Treatment of ISR
Data of the Copa Cabana Study and other possible solutions

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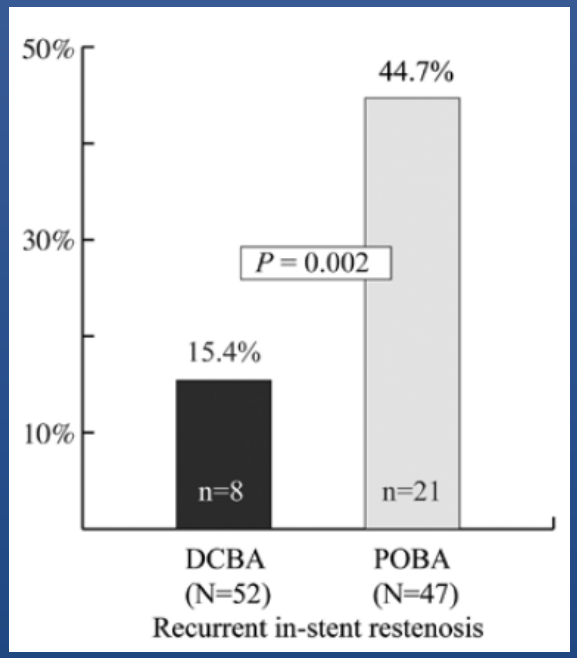
Disclosures

Study support by BART, Bayer, BBraun, Biotronic, Gore, Phillips, Medtronic, Shockwave, Verian

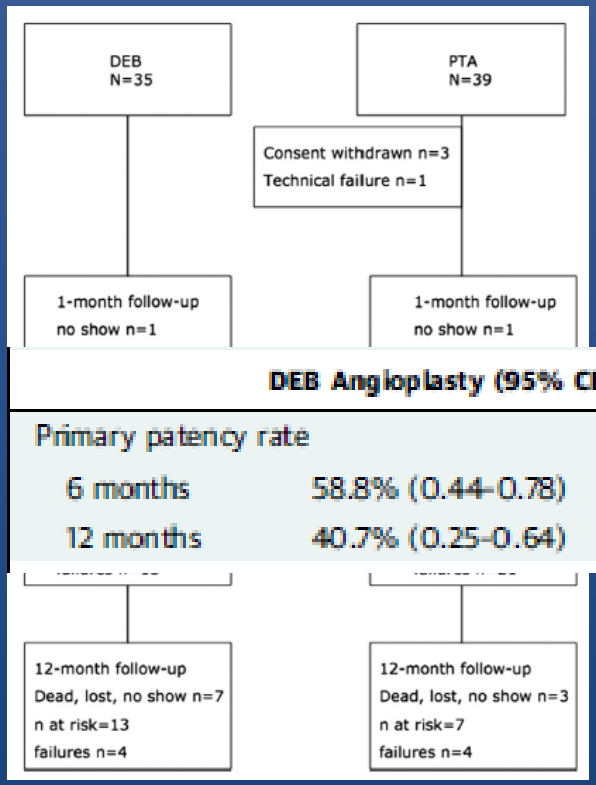
FAIR and PACUBA (DCB)

FAIR 6 mo RS rate



Length: 8.1 cm

PACUBA 6 and 12 mo



	DEB Angioplasty (95% CI)	PTA (95% CI)
Primary patency rate		
6 months	58.8% (0.44-0.78)	31.3% (0.18-0.52)
12 months	40.7% (0.25-0.64)	13.4% (0.05-0.36)*

