

Combination Therapy Tackling ISR: Laser and DCB Two-Year Results

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Disclosure

Speaker name: Ehrin J. Armstrong MD

I have the following potential conflicts of interest to report:

- Consulting: Abbott Vascular, Boston Scientific, Cardiovascular Systems, Gore, Medtronic, Philips
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

DCBs in Complex ISR

DCB better than PTA @ 1 year, however:

- Tosaka III indep. predictor of re-restenosis and re-occlusion
- Complete catch-up @ 3 years

2y ISR recurrence based on baseline Tosaka class

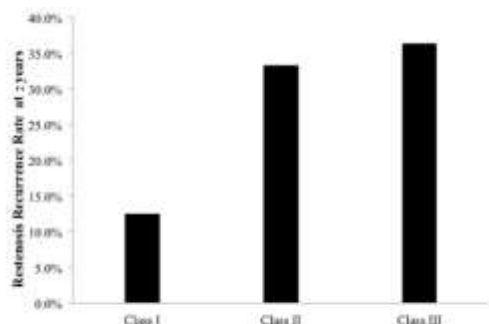


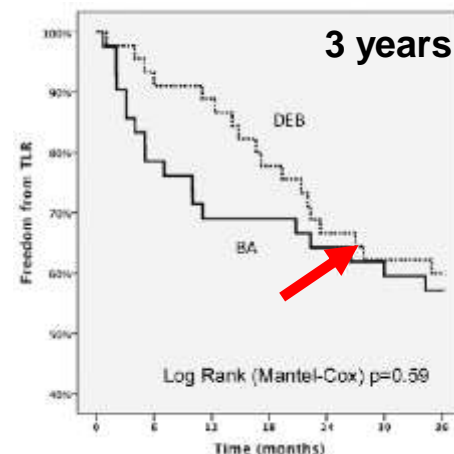
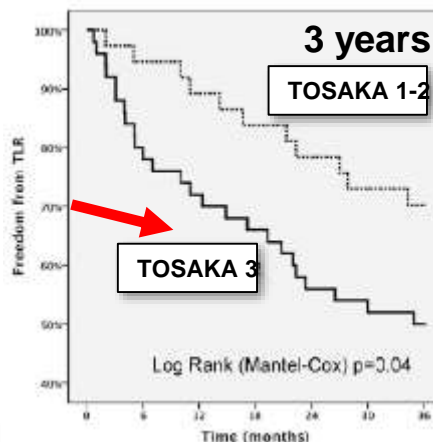
Figure 3. Restenosis Recurrence According to Baseline ISR Class

Bar graph representing percentage of restenosis (ISR) recurrence at 2 years in patients treated with drug-eluting balloons for STA ISR according to ISR class at baseline ($p < .001$).

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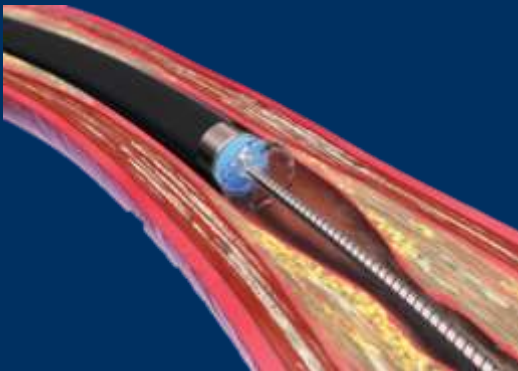
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Benefits of Laser Atherectomy in ISR



- Only FDA indicated atherectomy technology for ISR
- Treat multiple lesion morphologies
- Debulk lesion from the tip with no moving parts
- Gain 27% larger lumen with Turbo-Power vs. Turbo-Elite
- Directional debulking with Turbo-Power

Laser+DCB in ISR: pre-Clinical Insights

Rabbit model of (carotid) CTO ISR by Fogarty Injury and BMS implant
Reduced % stenosis and intimal thickness with Laser+DCB vs. DCB alone at 28 days



	Sections	Lumen Area (mm ²)	Neointimal Area (mm ²)	Stenosis (%)	Neointimal Thickness (mm)
PTA + DCB	6	2.91 ± 0.58	2.82 ± 0.3	49.59 ± 6.74	0.35 ± 0.05
Laser + DCB	12	3.6 ± 0.94	2.36 ± 0.54	40.27 ± 11.50	0.21 ± 0.12
P-value	-	0.060	0.036*	0.044*	0.012*

