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MYOCARDIAL INFARCTION INCIDENCE IN CLINICAL TRIALS OF 4 PROTEASE INHIBITORS.

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BACKGROUND: The incidence of myocardial infarction (MI) was assessed in clinical trials of 4 protease inhibitors (PIs) with randomization to PIs + reverse transcriptase inhibitors (RTIs) or RTI-only therapy.

METHODS: MIs were ascertained from investigator reports in trials. Person-years (PY) on therapy for each patient were calculated from treatment start to MI onset or to stop dates for RTI therapy and to study end for PI. PY were pooled for each PI. Analyses were conducted for randomized and randomized plus extension phases with switching from RTI-only to PI; since results were similar, the latter with longer follow-up are shown. All MI rates and 95% confidence intervals (CIs) shown are rates per 1,000 PY.

RESULTS:

Results Therapy	Indinavir			Nelfinavir			Invirase			Ritonavir		
	N	PY	Rate	N	PY	Rate	N	PY	Rate	N	PY	Rate
PI+RTI	4	1922	2.08	1	1129	0.89	7	3944	1.77	4	1794	2.23
RTI (no PI)	2	674	2.97	0	105	0.00	0	1727	0.00	1	356	2.81

MI rates were similar among patients on PIs or on RTI-only therapy. Mean follow-up was around 12 months. Exact 95% CIs for MI rates were: indinavir (0.6-5.3), Nelfinavir (0.02-4.9), Invirase (0.7-3.7), and Ritonavir (0.6-5.7). MI rates on PI therapy were consistent with a MI rate of 2.73 in a 2-year trial of RTIs without PIs (ACTG 193a, n=1,313, CD4 ≤ 50) and with MI rates in the general male

population (per 1000 PY): 1.03 (30-34 yrs), 3.17 (34-44 yrs), and 5.46 (45-54 yrs) in Framingham (Kannel 1984); 3.10 (40-75 yrs) in Health Professionals (Ascherio 1996); 2.80 (45-50 yrs) in ENIM (Jungers 1997); and 6.32 (45-64 yrs) in MONICA (Stender 1993).

CONCLUSIONS: The data suggest that the risk of MI is not increased by PI therapy in approximately 12 months of follow-up.

Keywords: AEGIS, Protease Inhibitors, Myocardial Infarction, Nelfinavir, Clinical Trials, Incidence, Indinavir, Ritonavir, Saquinavir, HIV Protease Inhibitors, Reverse Transcriptase Inhibitors, Fibrinolytic Agents, Commonwealth of Independent States, Male, Human, epidemiology, AIDS

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