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PREVALENCE OF LIPODYSTROPHY IN THE LONG-TERM FOLLOW-UP OF A CLINICAL TRIAL COMPARING VARIOUS COMBINATIONS OF NUCLEOSIDE ANALOGUE REVERSE TRANSCRIPTASE INHIBITORS, ALBI TRIAL (ANRS 070).

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J. M. Molina, E. Angelini, L. Cotte, J. M. Lang, P. Morlat, C. Rancinan, T. May, V. Journot, F. Raffi, B. Jarrousse, M. Grappin, G. Lepeu, G. Chene, And The Albi Study Group

St-Louis Hosp, Paris; INSERM U. 330, Bordeaux; Hotel Dieu, Lyon; Strasbourg Hosp., Strasbourg; St-Andre Hosp., Bordeaux; Brabois Hosp., Nancy; Nantes Hosp., Nantes; Avicenne Hosp., Bobigny; Bocage Hosp., Dijon; H. Duffaut Hosp., Avignon; Agence Natl. de Recherches sur le Sida (ANRS), Paris, France

BACKGROUND: Whether the use of nucleoside analogue reverse transcriptase inhibitors (NRTI) is associated with an increased risk of a lipodystrophic syndrom remains controversial. We describe results obtained from the long-term follow-up of a randomized trial comparing various NRTI-containing regimens.

METHODS: 151 previously untreated HIV-1 infected patients with baseline mean CD4+ cell counts 404/mm³ and mean plasma HIV RNA 4.5 log₁₀ copies/ml were randomly assigned to 6 months of open-labeled d4T plus ddI, ZDV plus 3TC or d4T+ddI followed by ZDV+3TC (alternating group). At 6 months, the combination of d4T+ddI reduced plasma HIV-1 RNA and increased CD4+ cell counts more effectively than did the other combinations. At Month 30 (M30) of the long-term follow-up, investigators were asked whether patients presented physical manifestations of fat redistribution.

RESULTS: Data were available for 83 patients (55%): 25 randomized in the d4T-ddI group, 29 in the ZDV-3TC group and 30 in the alternating group. Switch to a protease inhibitor (PI) had occurred in 16%, 55% and 27% in each arm respectively and to a non nucleoside analogue (NNRTI) in 28%, 38% and 40% respectively. Overall, 35% presented at least one manifestation of lipodystrophy (LD) (95% CI: 25%-46%). In 42 patients continuing to receive only NRTI, it was 37% (95%CI :22-55%). Prevalence of LD was 52%, 28% and 27% in each arm respectively ($p=0.09$). The prevalence of

lipoatrophy was 44%, 21% and 23%, respectively ($p=0.12$). The prevalence of truncular adiposity was 28%, 10% and 13%, respectively ($p=0.19$). In patients with LD at M30 compared to those without, there was a higher mean duration of exposure to d4T: 19 vs 13 months ($p=0.01$) and a higher mean duration of ddI: 18.5 vs 11.5 months ($p=0.01$). Duration of exposure to ZDV (10 vs 15 months), 3TC (10 vs 16 months), PI (5 vs 5 months), or NNRTI (3 vs 3 months) did not differ significantly.

CONCLUSION: In the ALBI trial, overall prevalence of LD at M30 was 35%. It was twice higher in patients randomized in the d4T-ddI arm than in patients randomized in the other arms, although patients in other arms were switched more frequently to a PI-containing regimen.

Keywords: AEGIS, Reverse Transcriptase Inhibitors, Lipodystrophy, Stavudine, Lamivudine, Didanosine, Zidovudine, CD4 Lymphocyte Count, Anti-HIV Agents, HIV-1, HIV Protease Inhibitors, Clinical Trials, HIV Infections, Diabetes Mellitus, Lipoatrophic, HIV, Prevalence, Human, AIDS

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19

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