RIVAROXaban IN THE SETTING OF CONTINued DUAL ANTIPLATELET THERAPY: FINDINGS FROM THE ATLAS ACS 2-TIMI 51 TRIAL

Oral Contributions
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Background: In ATLAS ACS 2-TIMI 51, rivaroxaban reduced CV events in patients (pts) with a recent ACS. The present analysis is restricted to those pts who continued their background dual antiplatelet therapies during the trial, thus avoiding dilution by pts who did not receive such therapies and providing a rigorous test of the additive role of rivaroxaban.

Methods: 14473 pts were randomized to BID dosing of rivaroxaban 2.5 mg, 5 mg, or placebo with the intent to also be treated with background aspirin + clopidogrel/ticlopidine. Analyses were conducted to assess only those events (84%) that occurred while pts were continuing their antiplatelet agents.

Results: In this group, rivaroxaban reduced the primary endpoint of CV death, MI, or stroke (8.6% vs 11.9%, HR 0.83, 95% CI 0.72-0.95, P=0.007, Figure). Both rivaroxaban 2.5 mg BID and 5 mg BID reduced the primary endpoint (9.3% vs 11.9%, P=0.031 and 7.9% vs 11.9%, P=0.014). Rivaroxaban 2.5 mg BID reduced CV death (2.1% vs 3.6%, P=0.005) and all-cause death (2.4% vs 4.0%, P=0.004), which was not seen with 5 mg BID. Rivaroxaban vs placebo increased non-CABG TIMI major bleeding (2.0% vs 0.6%, P<0.001) and ICH (0.5% vs 0.3%, P=0.019), without a significant increase in fatal bleeding (0.3% vs 0.2%, P=0.39).

Conclusions: In patients with a recent ACS, rivaroxaban significantly reduced CV events in pts continuing on background dual antiplatelet therapy. Among this group, rivaroxaban increased the rate of major bleeding, without a significant increase in fatal bleeding.