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DIAGNOSIS OF ABACAVIR HYPERSENSITIVITY REACTIONS AMONG PATIENTS NOT RECEIVING ABACAVIR IN TWO BLINDED STUDIES

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AIM/METHODS: Abacavir is a potent nucleoside analogue, generally safe and well tolerated by most HIV-infected individuals. A hypersensitivity reaction of unknown cause is reported in approximately 5% of subjects receiving abacavir in controlled clinical trials. To assess the frequency and clinical characteristics of subjects diagnosed as having a hypersensitivity reaction to abacavir in control arms of double-blinded studies, we performed a retrospective review of two studies conducted in antiretroviral therapy-naïve HIV 1-infected adults starting lamivudine/zidovudine + indinavir or lamivudine + zidovudine + efavirenz. All subjects also received placebo resembling abacavir. Records were analysed for the occurrence of serious adverse events and diagnoses of hypersensitivity reactions.

RESULTS: Two-hundred-and-sixty-five subjects (median age 36 years, 86% male, 75% white) started lamivudine/zidovudine + indinavir with abacavir placebo (CNA3005). Median plasma HIV-1 RNA was 4.82 log₁₀ copies/ml; median CD4 cell count was 360 cells/mm³. Three-hundred-and-twenty-five subjects (median age 35 years, 82% male, 51% white) started zidovudine + lamivudine + efavirenz with abacavir placebo (CNA30024). Median HIV-1 RNA was 4.79 log₁₀ copies/ml; median CD4 cell count was 258 cells/mm³. Six subjects not receiving abacavir were diagnosed by investigators as having abacavir hypersensitivity reactions in CNA3005 [rate 2% (6/265)], and ten in CNA30024 [rate 3% (10/325)]. In most cases, either rash alone or rash or fever plus non-specific symptoms were reported. None of these cases were considered abacavir hypersensitivity reactions after an internal partially blinded medical review. One case was considered life-threatening and two were hospitalized (CNA30024).

CONCLUSIONS: Diagnosis of hypersensitivity reaction to abacavir occurred in 2 to 3% of subjects not receiving abacavir in double-blinded studies. Most cases had rash alone or rash accompanied by non-specific, mild symptoms. These data underscore the importance of assessing hypersensitivity reactions to abacavir as a multi-symptom syndrome and suggest that hypersensitivity reactions to abacavir may be overdiagnosed, particularly in the presence of rash due to other agents. However, when a distinction cannot be made, abacavir should be discontinued.

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