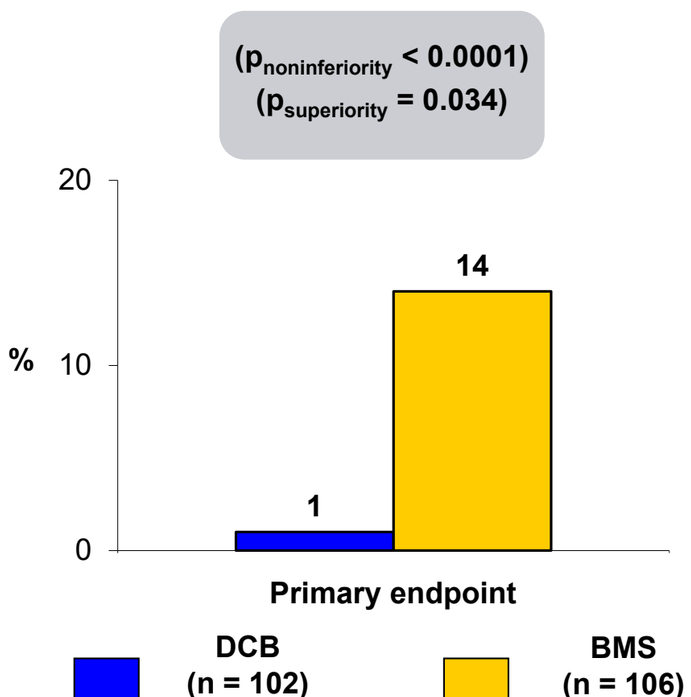
DEBUT

Trial Description: Patients with *de novo* lesions and high bleeding risk were randomized in a 1:1 fashion to PCI with a paclitaxel-based drug-coated balloon (DCB) or BMS after successful predilation. They were followed for 9 months.



RESULTS

- Primary endpoint, MACE (CV death, MI, TLR) at 9 months: DCB vs. BMS: 1% vs. 14% ($p_{noninferiority}$ < 0.0001, $p_{superiority}$ = 0.00034)
- CV death: 1% vs. 6% (p = 0.061); MI: 0% vs. 6% (p = 0.015), TLR: 0% vs. 6% (p = 0.15)
- Vessel closures/stent thrombosis: 0% vs. 1.9%
- MACE at 12 months: 4% vs. 14% (p = 0.015)

CONCLUSIONS

- Use of a paclitaxel-based coronary DCB was superior to BMS implantation among patients undergoing *de novo* PCI and high bleeding risk
- DCBs are approved for coronary PCI in Europe, but not FDA approved in the US
- Optimal control for comparison for DCBs may be DES with shorter durations or BPS-DES

Rissanen TT, Lancet 2019;Jun 13:[Epub]