.

Self-expanding stent (SE)	Balloon-expandable stent (BE)
Flexible • Easy to adapt wall pulsatility • Conform to various vessel diameters • Less Neointimahyperlasia • Tapering lesions? • Tortuous lesions? • Longer lesions?	High radial outward force Can be placed more precisely • Heavily calcified lesions? • Lesions prone to recoil? • Ostial CIA lesions? • Kissing balloon? • Shorter lesions?

Following Feldman and Klein J Am Coll Cardiol Intv 2017;10:1705-7

ICE Trial

Prospective, multicenter, randomized, investigator initiated



Krankenberg et al. J Am Coll Cardiol Intv 2017;10:1694–704.

ICE Trial

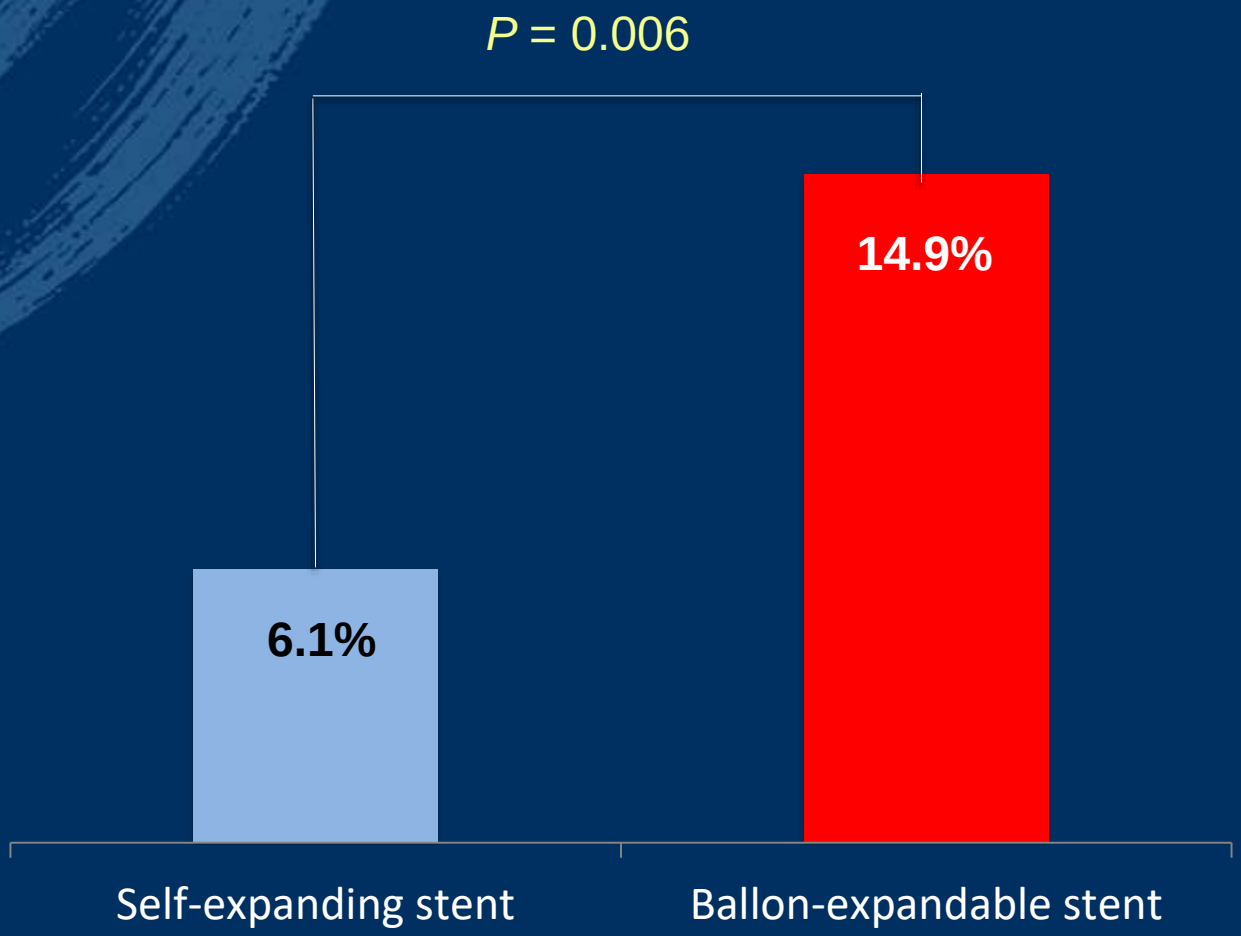
Lesion Characteristics

	SE	BE	*P*
N	340	320	
CIA (%)	60.3	57.8	*ns*
EIA (%)	39.7	42.2	*ns*
DS (%)	85.1 ± 10.0	84.2 ± 9.6	*ns*
RVD (mm)	8.3 ± 1.1	7.7 ± 1.2	*<0.0001*
Lesion length (mm)	41.1 ± 32.9	33.7 ± 26.5	*0.005*
Heavy calcification (%)	26.5	24.7	*ns*
Total occlusion (%)	18.2	14.7	*ns*
In-stent restenosis (%)	4.1	3.4	*ns*

Krankenberg et al. J Am Coll Cardiol Intv 2017;10:1694–704.

ICE Trial

Primary endpoint
12-month binary restenosis



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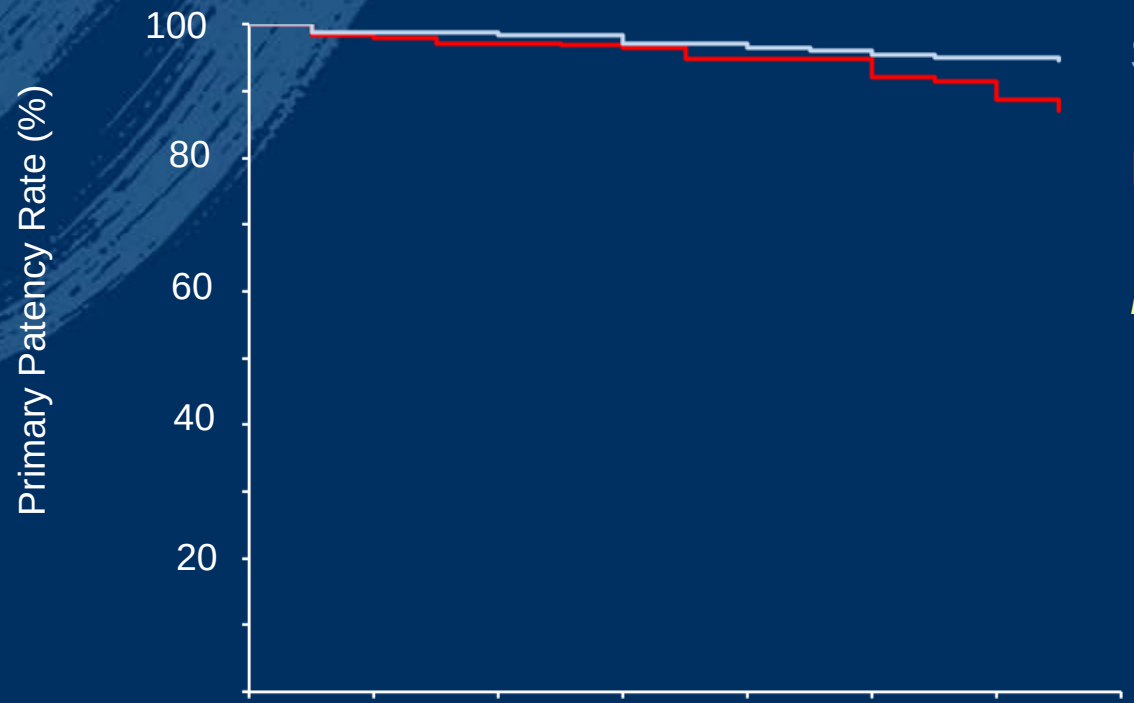
ICE Trial

