AGENT IDE Trial

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AGENT IDE is a prospective, multicenter, randomized controlled trial in the United States to evaluate the safety and effectiveness of the AGENT™ Drug-Coated Balloon (DCB) compared to balloon angioplasty in patients with in-stent restenosis (ISR).[1]

AGENT IDE Study Design

Prospective, randomized, multicenter, superiority trial across 40 US Site (N=480 patients*)

- Key Inclusion Criteria: Patients with ISR of a lesion previously treated with BMS or DES; lesion length <26 mm, RVD >2.0 - ≤4.0 mm, and %DS >70 - <100% (asymptomatic) or %DS >50 - <100% (symptomatic)
- Key Exclusion Criteria: Recent STEMI, bifurcation, LM, SVG or arterial graft, thrombus in target vessel

2:1 randomized after successful pre-dilation of target lesion

AGENT DCB
n=321

Balloon Angioplasty
n=159

Primary Endpoint: Target Lesion Failure at 1-year (composite of TLR, TV-MI, or cardiac death)
Clinical follow-up: In-hospital, 30 days, 6 months, 1-year and annually between 2 and 5 years)

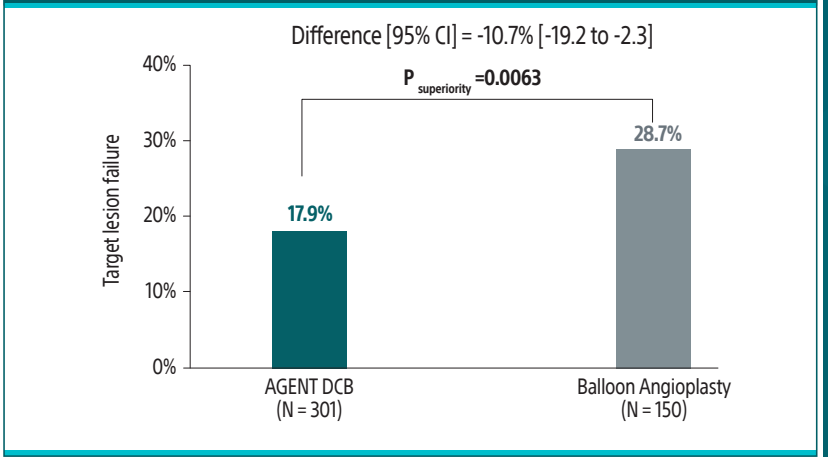
Primary Endpoint[2]

AGENT DCB showed statistically superior outcomes compared to balloon angioplasty for TLF at 1-year. (17.9% versus 28.7%, P=0.0063).

The TLF relative risk reduction from using AGENT DCB was approximately 38%.

38% relative risk reduction for **TLF**

Primary Endpoint: TLF at 1-Year



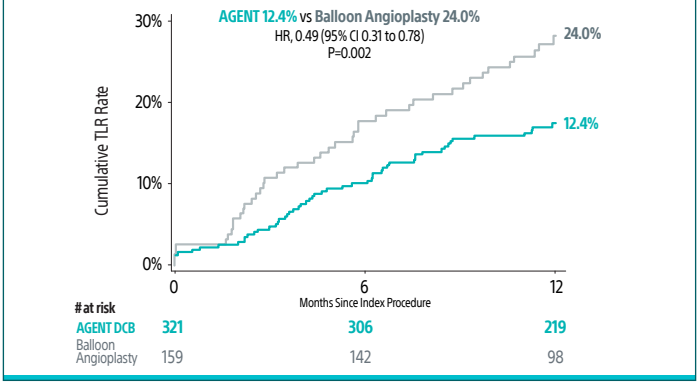
*Based on an adaptive trial design. The primary endpoint analysis was conducted on the first 480 patients enrolled. Data on the full 600 patient cohort will also be analyzed when available. Yeh et al. Am Heart J. 2021;241:101-107

