

New Long-term Information on PTX Coated DCB 5-year Results from the AcoArt I Study

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Disclosure

Speaker name: Xin Jia

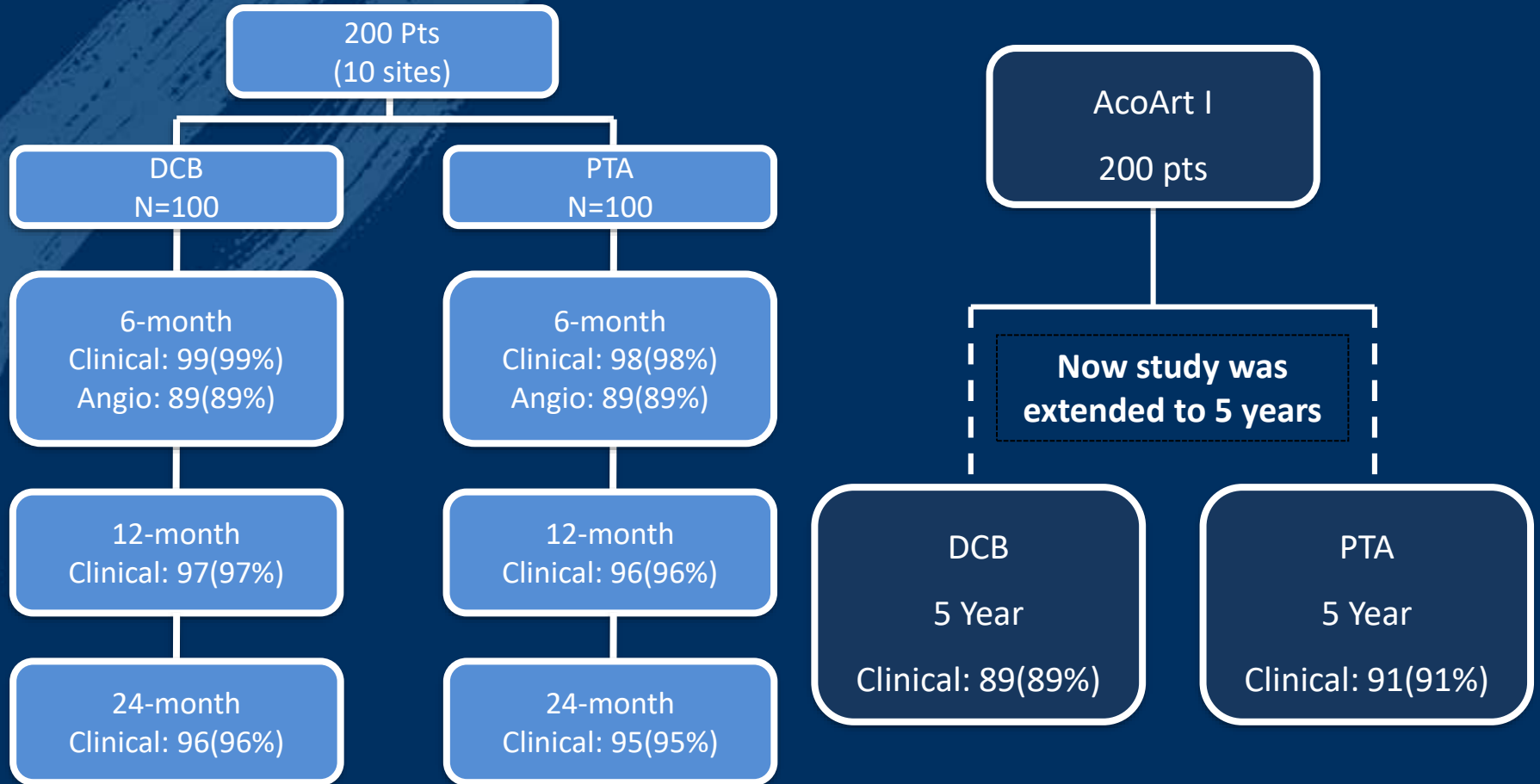
I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

