

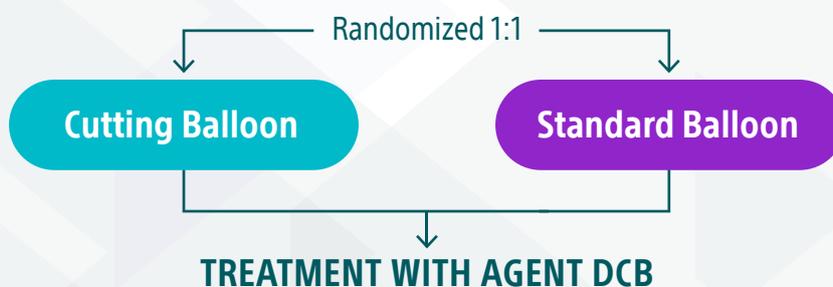


# Nature RCT<sup>1</sup>

Cutting Balloon vs POBA before DCB treatment of de novo lesions

## Nature RCT Study Design

Prospective, Randomized Pilot Study with n = 200 patients in Japan with de novo lesions of 2.5 – 4.0 mm diameter and ≤ 28 mm length

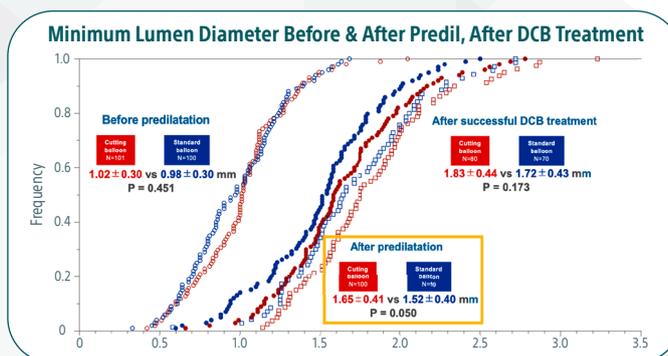


**Primary Endpoint:** Optimal preparation based on the international DCB consensus group definition

### Primary Endpoint

Achievement	CB	SB	p value
No flow-limiting dissection	99 (98.0 %)	97 (97.0 %)	0.68
% DS ≤ 30 %	49 (48.5 %)	43 (43.0 %)	0.48
FFR > 0.80	75 (74.3 %)	74 (74.0 %)	1.00
All 3 Criteria met	36 (35.6 %)	31 (31.0 %)	0.55

Cutting Balloon led to significantly better pre-DCB preparation based on MLD (but not based on the international consensus definition).



**This study demonstrates that WOLVERINE through its MOA, creating controlled micro-incisions, enables SAFE and PREDICTABLE plaque modification prior to DCB use.<sup>1</sup>**

<sup>1</sup> Presented by Ken Kozuma @ TCT 2025

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