Additional Endpoints[2]

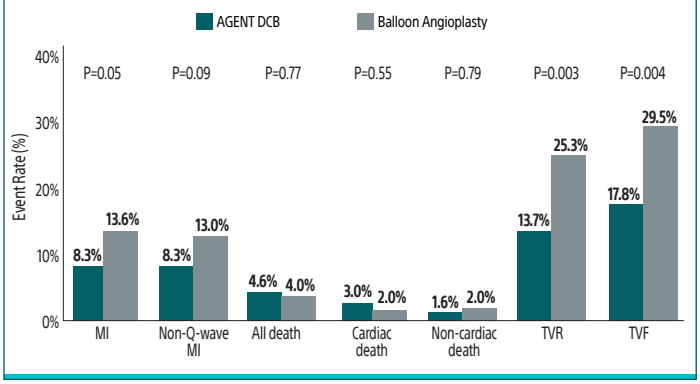
At 1-year, AGENT DCB also demonstrated statistically lower event rates:

- 51% risk reduction in TLR (12.4% vs. 24.0%, P=0.002)
- 49% risk reduction in TV-MI (6.4% vs 12.3%, P=0.03)
- Zero definite/probable ST (0.0% vs. 3.9%, P=0.001)

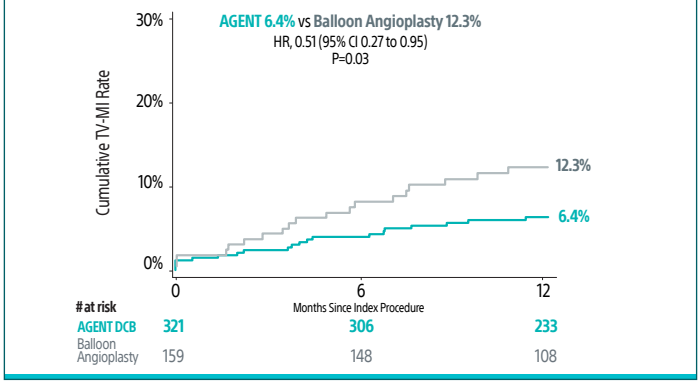
Target Lesion Revascularization (TLR) at 1-Year



Additional Endpoints at 1-Year



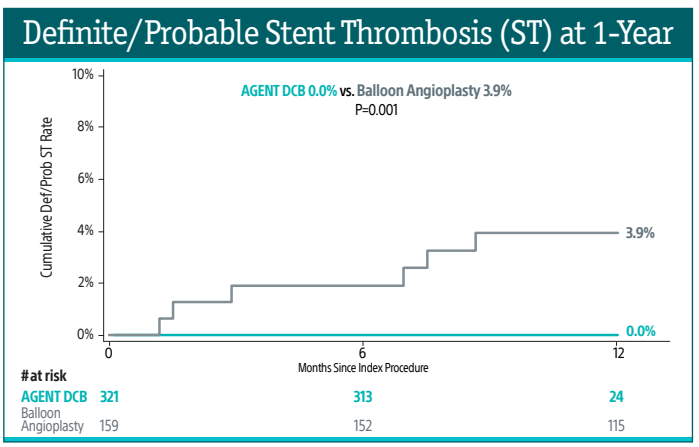
Target Vessel Related MI (TV-MI) at 1-Year



Antiplatelet Therapy

DAPT with aspirin and a P2Y12 inhibitor was required for at least 1-month post-procedure. Antiplatelet monotherapy was continued thereafter for the entire duration of the study.

Definite/Probable Stent Thrombosis (ST) at 1-Year



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1. Yeh, R, et all, Rationale and design of a randomized study comparing the agent drug coated balloon to the plain old balloon angioplasty in patients with In-Stent Restenosis, American Heart Journal 2021.
2. AGENT IDE Clinical Trial data presented at TCT 2023 by Dr. Robert Yeh.

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