AcoArt I Study Design

AcoArt I was initially designed to be a 2 Year FU study



AcoArt DCB

- produced by Acotec Scientific Co., Ltd, Beijing, China
- Paclitaxel dose:
 - 3.3 μ g/mm²
- Excipient: Mg-stearate
 - Minimize drug loss (<10%) during delivery
 - Less volume enables lower profile (6F compatible in most of sizes)
- Balloon sizes
 - Diameter(mm): 3.0-12.0, with half sizes (4.5, 5.5) design, match vessel precisely
 - Length(mm): 20, 30, 40, 60, 80, 100, 120, 150, 200, 250, 300, treat long lesion easily
- GW Compatible
 - AcoArt Orchid 0.035" GW compatible
 - AcoArt Tulip 0.018" GW compatible
 - AcoArt Litos 0.014" GW compatible

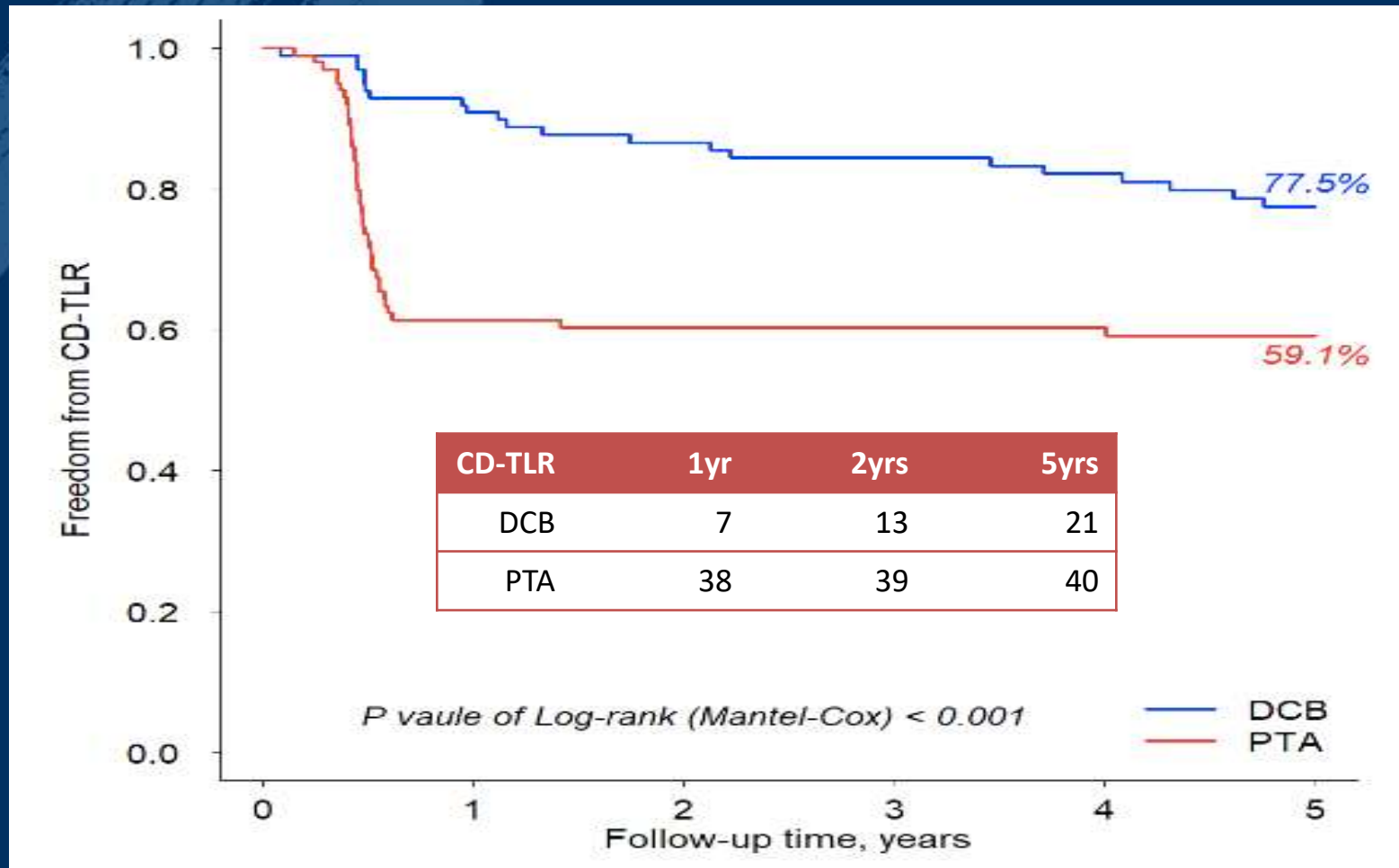


Major Baseline Characteristics

	DCB	PTA	P
Diabetes (%)	54/100 (54%)	57/100 (57%)	0.67
Rutherford			
2	14%	12%	
3	46%	44%	0.94
4	24%	27%	
5	16%	17%	
Lesion Length(mm)	147.26±109.52	151.59±108.94	0.78
Total Occlusions	57% (57/100)	52% (52/100)	0.48
ISR	27% (27/100)	23% (23/100)	0.51

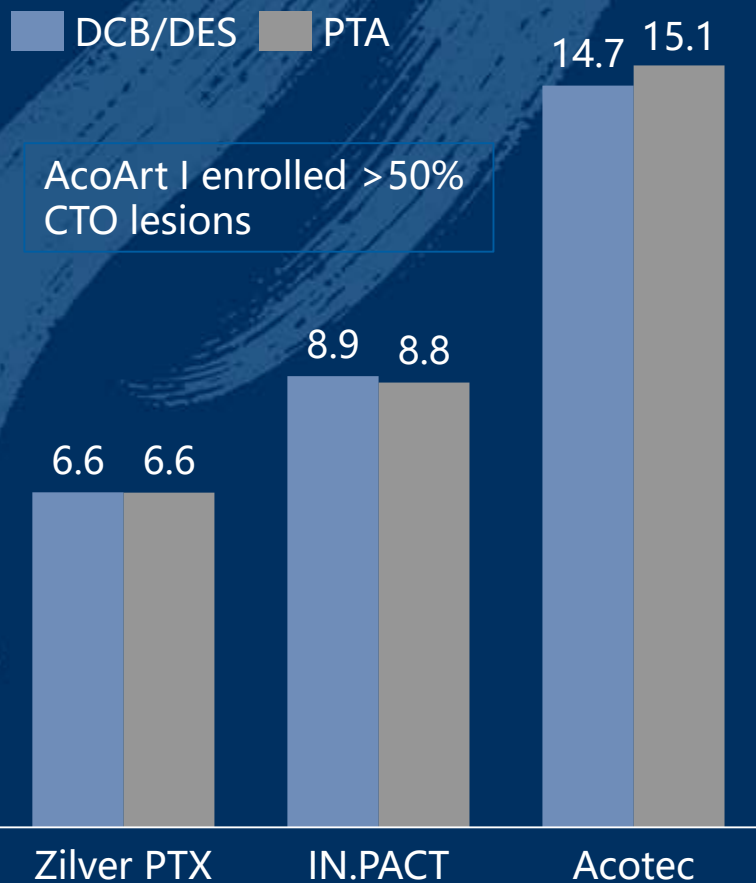
Freedom from CD-TLR through 5 years

Less CD-TLR in DCB group through 5 years, compare to PTA group ($p < 0.001$).