Length: 17.9 cm

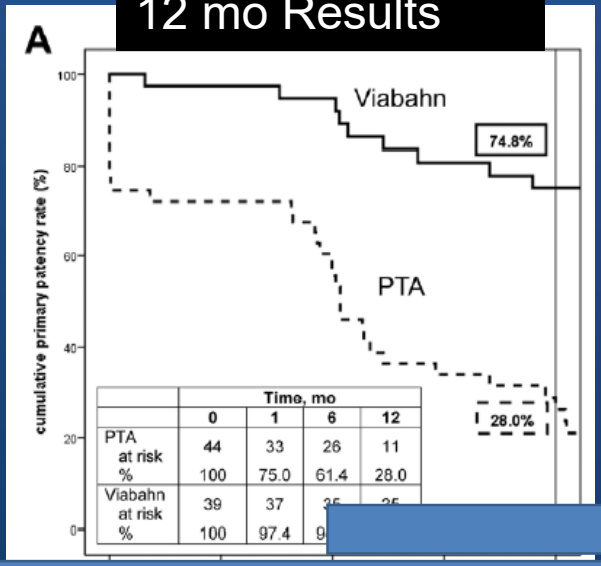
Good results after 6 months but nothing beyond!

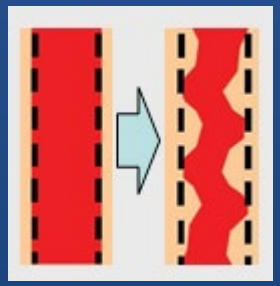
RELINE (Viabahn)

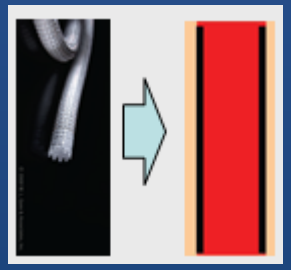
Baseline

	Viabahn (n=39)	PTA (n=44)	p
Lesion length, mm	173.0±77.8 (30–330)[b]	190.0±72.1 (30–270)	0.309
Lesion type			0.840
Stenosis	30 (76.9)	33 (75.0)	
Occlusion	9 (23.1)	11 (25.0)	
Calcified lesion	13 (33.3)	11 (25.0)[c]	0.447

12 mo Results



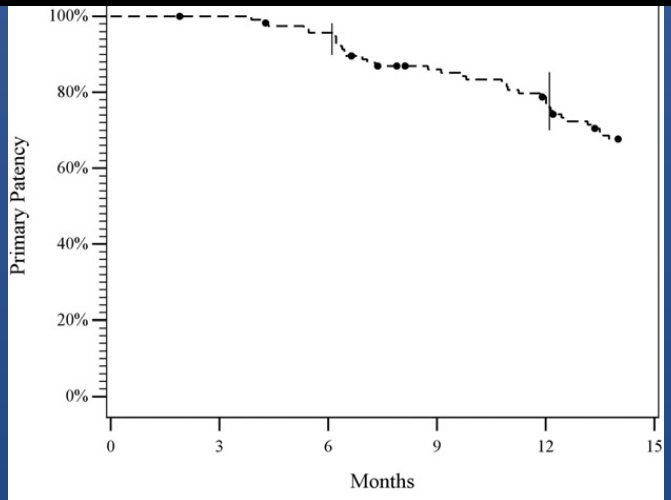




Good results after 12 months

DES (Zilver PTX)

In-Stent RS, n=118, m. length: 13 cm



Kaplan Meier Estimates of Primary Patency by Lesion				
Months Post-procedure	Patency ± Standard Error	Cumulative Failed	Cumulative Censored	Remaining at Risk
6	95.7% ± 1.9%	5	2	110
12	78.8% ± 3.8%	24	7	86

Good results? after 12 months, no control group

Study flow chart

Follow-up

Clinical/Functional: 1, 6, 12, 24 months
DSA: 6 and 24 months with core lab
DSA: any TLR with core lab
DUS: 6,12, 24 months

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Baseline Characteristics

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		DCB	POBA
Calcification	**within stent**		
	None/Mild	70.2%	72.3%
	Moderate/Severe	29.8%	24.4%
	missing		2.4%
Total occlusion of the stent		25.5%	36.6%
% maximal stenosis		91.4 ± 9.0	92.0 ± 9.1
Former revascularization		38.3%	19.5%
Stent fracture		N=4	N=0
Target lesion length [mm]		119.8 ± 96.5	109.3 ± 78.1