Primary patency at 12 months



SE 94.5%

BE 87.0%

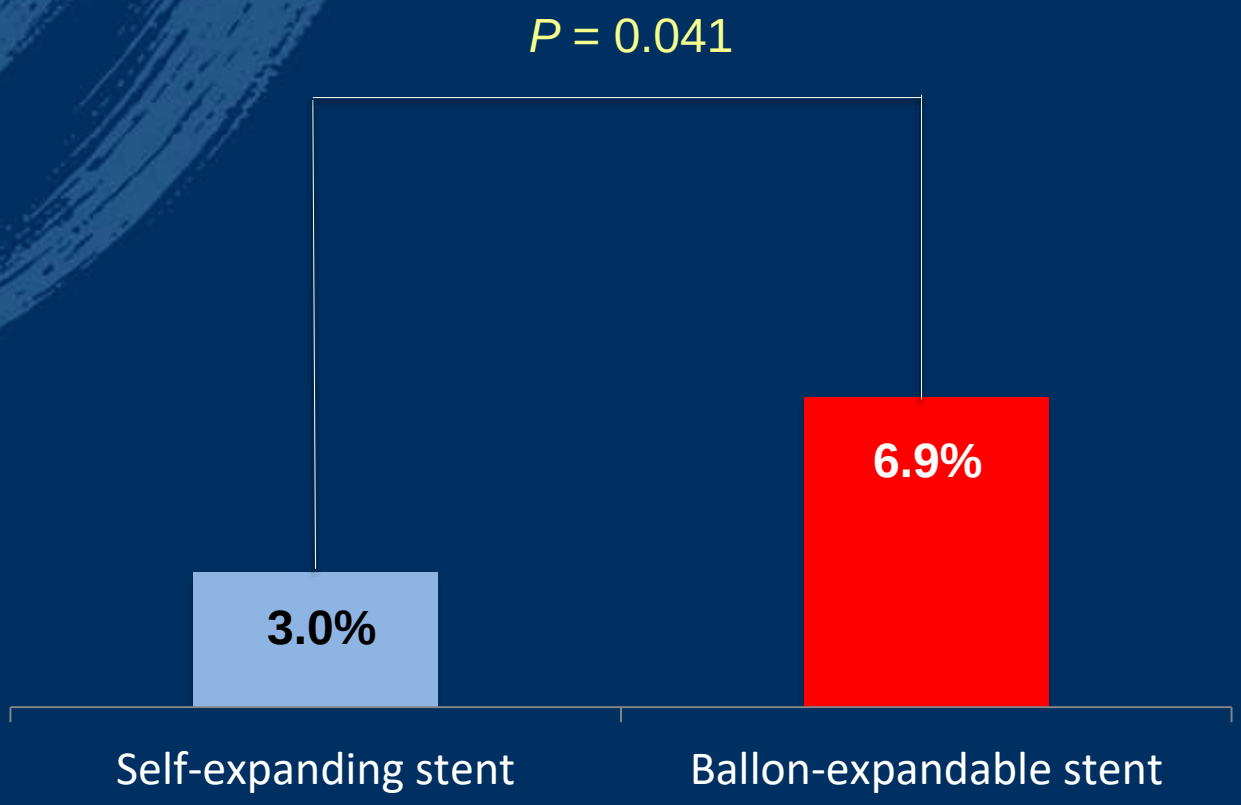
P = 0.026

Patients at risk							
SE	340	233	229	228	196	194	192
BE	320	244	243	238	175	172	166

Krankenberg et al. J Am Coll Cardiol Intv 2017;10:1694–704.