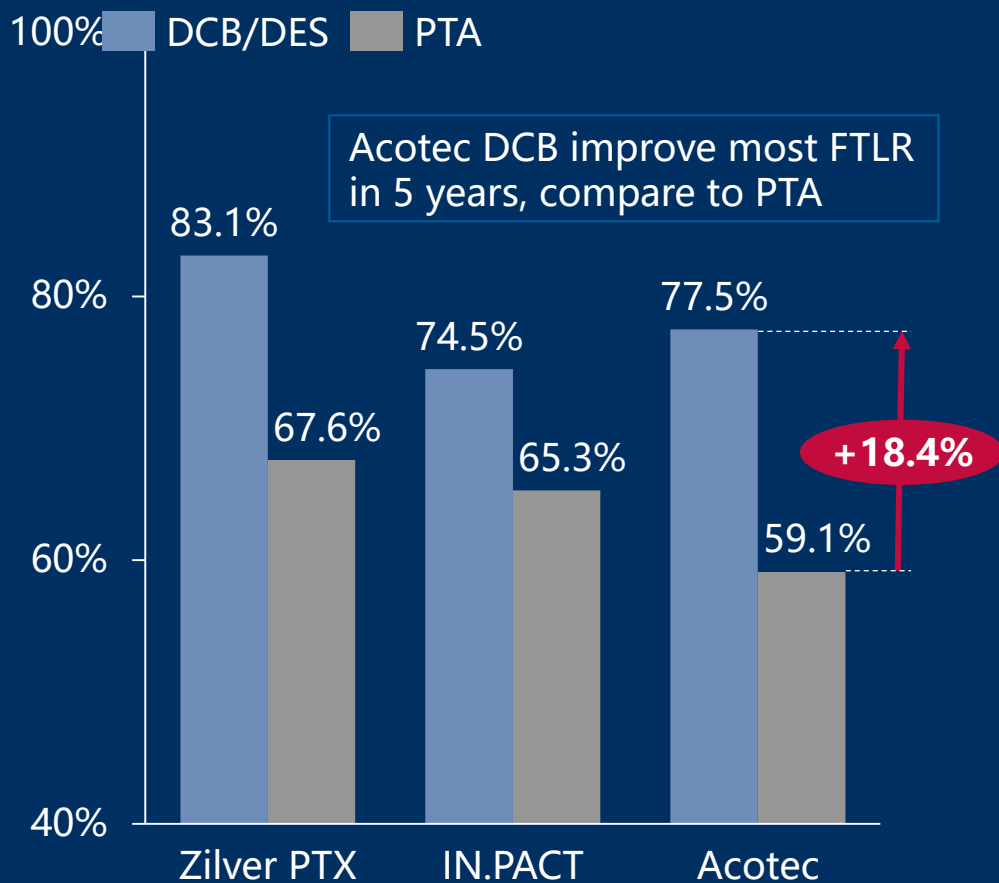


Comparable results with previous Studies

Mean Lesion Length(cm)