Continuous data: mean ± SD (n); Categorical data: % of n (n)
(n) = total number of patients in the group for whom the information is available (results of the intention-to-treat set (ITT))
Number of patients in the ITT: DCB: 38, POBA: 28
*instent lesions

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Results, LLL

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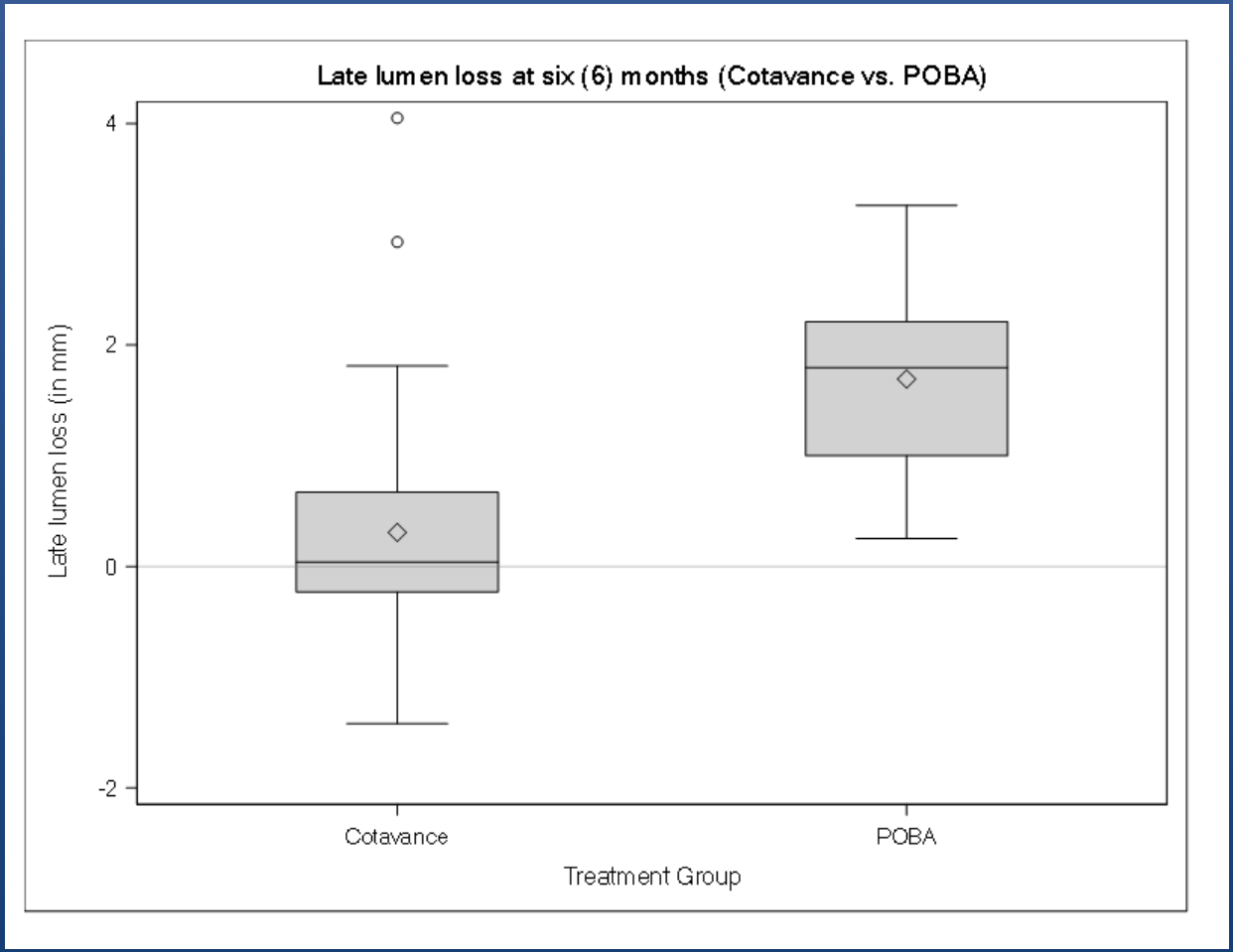

