# 2 year results from the COMPARE trial
# -
# Low-dose vs. high-dose DCB in femoropopliteal arteries

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# Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☒ Others: Bayer, C.R. Bard

☐ I do not have any potential conflict of interest

# COMPARE RCT: Study objectives

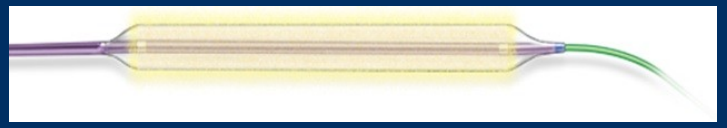
| | |
|---|---|
| **Study aim** | To compare high dose vs. low dose paclitaxel coated balloons for the treatment of high grade stenotic or occluded femoropopliteal lesions |
| **Patient population** | Patients with Rutherford class 2-4 |
| **Principal investigator** | Dierk Scheinert, MD; University of Leipzig |
| **Study sites** | 15 sites in Germany |

## Investigational Device

**Low dose DCB: Ranger™**
Paclitaxel Dose: 2.0µg/mm²
TransPax coating; Excipient: Citrate ester

## Control Device

**High dose DCB: IN.PACT Admiral™/ IN.PACT Pacific™**
Paclitaxel Dose: 3.5µg/mm²
FreePac™ hydrophilic coating; Excipient: Urea



# COMPARE RCT: Study Design and Methods

| | |
|---|---|
| **Study Design** | ➢ Investigator-initiated, prospective, multicenter, non-inferiority trial<br>➢ 414 patients undergoing 1:1 randomization<br>➢ Stratification according to lesion length<br>➢ Independent monitoring with 100% source data verification<br>➢ Independent corelab for angio and duplex<br>➢ Clinical events committee |
| **Funding** | ➢ Study sponsor: University of Leipzig<br>➢ Funding through a research grant from Boston Scientific<br>➢ Funding source not involved in collecting, monitoring and analyzing study data |
| **Follow-up** | ➢ In-house visits: 6, 12, **24 months (efficacy and safety)**<br>➢ Telephone calls: 1 month, 36, 48, 60 months (safety) |

# Key baseline characteristics

| | | Low dose DCB (n=207) | High dose DCB (n=207) | P value |
|---|---|---|---|---|
| Demographics | Age (years) | 68.2 ± 10.0 | 68.4 ± 9.3 | 0.79 |
| | Female gender | 79 (38.2) | 75 (36.2) | 0.68 |
| | Rutherford class (RC) ≥ 3 | 184 (88.9) | 176 (85) | 0.56 |
| | Diabetes mellitus | 63 (30.6) | 76 (36.9) | 0.18 |
| | Previous/current smoking | 160 (77.3) | 155 (74.9) | 0.63 |
| Lesion | Lesion length (mm) | 123.9±97.8 | 128.3±97.3 | 0.65 |
| | Total occlusions | 84 (40.6) | 89 (43) | 0.62 |
| | Calcification PACSS 3-4 | 105 (50.5) | 117 (57.1) | 0.80 |
| | 0-1 run off vessels | 75 (38.5) | 71 (36.6) | 0.89 |
| Procedural | Total paclitaxel dose (µg) | 6971±4026 | 13035±7483 | <0.0001 |
| | Bail-out stenting | 62 (30.0) | 53 (25.6) | 0.32 |
| | Type E-F Dissection | 4 (2.0) | 2 (1) | 0.61 |
| | Diameter stenosis pp (%) | 26.4±12.5 | 26.1±12.5 | 0.8 |
| | Residual stenosis ≥ 30% | 74 (35.8) | 81 (39.1) | 0.48 |

Data are given as mean±std or number (%).

# Primary endpoint analysis at 12 months

## Efficacy: Primary patency

| DCB | | Δ | |
|---|---|---|---|
| Low dose | High dose | (two-sided 90% lower bound) | $P_{non\text{-}inferiority}$ |
| 83% (156/188) | 81.5% (141/173) | 1.5% (-5.2%) | <0.01 |