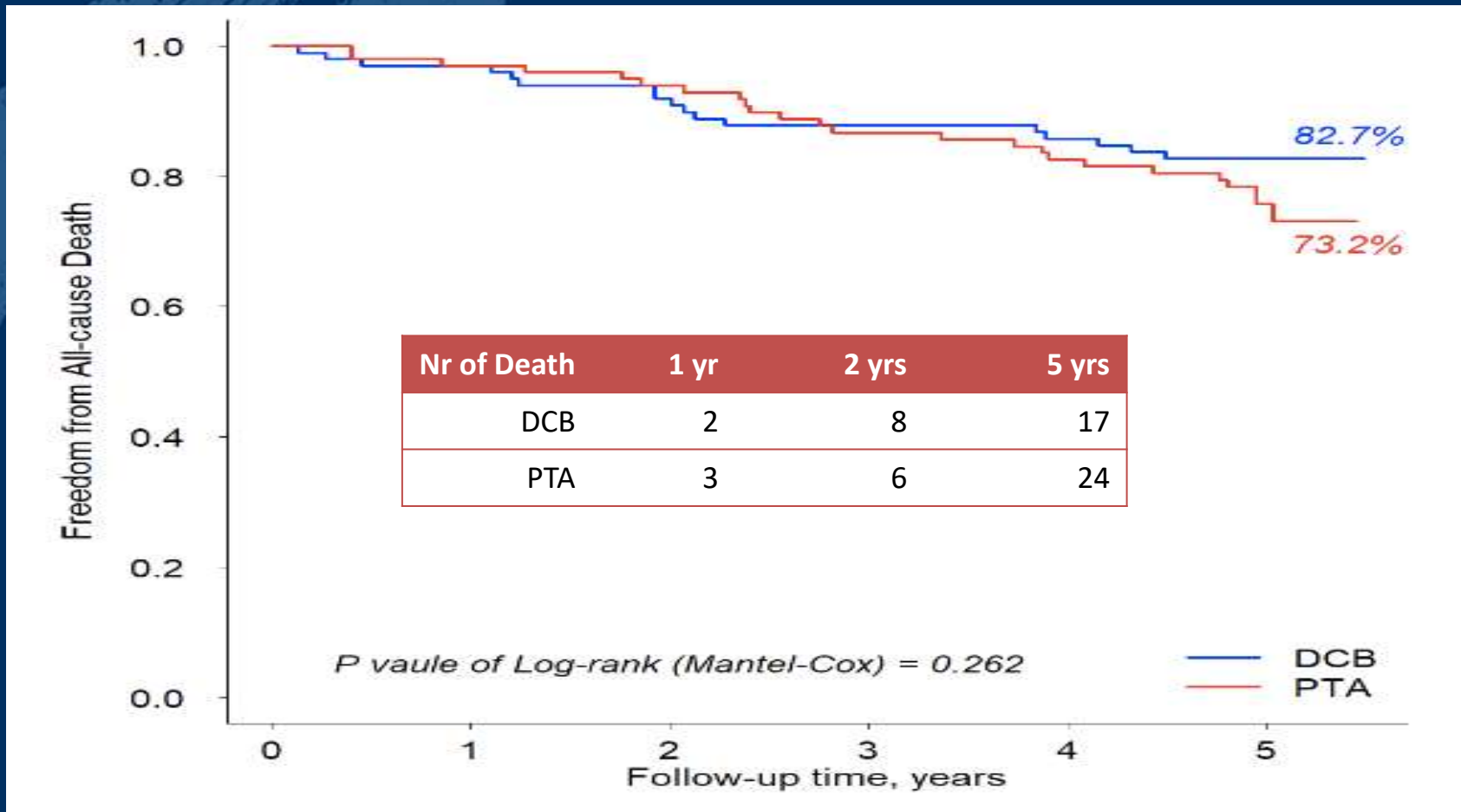


5 years Freedom from CD-TLR



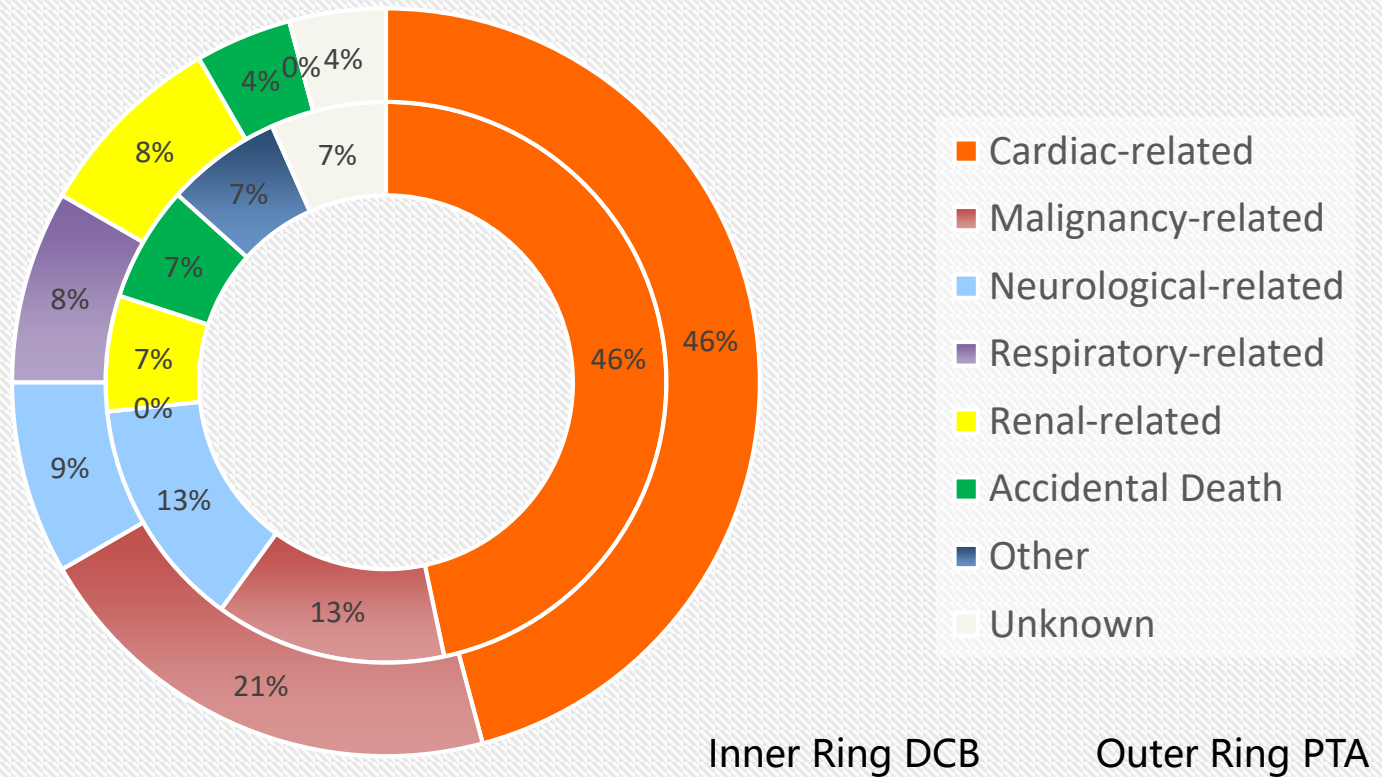
Freedom from All-cause Death through 5 years

No significant statistical difference on mortality between DCB and PTA within 5-year follow up



Cause of Death in Patient Level

No significant statistical difference in Cause of Death between DCB and PTA within 5-year follow up.