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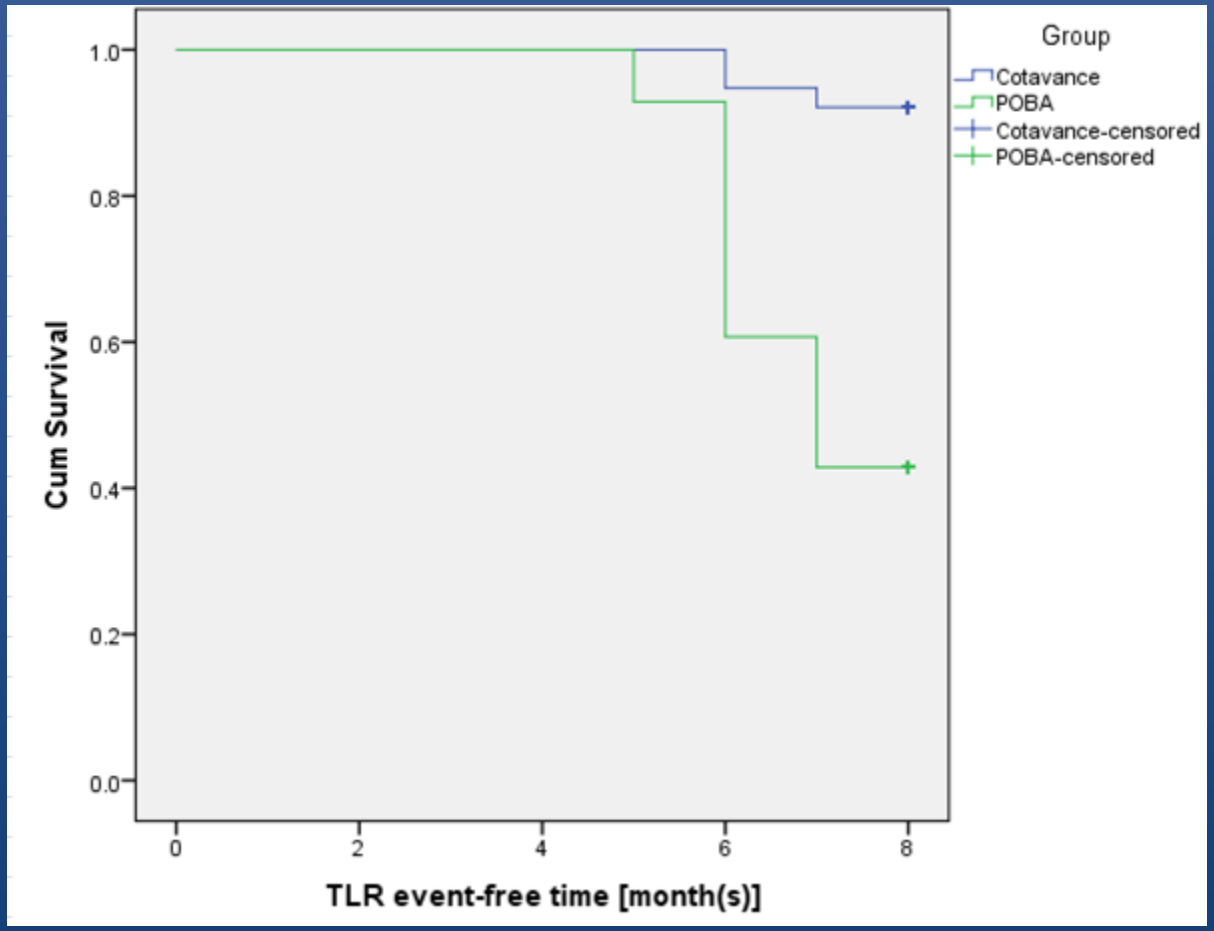
Results, TLR 6 mo

