Icatibant, a new bradykinin-receptor antagonist, in hereditary angioedema.

Abstract:
Hereditary angioedema is characterized by recurrent attacks of angioedema of the skin, larynx, and gastrointestinal tract. Bradykinin is the key mediator of symptoms. Icatibant is a selective bradykinin B2 receptor antagonist. In two double-blind, randomized, multicenter trials, we evaluated the effect of icatibant in patients with hereditary angioedema presenting with cutaneous or abdominal attacks. In the For Angioedema Subcutaneous Treatment (FAST) 1 trial, patients received either icatibant or placebo; in FAST-2, patients received either icatibant or oral tranexamic acid, at a dose of 3 g daily for 2 days. Icatibant was given once, subcutaneously, at a dose of 30 mg. The primary end point was the median time to clinically significant relief of symptoms. A total of 56 and 74 patients underwent randomization in the FAST-1 and FAST-2 trials,
respectively. The primary end point was reached in 2.5 hours with icatibant versus 4.6 hours with placebo in the FAST-1 trial (P=0.14) and in 2.0 hours with icatibant versus 12.0 hours with tranexamic acid in the FAST-2 trial (P<0.001). In the FAST-1 study, 3 recipients of icatibant and 13 recipients of placebo needed treatment with rescue medication. The median time to first improvement of symptoms, as assessed by patients and by investigators, was significantly shorter with icatibant in both trials. No icatibant-related serious adverse events were reported. In patients with hereditary angioedema having acute attacks, we found a significant benefit of icatibant as compared with tranexamic acid in one trial and a nonsignificant benefit of icatibant as compared with placebo in the other trial with regard to the primary end point. The early use of rescue medication may have obscured the benefit of icatibant in the placebo trial. (Funded by Jerini; ClinicalTrials.gov numbers, NCT00097695 and NCT00500656.)

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