Death vs Survival Analysis

Overall Cohort - Death vs Survival

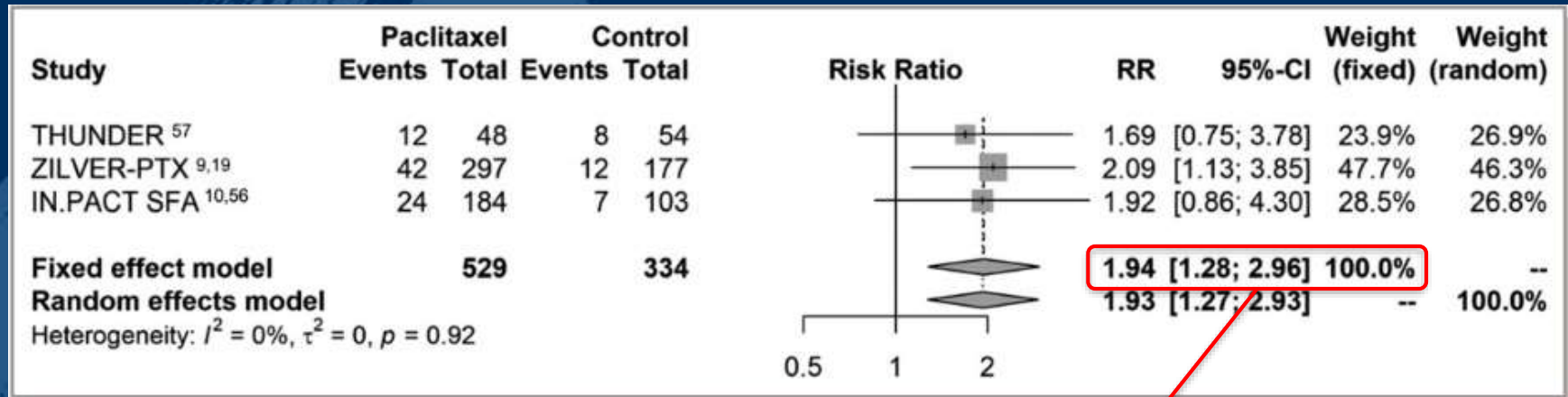
Patient / Lesion Characteristics	Death(N=41)	Survival(N=138)	p-value
Age	68.90 ± 7.65	65.03 ± 8.65	0.011
CHD	16 (39.02%)	32 (23.02%)	0.042
Bail-out stent	14 (34.15%)	23 (16.55%)	0.014
Lesion length (mm)	178.11 ± 108.13	139.29 ± 109.47	0.047