RoMed Kliniken



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Results, TLR 2y

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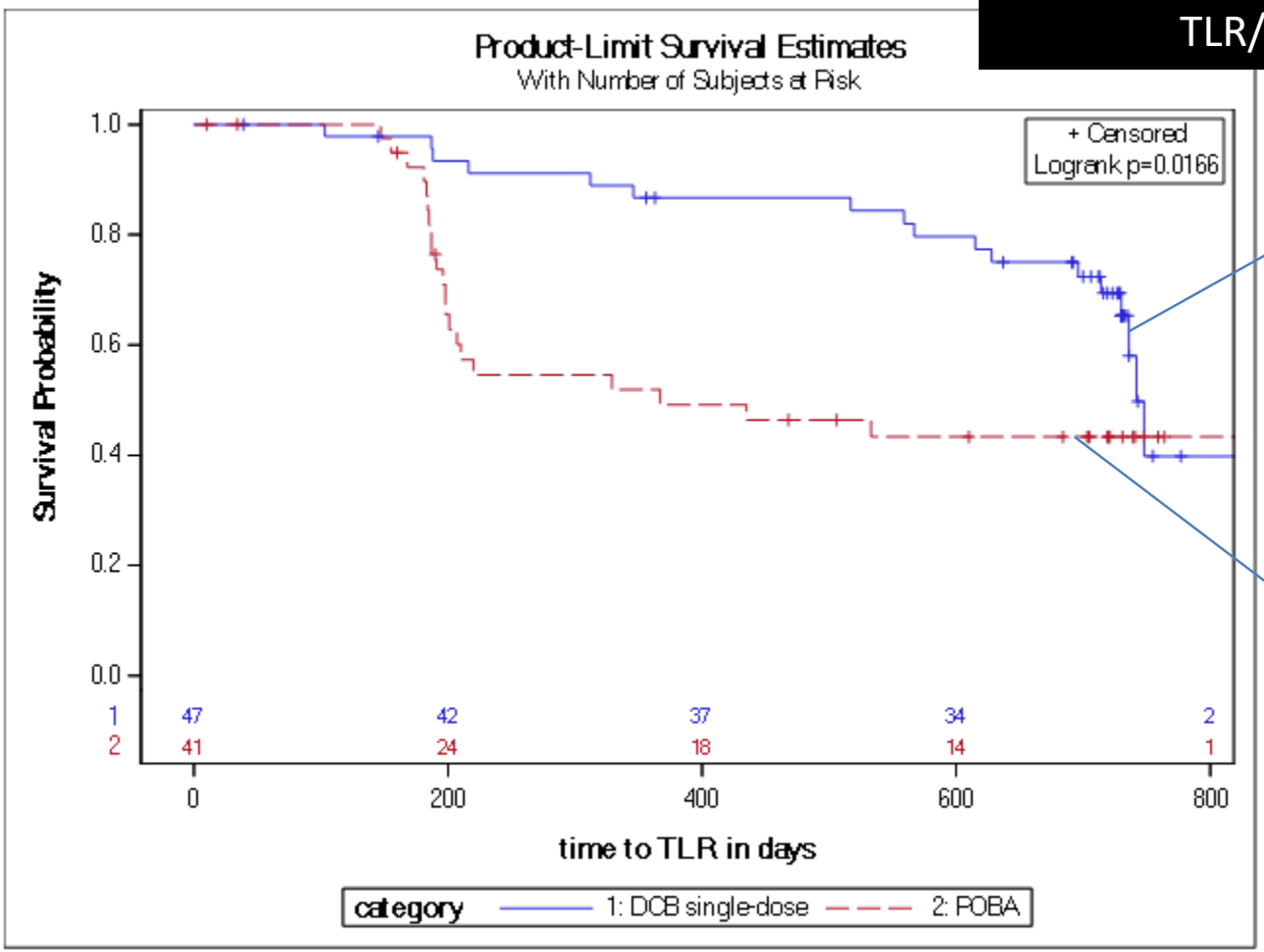
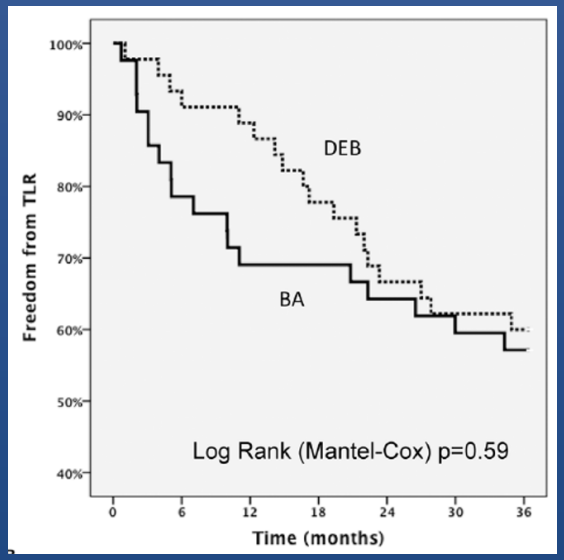
Numbers of patients with TLR/group



