Efficacy and Safety of Long-term Evolocumab Use in Asian versus Other Subjects: the FOURIER trial

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Abstract:
Background: There are concerns that Asian people respond differently to some medications. We evaluated the efficacy and safety of evolocumab use in the FOURIER trial among participants of Asian versus other backgrounds.

Methods: The effects of adding evolocumab (either 140 mg subcutaneously every 2 weeks or 420 mg subcutaneously monthly) versus matching placebo to background optimized statin therapy over a median 2.2 years follow-up, on LDL-C reductions, cardiovascular events and adverse safety events were compared among all 27,564 FOURIER participants with prior MI, stroke or PAD, according to Asian (n=2,723) versus other (n=24,841) declared race.

Results: High-intensity statin use, compared with moderate dosing, was less frequent in Asian subjects compared with others (33% vs. 73%). Stroke was the qualifying atherosclerotic event in Asians more than in others (29% vs. 18%). Baseline LDL-C levels were similar among Asians and others (89 vs. 92 mg/dL) and evolocumab lowered LDL-C (baseline to 48 weeks) similarly in Asians and others from median 89 to 22mg/dL, and from 92 to 30mg/dL respectively. Compared with placebo, reductions with evolocumab in annualized primary endpoint (PEP: CV death, MI, stroke, hospitalization for unstable angina, coronary revascularization) events and in key secondary endpoint (SEP: CV death, MI, stroke) events were comparable; 5.2% vs 4.2% Relative Risk Reduction (RRR) (95%CI) 0.79 (0.61, 1.05), and 3.6% vs 2.7% RRR (95%CI) 0.73 (0.53, 1.01) respectively in Asian patients and 5.4% vs 4.6% RRR (95%CI) 0.86 (0.79, 0.93), and 3.4% vs 2.8% RRR (95%CI) 0.81 (0.73, 0.89), in others (both p for treatment interactions = ns). Serious adverse event rates were no higher among participants of Asian versus other races (11.8% versus 12.5% respectively per annum), and active study drug discontinuations due to adverse events were low in both Asian and other subjects (15% vs 21% per annum).

Conclusion: Use of evolocumab among Asian subjects was safe, lowered LDL-C comparably, and reduced CVD events at least as effectively as in patients of non-Asian background in FOURIER. No need was identified to modify the evolocumab dose for individuals of Asian race.

Category (Complete): 03. Acute and Stable Ischemic Heart Disease: Therapy
Keyword (Complete): PCSK9 ; Statin ; Asian
Suggested Keyword (Complete): Evolocumab

Clinical Implications (Complete):
*My study will help enable cardiovascular clinicians to... prescribe evolocumab to Asian subjects knowing that it is safe, lowers LDL-C comparably, and reduces CVD events at least as effectively as in patients of non-Asian background

Presentation Preference (Complete): Oral or Poster Presentation
Institution Information (Complete):
*Responsible Institution : NHMRC Clinical Trials Centre
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