DCB Cohort - Death vs Survival

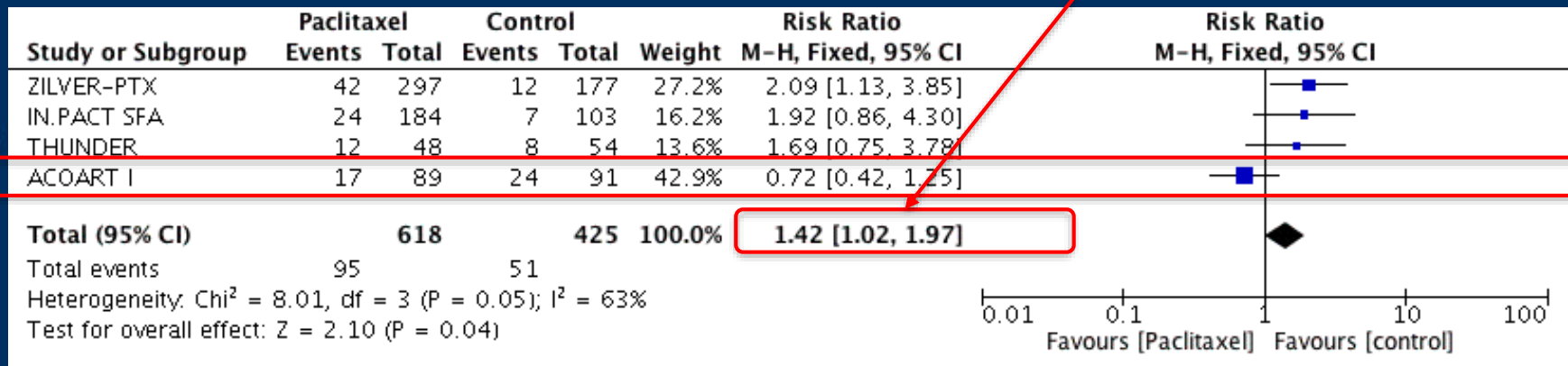
Patient / Lesion Characteristics	Death(N=17)	Survival(N=172)	p-value
CHD	8 (47.06%)	13 (18.06%)	0.011
Bail-out stent	8 (47.06%)	10 (13.89%)	0.002
Paclitaxel Dose(mg)	13.77 ± 6.96	12.52 ± 9.12	0.597

Meta-analysis of mortality at 5years

Meta-analysis of mortality at 4-5years By Prof. Katsanos*.



Results when AcoArt I study is included.



*Deaths After Paclitaxel Interventions in the Leg Katsanos et al, DOI: 10.1161/JAHA.118.011245 Journal of the American Heart Association

Conclusions

- The efficacy of AcoArt Orchid drug coated balloon maintained over 5 years, even in complex lesions.
- No paclitaxel-related safety event observed during AcoArt I 5ys follow up.
- No different in cause of death between DCB and PTA arms.
- It is noticeable that no different in paclitaxel dose between death and survival group.

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