*Significant based on 1-tailed t-test (p < 0.05)

Laser + DCB in ISR

Single center, randomized trial in complex ISR

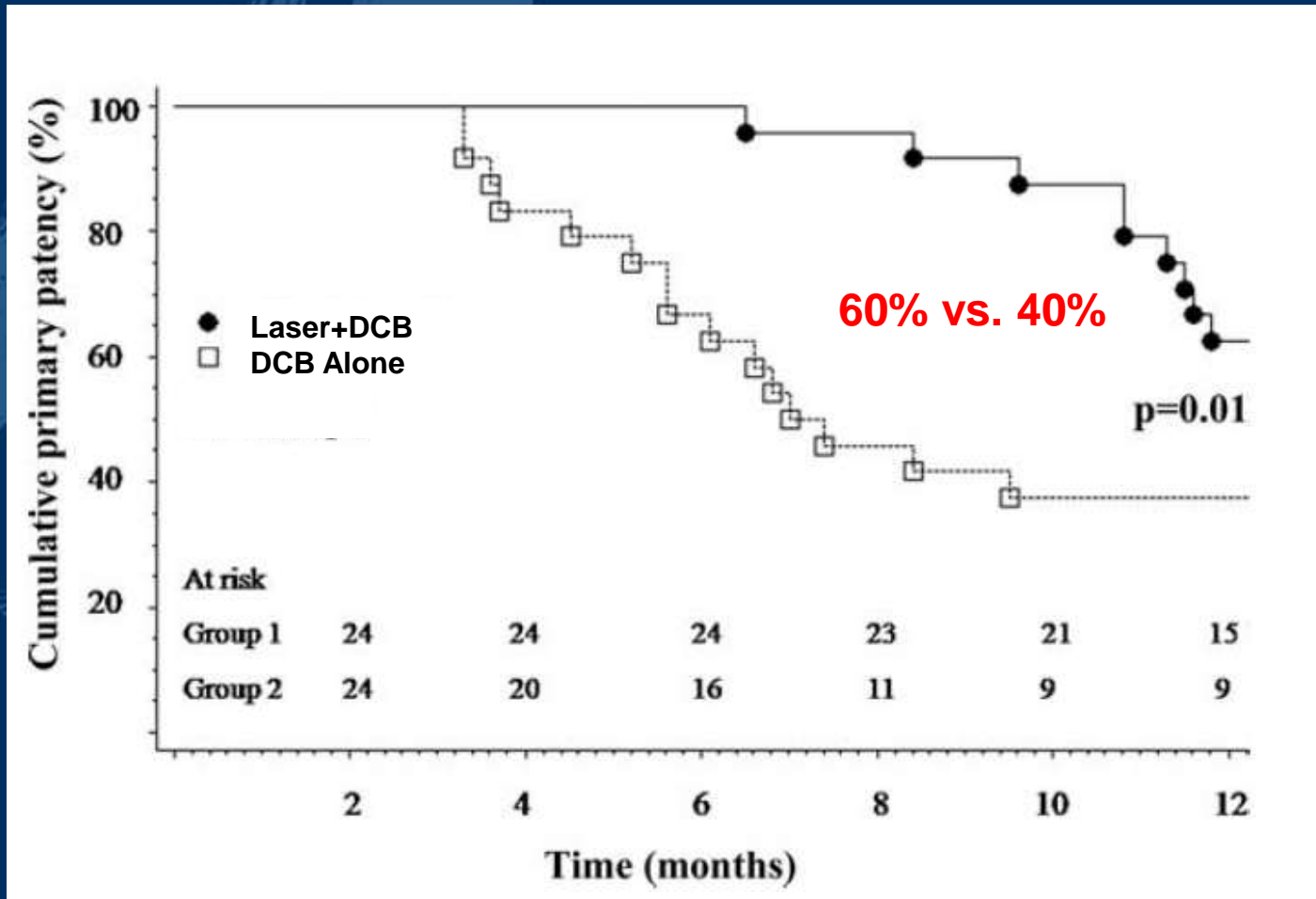
- Compare safety and efficacy of laser debulking and DCB vs. DCB alone in CLI patients with complex SFA ISR
- N=48 (24 patients w/ Laser+DCB; 24 patients w/ DCB alone)
- Outcomes assessed at 12 months post-procedure

