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ALTERATIONS IN PLASMA TRIGLYCERIDES LEVELS DURING TREATMENT WITH THREE DIFFERENT PROTEASE INHIBITOR REGIMENS: A RANDOMIZED STUDY

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BACKGROUND: Hyperlipidaemia has been observed in patients treated with protease inhibitors (PI). However, very few results from comparative randomized studies are available.

METHODS: One hundred and fourteen consecutive, PI-naïve patients participating in a multicentre study were randomized to treatment with either indinavir (800 mg three times daily), ritonavir (600 mg twice daily), or ritonavir plus saquinavir (400 mg each twice daily), in addition to two NRTIs. Plasma triglycerides (PT) (non-fasting) were measured at baseline and at regular intervals until week 96. PT levels were evaluated at week 36 and 48 in relation to the individual PI regime, pre-treatment levels of PT, CD4 count, weight change and prior NA experience. Analyses were performed as both intention-to-treat and as remained-on-randomized-treatment. The non-parametric Kruskal-Wallis test and the Wilcoxon signed ranks test were used.

RESULTS: In the ritonavir-containing arms ($n=46$) PT triglycerides increased significantly ($P<0.001$) and remained at an elevated level throughout the period of observation (median value at baseline 1.80 mmol/l, at week 36 2.3 mmol/l). In the indinavir arm ($n=27$) no rise in PT was observed ($P=0.58$). Comparing values in week 36 and week 48 showed significantly higher levels of PT in the ritonavir arm, than in the indinavir arm ($n=73$, $P<0.001$). The PT levels of the ritonavir plus saquinavir arm did not differ significantly from both single PI arms. Differences were even greater when the analyses were performed on remained-on-randomized treatment values. PT levels at baseline did not differ between patients with or without prior NA experience. At baseline

patients with CD4 cell count >200 cells/mm³ had significant lower PT values than patients with CD4 cell count <200 cells/mm³ ($n=96$, $P=0.01$), but this difference disappeared early on treatment. In the individual patient there was a high correlation between fasting and non-fasting PT values.

CONCLUSION: Ritonavir-containing regimens caused a sustained elevation of PT. Indinavir did not significantly increase PT.

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