ICE Trial

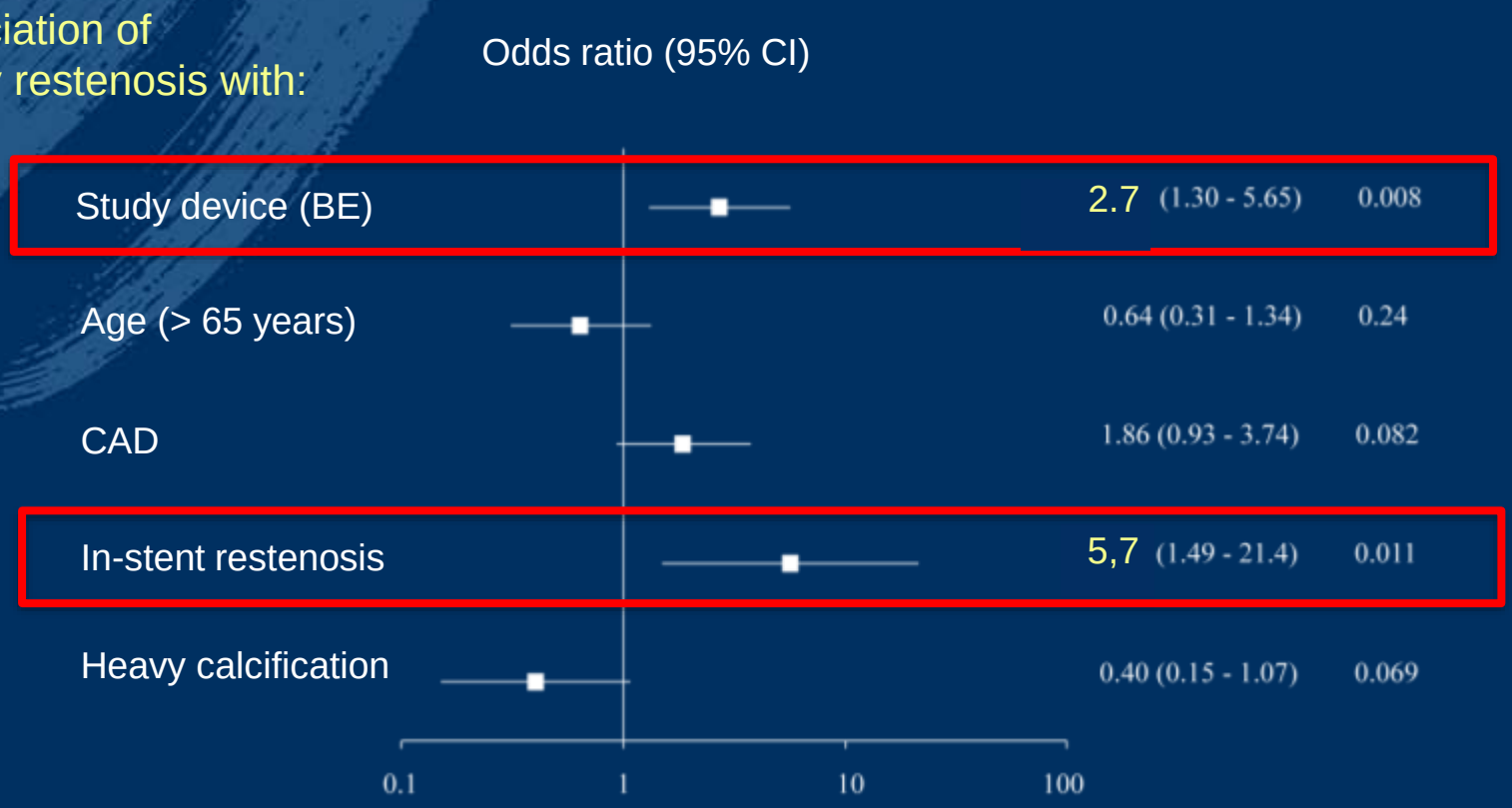
12-month TLR



Krankenberg et al. J Am Coll Cardiol Intv 2017;10:1694–704.