N=17

N=21

DCB vs. POBA with longer f/u



46 patients with In.Pact DCB vs. 42 patients with POBA (historic control)

Limitations: mono-center, no core lab, historic control

The same results!

Debate ISR 3 Y

Grotti et al., JEVT, 2016; 23: 52-57

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Results, TLR 2y with Double Dose DCB

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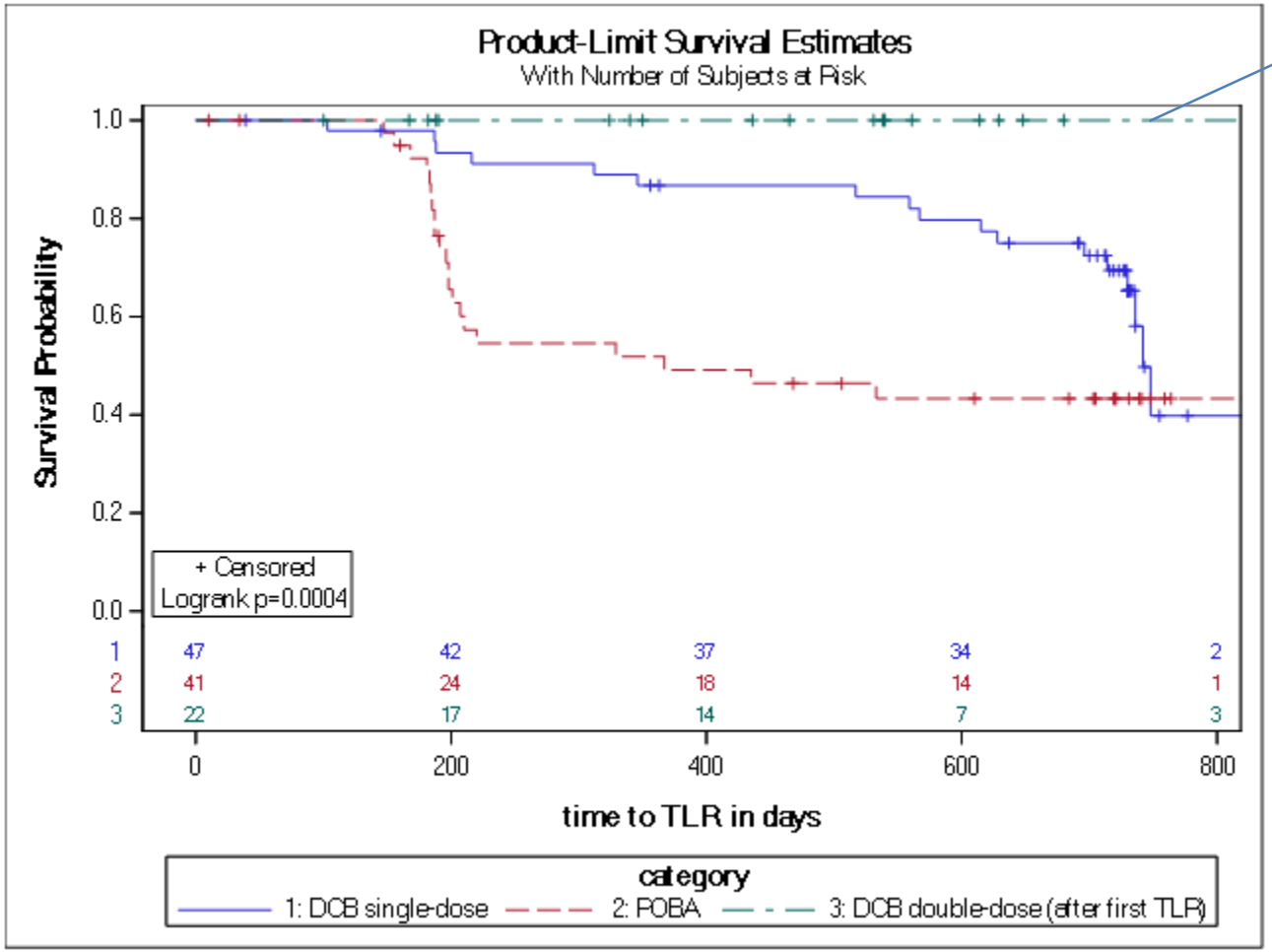

