Journal of the International AIDS Society

Poster presentation

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Impact on bone mineral density of tenofovir-containing HAART in HIV-1 infected children and adolescents: a report from 5 years of clinical experience

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from Ninth International Congress on Drug Therapy in HIV Infection
Glasgow, UK. 9–13 November 2008

Published: 10 November 2008

Journal of the International AIDS Society 2008, **11**(Suppl 1):P215 doi:10.1186/1758-2652-11-S1-P215

This abstract is available from: http://www.jiasociety.org/content/11/S1/P215

Purpose of the study

Tenofovir disoproxil fumarate (TDF) is not approved for use in HIV-infected children (<18 years). In clinical practice a TAMs-sparing regimen may be needed. Use of TDF in children seems to be associated with decrease in bone mineral density that sometimes can stabilize after 24 weeks. The primary purpose was to characterized the change in bone mineral density (BMD), as measured by osteosonography (QUS), during and after treatment with tenofovir-containing HAART.

Methods

We enrolled all HIV-infected children (6–18 years), who required a change in therapy. They received TDF (children aged 2–8 years, 8 mg/kg once daily; children aged >8 years, median dose of 210 mg/m2 once daily, maximum dose of 300 mg once daily) as part of HAART, and were longitudinally observed during a follow-up of 62 months. QUS were measured at five follow-up steps: 12, 25, 35, 46, 62 months. At every step at least two patients had BMD measurements.

Summary of results

We evaluated eight perinatally HIV-infected patients (mean age 11.3 years ± 4.1. 6 males). All subjects, except one, had extensive antiretroviral treatment exposure (mean time 116.1 ± 51.5 months). Not all the patients were evaluated about the BMD annually, but everybody had at least two measurements. At baseline (median time before TDF treatment 9 months), the median ADSoS Z-score was -0.39 (SD 0.75) and the BTT Z-score was -0.12 (SD 0.61). In our patients, ADSoS and BTT Z-score values, observed during all the follow-up period, did not show significant statistical differences from the baseline values (t-student, 2-tails). At week 62, mean AD-SoS z-score and BTT Z-score were -0.12 and 1.37, respectively. Response to therapy was good: five patients maintained their same therapy with a median increase in absolute CD4 T-cell of +98 cells/mm3 and an undetectable viral load; the other

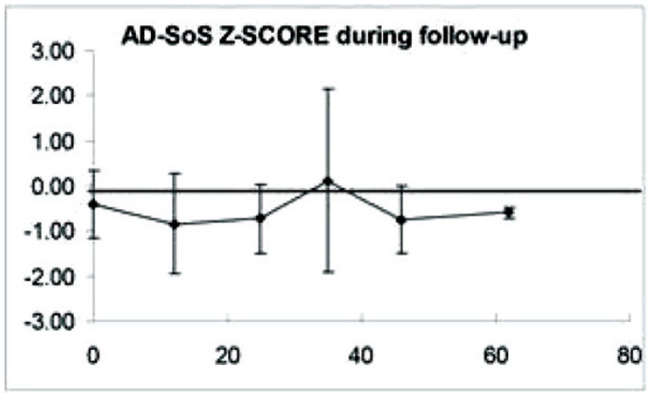

Figure 1
ADSoS Z-score during the follow-up period.

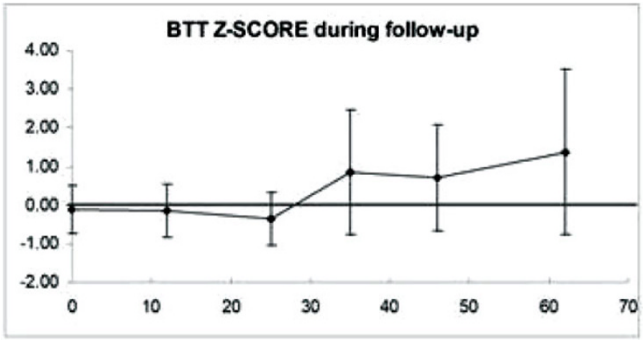

Figure 2
BTT Z-score during the follow-up period.

three patients, except one, changed their HAART, maintaining TDF, and obtain an undetectable viral load. No patients presented renal toxicity or any other clinically significant adverse events correlated to TDF. See Figures 1 and 2.

Conclusion

Our young patients do not seem to be at greater risk for bone toxicity. And a non-invasive technique, such as QUS technology, opens up new interesting perspectives, allowing following of bone mass changes in vertically infected patients and better multiple evaluation of the role of disease-related conditions or treatments able to interfere with bone mass acquisition during growth.

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