Prasugrel for stroke prevention

The safety of prasugrel in elderly and/or low body weight Japanese patients with ischemic stroke who have a relatively high bleeding risk with antiplatelet therapy remains unknown.

OBJECTIVE: We aimed to investigate the safety and efficacy of long-term prasugrel monotherapy for stroke prevention compared with clopidogrel in elderly and/or low body weight Japanese patients with non-cardioembolic ischemic stroke.

METHODS: In this randomized, double-blind, comparative, phase III study, elderly (age ≥75 years) and/or low body weight (≤50 kg) Japanese patients with a previous history of non-cardioembolic ischemic stroke were assigned to a prasugrel 3.75 mg (PRA3.75) group, a prasugrel 2.5 mg (PRA2.5) group, or a clopidogrel 50 mg (CLO50) group and followed up for 48 weeks. The primary safety endpoint was the combined incidence of primary safety events, defined as life-threatening, major, and other clinically relevant bleeding. The efficacy endpoint was a composite of ischemic stroke, myocardial infarction, and death from other vascular causes.

RESULTS: A total of 654 patients (age 76.4 ± 7.3 years, body weight 55.6 ± 9.3 kg, women 43.9%) from 74 medical institutions within Japan were enrolled. The combined incidence (95% CI) of primary safety events was 4.2% (1.9-7.8%), 1.9% (0.5-4.7%), and 3.6% (1.6-6.9%) in the PRA3.75 group (n = 216), PRA2.5 group (n = 215), and CLO50 group (n = 223), respectively (hazard ratios [HR] PRA3.75/CLO50, 1.13 [0.44-2.93]; PRA2.5/CLO50, 0.51 [0.15-1.69]). The incidences of bleeding leading to treatment discontinuation (95% CI) were 2.3% (0.8-5.3%), 0.9% (0.1-3.3%), and 2.2% (0.7-5.2%) in the PRA3.75, PRA2.5, and CLO50 groups, respectively (HRs PRA3.75/CLO50, 1.01 [0.29-3.48]; PRA2.5/CLO50, 0.41 [0.08-2.12]). There was no significant difference in all bleeding events between groups. The incidence of ischemic stroke, myocardial infarction, and death from other vascular causes was lower, but not significantly so, in patients treated with prasugrel than in patients treated with clopidogrel: PRA3.75, 0.0% (0/216); PRA2.5, 3.3% (7/215); and CLO50, 3.6% (8/223; HRs PRA3.75/CLO50, 0.00 [0.00-0.00]; PRA2.5/CLO50, 0.90 [0.32-2.47]).

Elderly and/or low body weight -Japanese patients with previous non-cardioembolic ischemic stroke who received PRA3.75 showed similar results in terms of primary safety endpoint, and a numerically lower incidence of ischemic stroke, myocardial infarction, and death from other vascular causes, compared with those who received CLO50 [1].

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Kitagawa K, Toyoda K, Kitazono T, Nishikawa M, Nanto S, Ikeda Y, Abe K, Ogawa A. Safety and Efficacy of Prasugrel in Elderly/Low Body Weight Japanese Patients with Ischemic Stroke: Randomized PRASTRO-II. Cerebrovasc Dis. 2020 Mar 24:1-8. doi: 10.1159/000506825. [Epub ahead of print] PubMed PMID: 32208397.

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