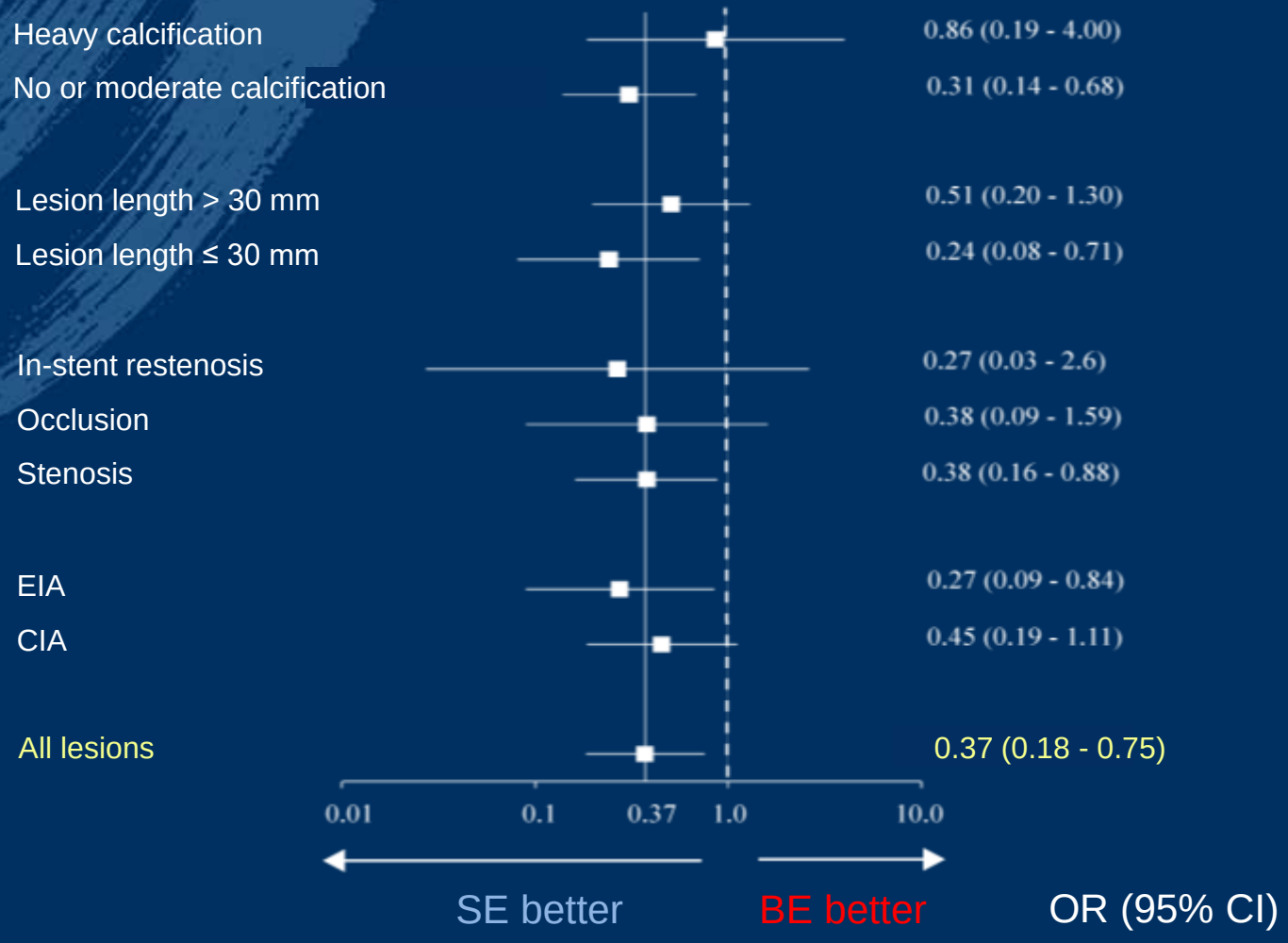
ICE Trial

Multivariable Analysis



Lesion Subgroups

Treatment effect on 12-month restenosis rate



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ICE Trial - Summary

- Treatment of IAOD with self-expanding stents as compared to balloon-expandable stents
  - resulted in a lower 12-month restenosis rate
  - a significantely reduced TLR rate
  - provided superior primary patency
- Multivariable analysis identified treatment with balloon-expandable stents and in-stent restenosis as predictors of binary restenosis
- None of the patient or lesion characteristics were found to interact with the treatment effect
- No safety concerns arose in both groups