**Non-inferiority met**

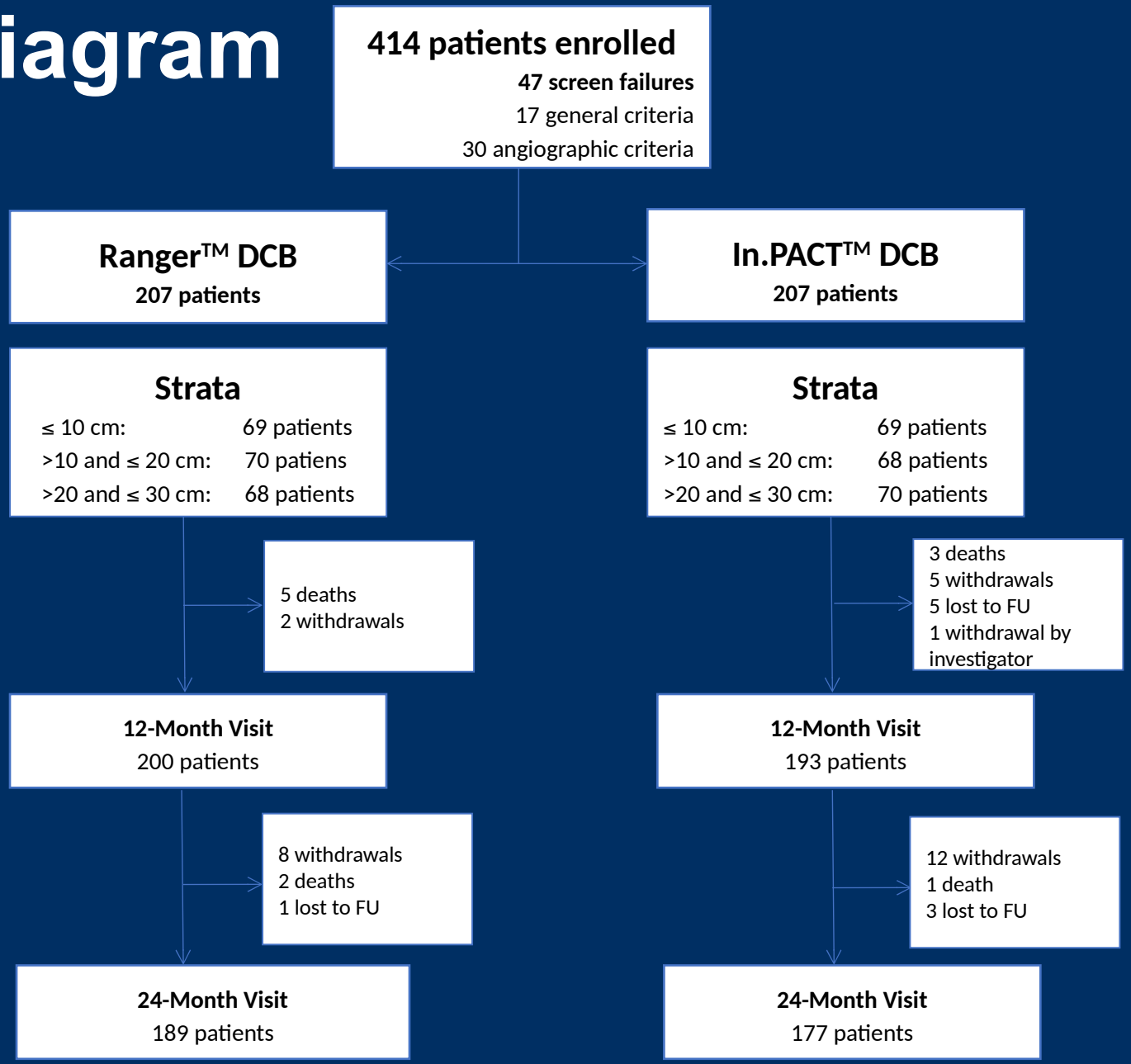
## Safety: Freedom from MAE

| DCB | | Δ | |
|---|---|---|---|
| Low dose | High dose | (two-sided 90% lower bound) | $P_{non\text{-}inferiority}$ |
| 91% (182/200) | 92.6% (175/189) | -1.6% (-6.5%) | <0.01 |

