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 Sites (N=600 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=406

Balloon Angioplasty
n=194

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)

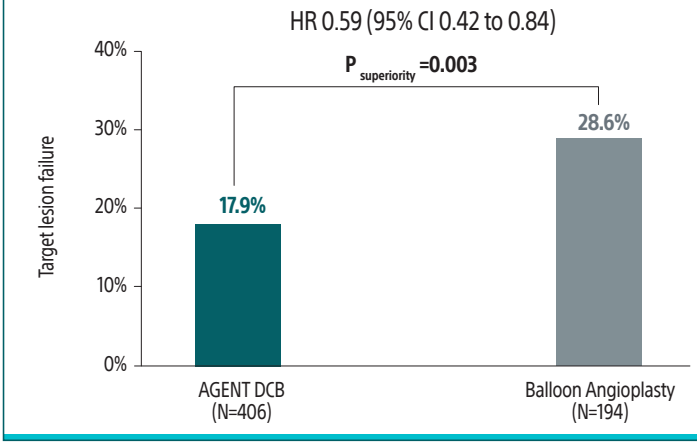
Primary Endpoint[2]

AGENT DCB showed statistically superior outcomes compared to balloon angioplasty for TLF at 1-year. (17.9% versus 28.6% P= 0.003).

The TLF relative risk reduction from using AGENT DCB was approximately 41%.

41% relative risk reduction for **TLF**

Primary Endpoint: TLF at 1-Year



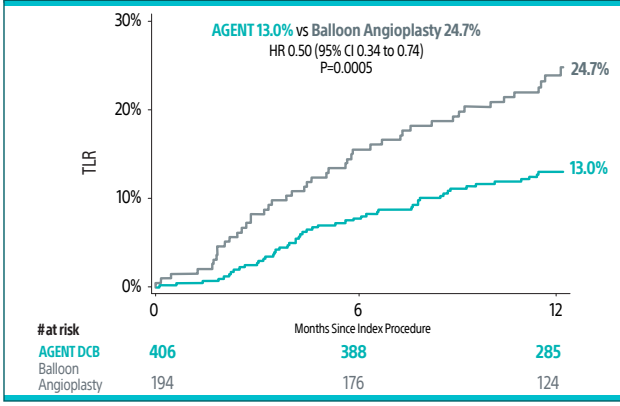
*Based on an adaptive trial design (interim analysis with pre-specified sample size readjustment plan); Yeh et al. Am Heart J. 2021;241:101-107

Additional Endpoints[2]

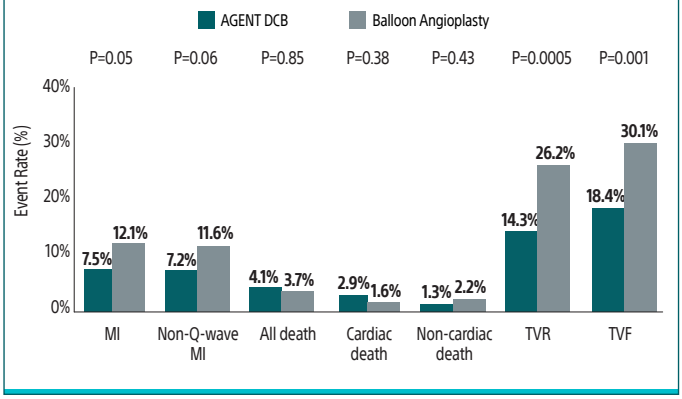
At 1-year, AGENT DCB also demonstrated statistically lower event rates:

- 50% risk reduction in TLR (13.0% vs. 24.7%, P=0.0005)
- 49% risk reduction in TV-MI (5.8% vs. 11.1%, P=0.023)
- Zero definite/probable ST (0.0% vs. 3.2%, P=0.0004)

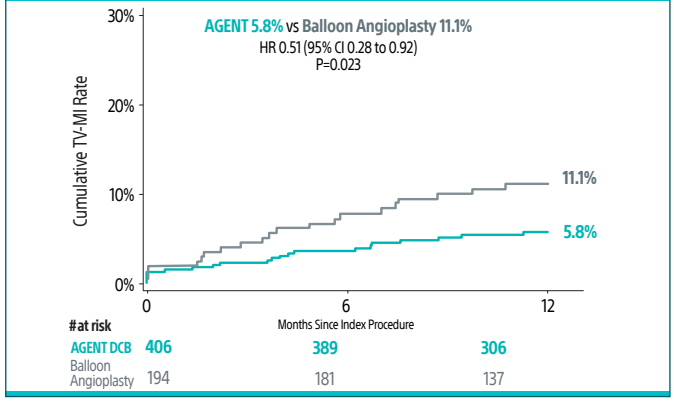
Target Lesion Revascularization



Additional Endpoints at 1-Year



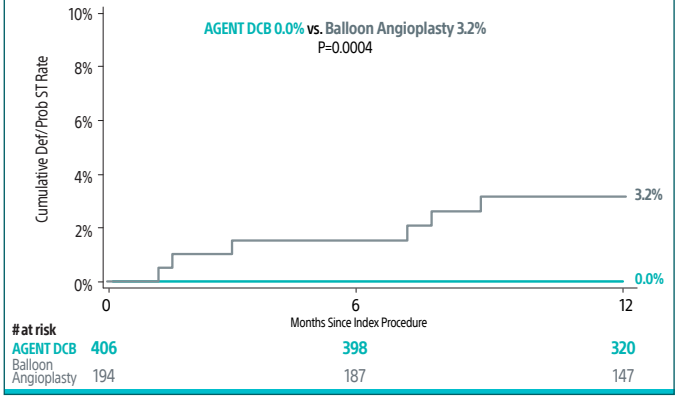
Target Vessel Myocardial Infarction



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 ST at 1-Year



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IC-1712710-AB

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 CRT 2024 by Dr. Robert Yeh.