VISIBILITY Iliac study

Prospective, observational, 17 centers, balloon-expandable stent*, 75 patients, 9-month FU

Ø Lesion length 2.9 cm; mod./severe Calcium 54%; CTO 8%

Primary patency 95.8%

TASC A/B	98.1%/ 92.9%	p<0.001
TASC C/D	83.3%	

No difference (ns): gender, lesion loc., calcification, occlusion

Freedom from cd-TLR 95.8%

MAE 4.0%

(5 cd-TLR in 3 patients)

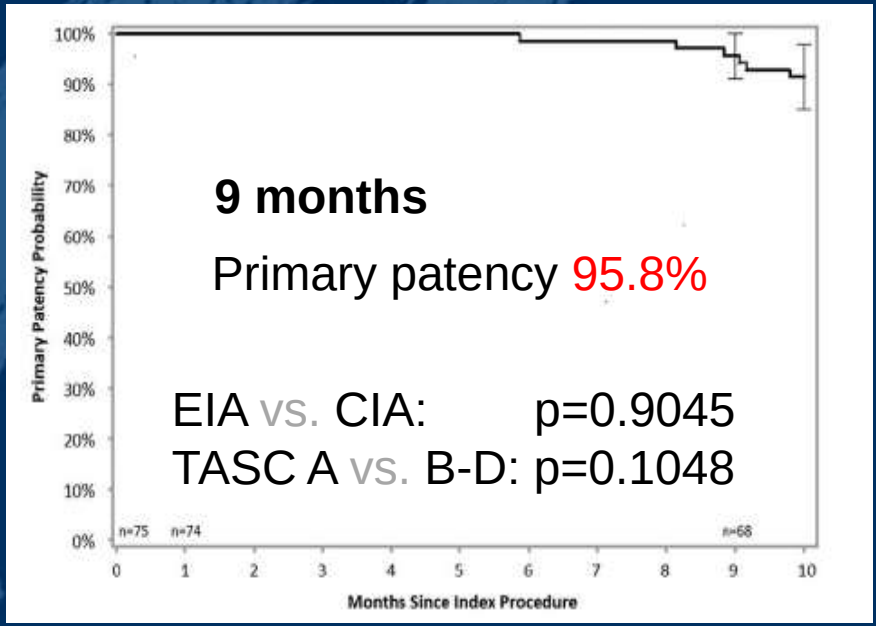
* Visi-Pro

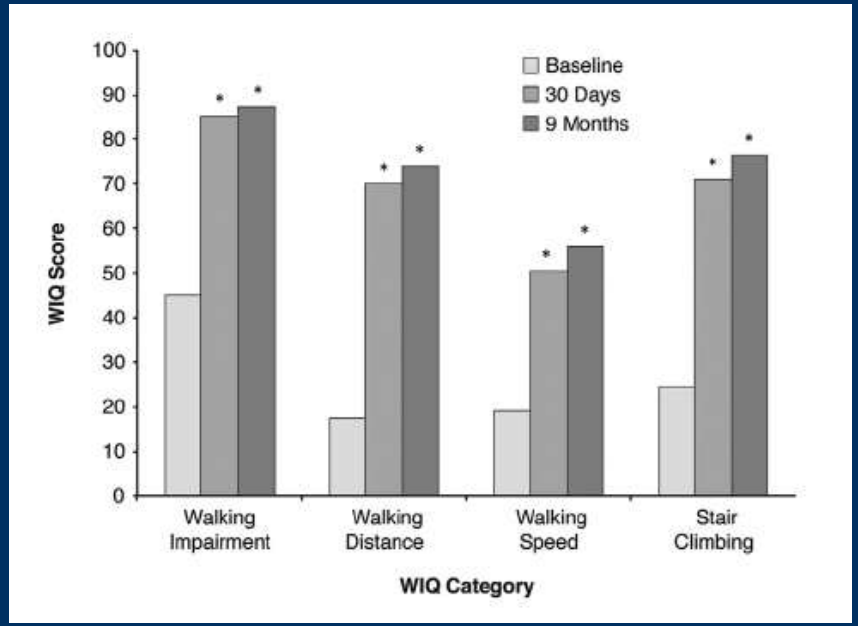
Rundback et al. Journal of Endovascular Therapy 2017, Vol. 24(3) 342–348