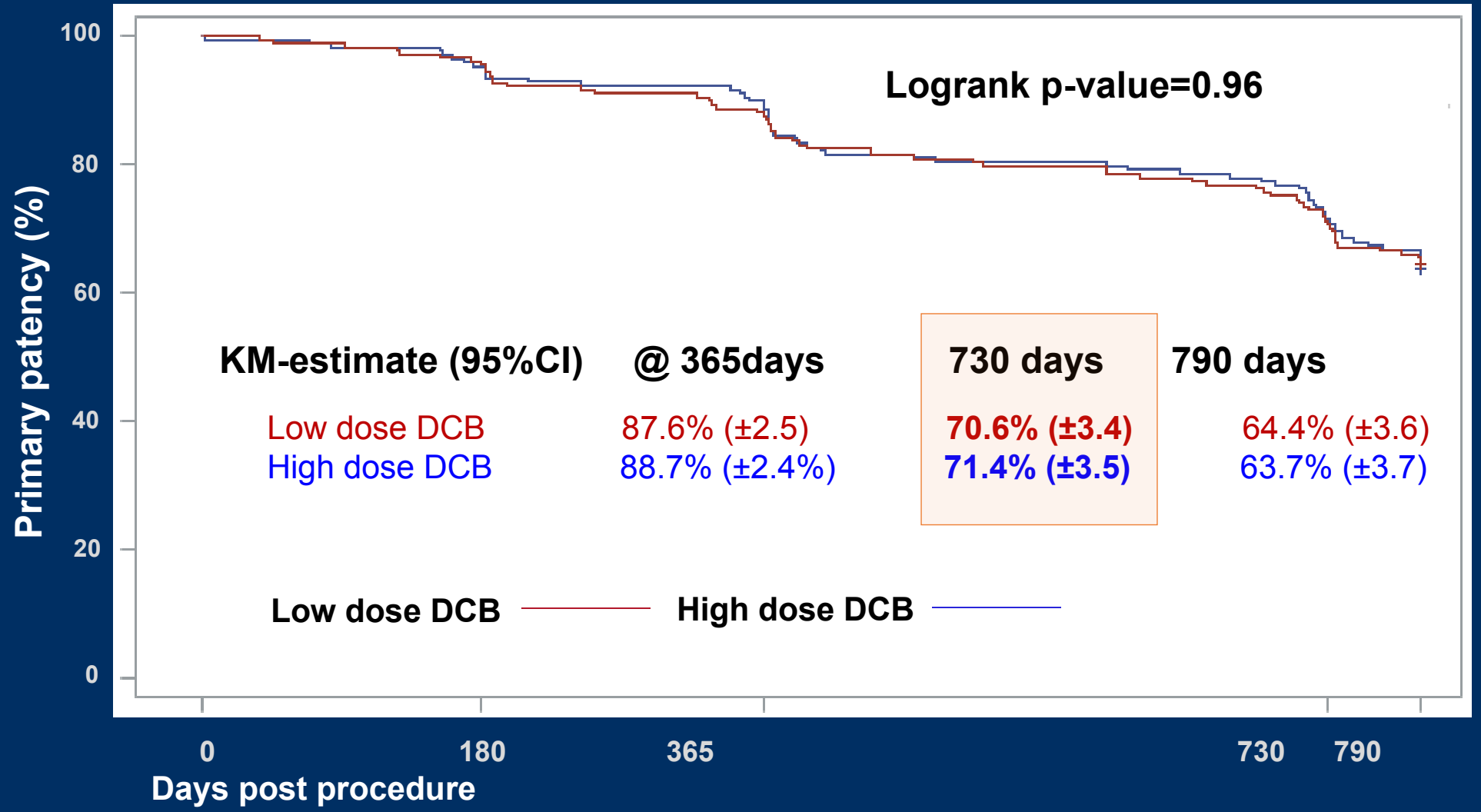
**Non-inferiority met**

Steiner S et al. Eur Heart J 2020;41(27):2541-2552

# Patient flow diagram through 2 years



# Primary patency through 790 days




Patients without an event at 790 days of follow-up or later were censored at 790 days.