Key Study Results	Laser + DCB (n=24)	DCB Alone (n=24)	P-value
Mean ISR Length (cm)	20	23	n/a
Primary Patency (12 mon)	66.7%	37.5%	0.01
TLR (12 mon)	16.7%	50%	0.01
Major Amputation	2 (8%)	11 (46%)	0.003
Limb Salvage (12 mon)	91.7%	54.2%	0.003
Wound Healing (12 mon)	87.5%	62.5%	0.03

Gandini R, Del Giudice C, Merolla S, Morosetti D, Pampana E, Simonetti G. Treatment of chronic SFA in-stent occlusion with combined laser atherectomy and drug-eluting balloon angioplasty in patients with critical limb ischemia: a single-center, prospective, randomized study. J Endovasc Ther. 2013 Dec;20(6):805-14

*Stellarex DCB is not currently approved for use in SFA ISR

Laser + DCB in ISR



‘In this small initial experience, laser and DCB angioplasty is correlated with better outcomes in CLI patients with occluded SFA stent’

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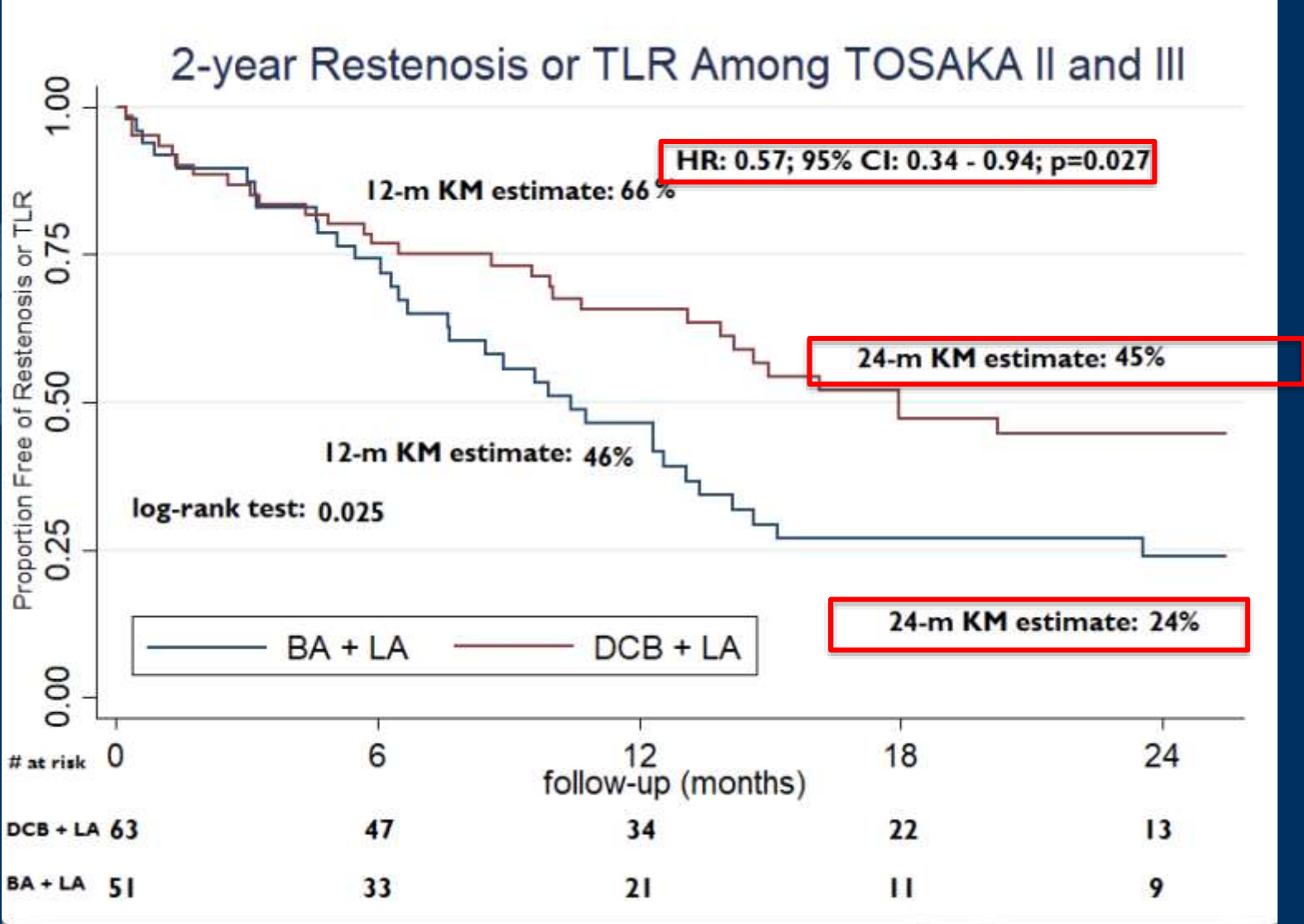
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Laser Atherectomy Combined with Drug-Coated Balloon Angioplasty for Treatment of Femoropopliteal Restenosis