DURABILITY Iliac study

Prospective, observational, 15 centers, self-expanding stent*, 75 patients, 9-month FU

Ø Lesion length 4.5 cm; mod./severe Calcium 67%; CTO 22%





9-month MAE: 1.3% (1 cd-TLR, no death, MI, or amputation)

* Protégé Everflex, Protégé GPS

Faries et al. Ann Vasc Surg 2018; 51: 37–47

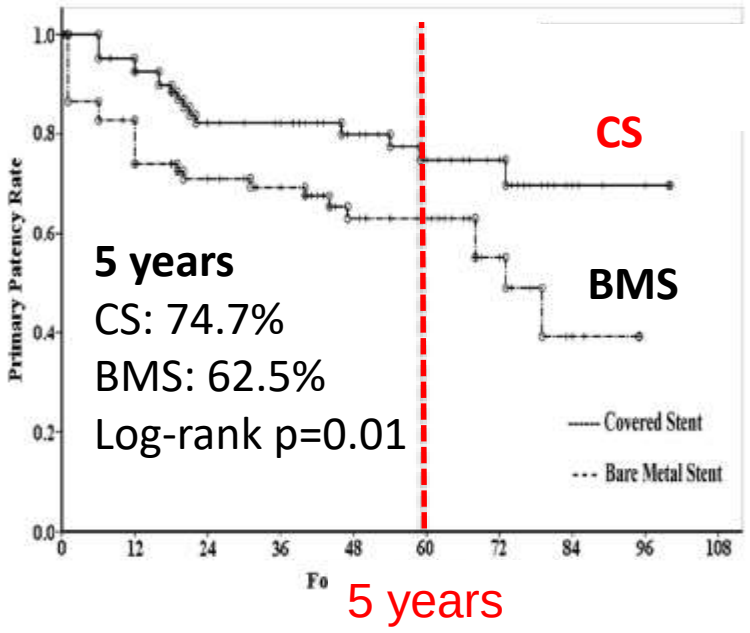
Covered stent* (BE) vs. BMS (BE, 6% SE)

COBEST (RCT) trial: 5-year results

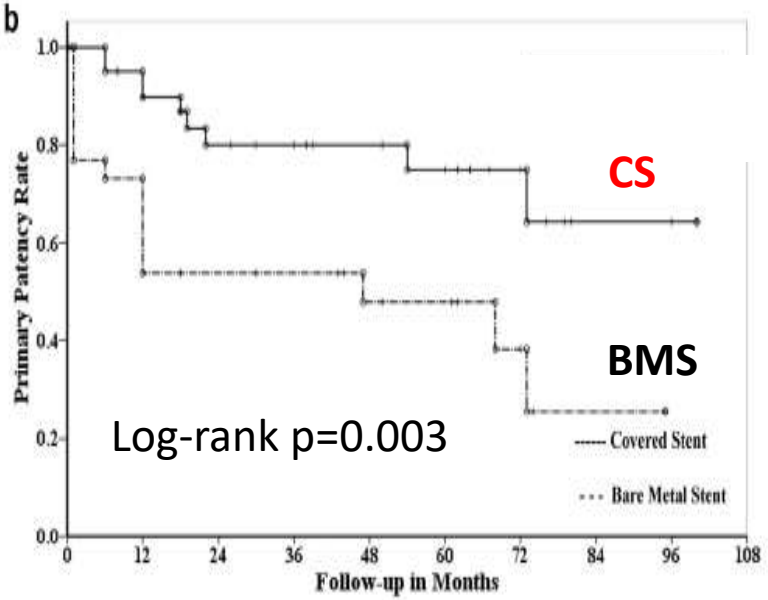
Iliac artery stenosis or occlusion: TASC B-D, 125 patients

Primäre Offenheit

TASC B-D



TASC C+D



(TASC B: CS vs. BMS: p=0.197)