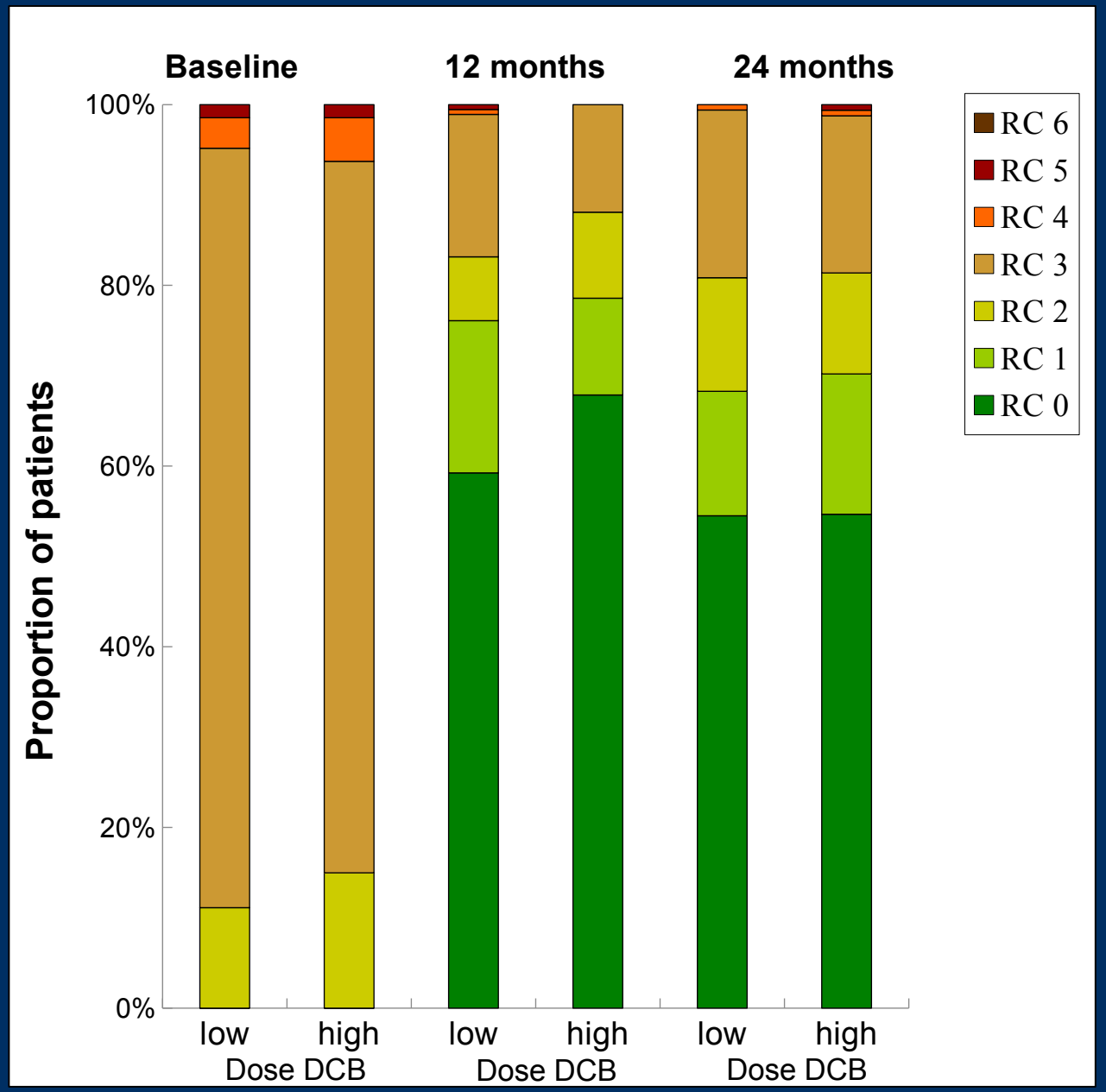
# Key outcomes through 790 days

| | Low dose DCB (n=207) | High dose DCB (n=207) | P value§ |
|---|---|---|---|
| All-cause mortality | 3.6% (7/196) | 2.2% (4/181) | 0.6 |
| Device or procedure-related death | 0 | 0 | 1.0 |
| Major amputation | 0% (0/189) | 0.6% (1/177) | 1.0 |
| Clinically driven TLR | 17.3% (33/191) | 13.0 % (23/177) | 0.3 |
| All TLR* | 17.8% (34/191) | 13.0 % (23/177) | 0.3 |
| Primary sustained clinical improvement† | 69.5% (121/174) | 74.3% (124/167) | 0.4 |
| Haemodynamic improvement‡ | 69.2% (117/169) | 67.3% (107/169) | 0.5 |

