

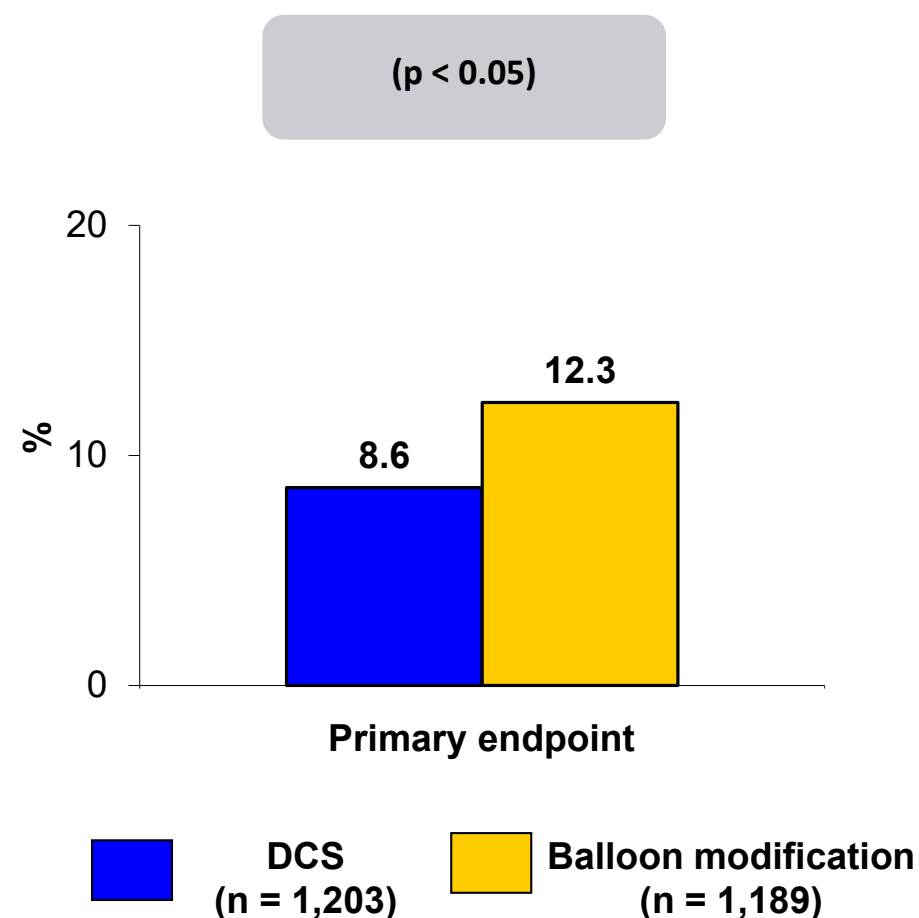
LEADERS FREE II

#TCT2018



AMERICAN
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Trial Description: Single-arm study; all received biolimus drug-coated stent (DCS). Outcomes compared with patients who received the bare-metal stent (BMS) in the LEADERS FREE trial. Patients were followed for 1 year.



RESULTS

- Primary safety endpoint: cardiac death, MI: DCS vs. BMS: 8.6% vs. 12.3%, HR 0.67, 95% CI 0.51-0.88
- Primary efficacy endpoint: TLR: 6.1% vs. 9.3%, HR 0.63, 95% CI 0.45-0.87

CONCLUSIONS

- Clinical outcomes following biolimus DCS implantation are superior to BMS in patients with high bleeding risk and able to take only 1 month of DAPT. There was a significant reduction in MI, TLR up to 1 year of follow-up, with similar rates of stent thrombosis
- Trial was designed for FDA approval of the stent in the US

Presented by Dr. Mitchell W. Krukoff at TCT 2018