Risk factors: Type of stent (HR 2.8), Rutherford category (HR 2.0)

* Advanta V12

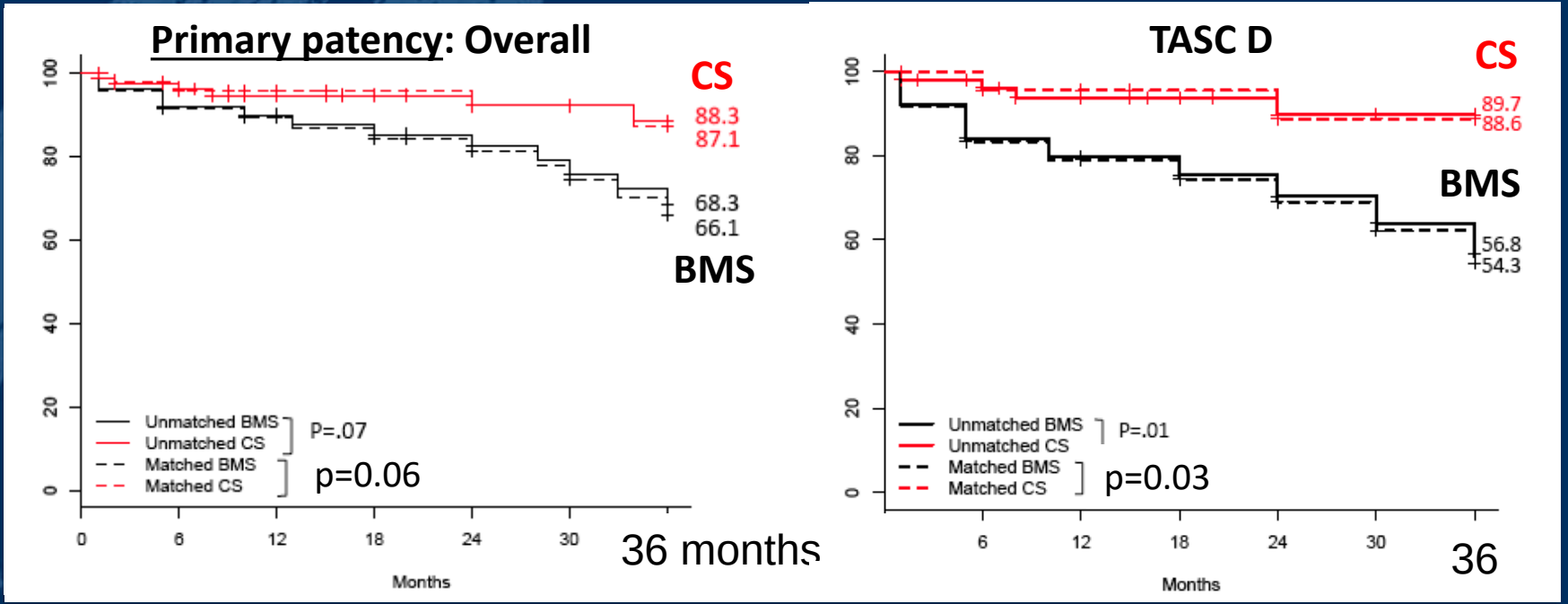
Mwipatayi et al. J Vasc Surg 2016;64:83-94

PTFE* covered stent (SE) vs. BMS (SE)

Iliac artery occlusions

Retrospective, 2 matched cohorts, 94 limbs, 3 years

Ø Lesion length 7/6 cm; mod./severe Calcium 47/41%; CTO 100%



Favours CS: **Occlusion length** > 3.5 cm:, p=0.04

Total lesion length ≥ 6.0 cm: p=0.04

Calcification > 75% of arterial circumference: p=0.01

* Polytetrafluoroethylene: Viabahn, Fluency

Piazza et al. Eur J Vasc Endovasc Surg (2017) 54, 177e185

Conclusion

- Both SE and BE perform well in IAOD.
- The randomised ICE trial favours SE over BE.
- Covered stents (SE and BE) might add some benefit in ISR and heavily calcified lesions.

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