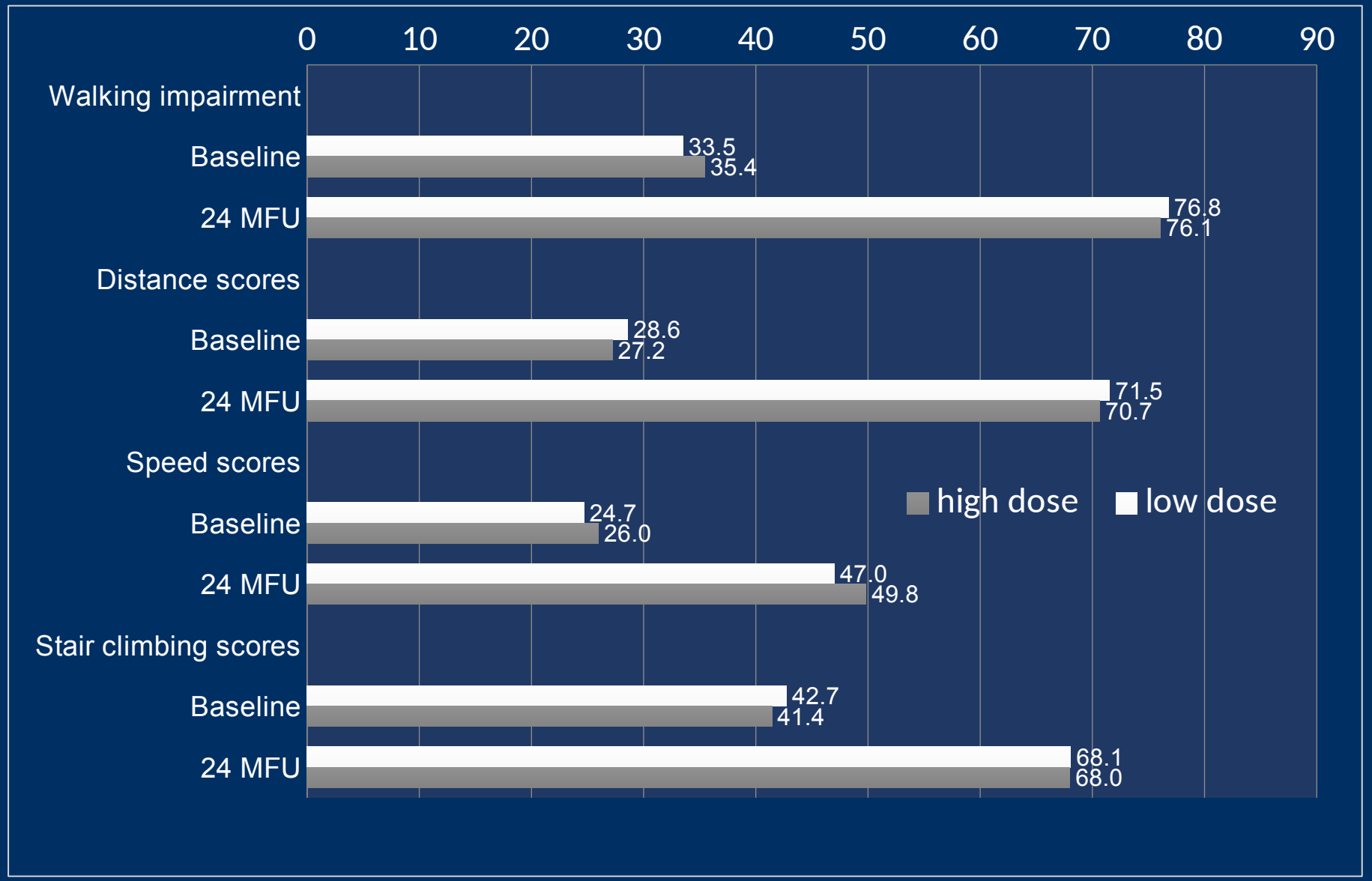
Values are percentage (n/N). The numerator is the number of subjects with events prior to the close of the visit window.
The denominator includes subjects with events or those without events having follow-up on or past the opening of the visit window.
*Includes clinically-driven TLR and duplex-driven/incidental TLR.
† Defined as improvement in Rutherford classification by one or more categories compared with baseline, without TRL.
‡ Defined as an increase in the ankle-brachial index by ≥0·10 compared with baseline or to an ankle-brachial index ≥0·90, without TLR.
§ P-values based on Fisher's-exact test.

# Distribution of Rutherford categories

≈70% of patients with no or minimal symptoms @ 2y



# Walking impairment questionnaire



# Summary

- First head-to-head comparison of two DCBs with different paclitaxel dosages and coating technologies for femoropopliteal interventions
- Complex real world lesion subset with high proportion of CTO`s >40%
- Low dose DCB (Ranger 2.0µg/mm$^2$ ) and high dose DCB (IN.PACT 3.5µg/mm$^2$) showing both excellent primary patency and low TLR rates through 2years
- Low mortality after 2 years; Follow-up ongoing up to 5 years