N=0

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Baseline DD vs. Other Groups

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Procedure information

	DCB	*POBA*	*Double Dose*
Total occlusion within stent			
Yes	25.5% (12 / 47)	36.6% (15 / 41)	27.3% (6 / 22)
No	74.5% (35 / 47)	58.5% (24 / 41)	68.2% (15 / 22)
Missing	0	4.9% (2 / 41)	4.5% (1 / 22)
% maximal stenosis			
N	47	41	22
mean ± SD	91.4 ± 9.0	92.0 ± 9.1	89.1 ± 14.4
median [IQR]	90.0 [90.0,100.0]	95.0 [90.0,100.0]	95.0 [85.0,100.0]
Range (Min, Max)	(70, 100)	(70, 100)	(50, 100)
Total lesion length (mm)			
N	47	41	22
mean ± SD	152.0 ± 85.2	128.0 ± 84.5	114.1 ± 67.0
median [IQR]	150.0 [60.0,220.0]	100.0 [60.0,195.0]	125.0 [60.0,150.0]
Range (Min, Max)	(20, 300)	(8, 350)	(10, 270)
Reference vessel diameter (mm)			
N	47	41	22
mean ± SD	5.2 ± 0.6	5.1 ± 0.8	5.4 ± 0.7
median [IQR]	5.0 [5.0,6.0]	5.0 [5.0,6.0]	5.0 [5.0,6.0]
Range (Min, Max)	(4, 7)	(4, 6)	(4, 6)
Stent fracture			
Yes	8.5% (4 / 47)	0	0
No	91.5% (43 / 47)	100.0% (41 / 41)	95.5% (21 / 22)
Missing	0	0	4.5% (1 / 22)

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Conclusions

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- Follow-up less than 2 y in in-stent RS has no value
- First prospective randomized DCB study which shows a catch-up of the DCB group after a certain time
- A delayed TLR after DCB might be driven
  - By the underlying disease (ISR, calcium burden)
  - By the DCB product
    (different drug content over time in the vessel wall)
- First DCB study which shows a dose effect of DCB therapy
  - Higher dose might be needed especially in complex SFA lesions with higher chance of restenosis