- “Real world” analysis of treatment of FP-ISR with laser + DCB (n=62) vs laser + PTA (n=50).
- Retrospective analysis, two centers
- N=112
- 33% CLI
- 74% Tosaka III
- Average Lesion Length 247 ± 115 mm

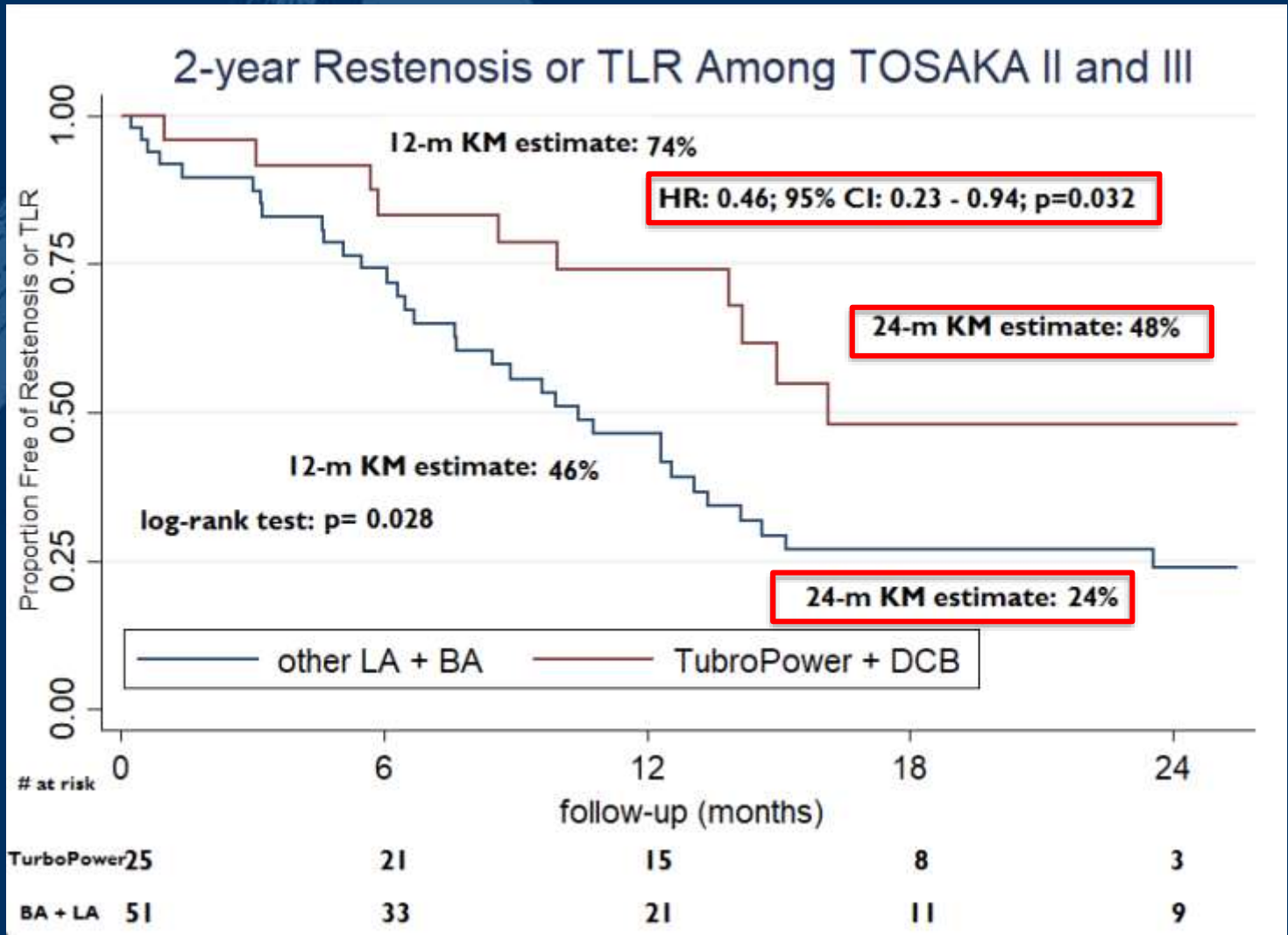
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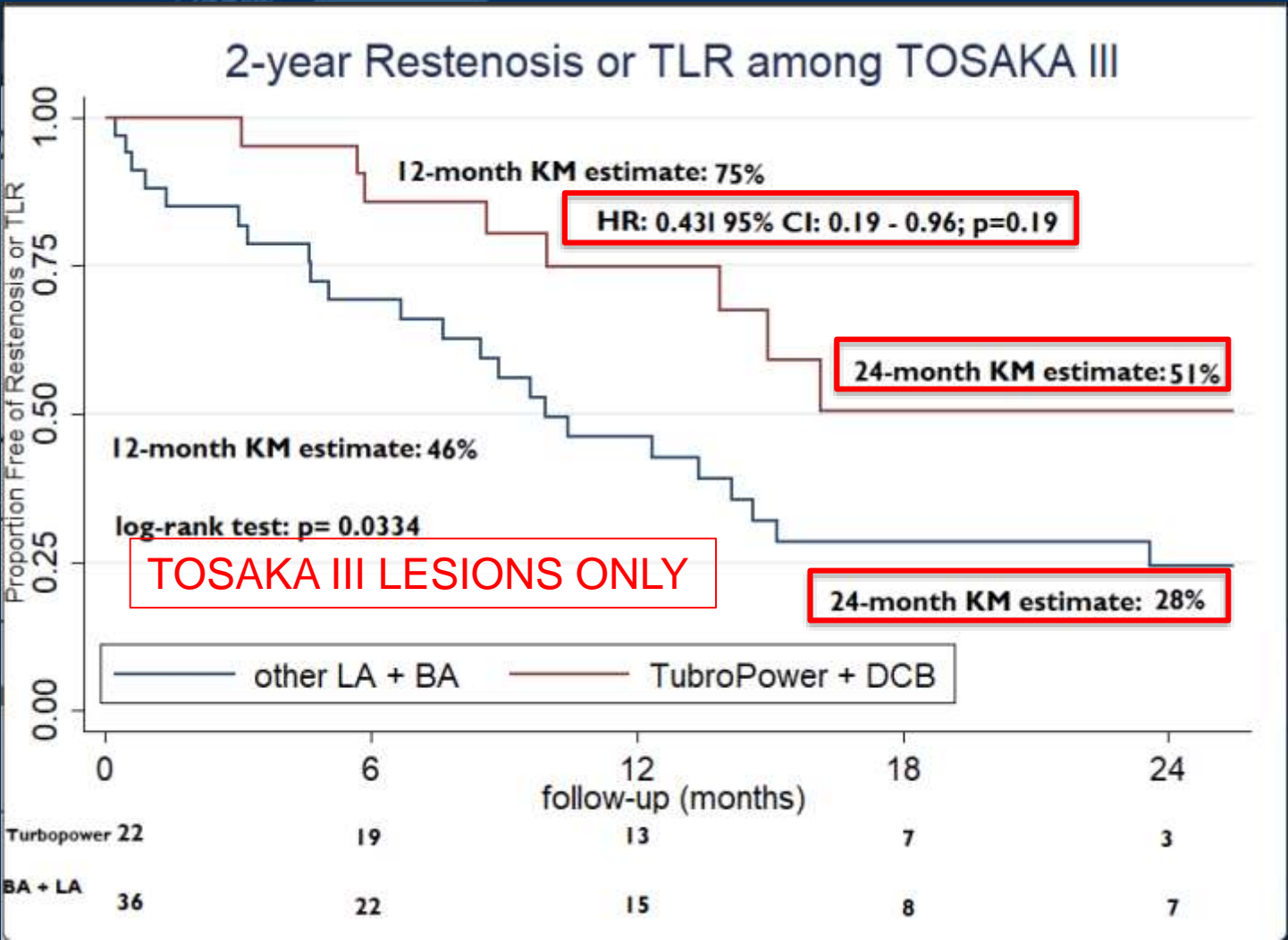
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Conclusions

- ISR remains a difficult to treat clinical problem.
- DCB have benefit compared to angioplasty, but there is late catch-up.
- Laser atherectomy has efficacy for ISR compared to balloon angioplasty alone.
- The combination of laser atherectomy and DCB may be the best currently available treatment for FP-ISR.

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