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Clinical effect of interleukin-2 (IL-2) immuno-adjuvant treatment in HIV+ advanced naïve patients

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Purpose of the study

The risk of opportunistic infections and inefficient immune reconstitution in advanced naive HIV+ patients starting HAART are critical issues in the management of HIV infection. We studied the effects of IL-2 adjuvant therapy in favoring a rapid CD4 cell rescue, shortening the time frame at highest risk of HIV-related clinical events in patients with severe immune impairment.

Methods

After 2 weeks of HAART, 73 HAART-naive patients with baseline CD4 cells <200/μL were randomized to receive IL-2+HAART (n = 33) or to continue ongoing HAART (n = 40). Three cycles of IL-2 were administered (one cycle: 3 × 106 IU QD sc at days 1–5 and 8–12), for an overall duration of 3 months. Patients were followed-up over 18 months. Patients failing to show a sustained CD4 recovery of >30% from baseline after 6 months (IL-2 non-responders, IL-2NR) received three further IL-2 cycles.

Summary of results

At baseline, IL-2 and HAART-control patients were comparable in terms of median CD4 counts (61/μL and 48/μL, respectively, p = 0.23) and prevalence of patients with AIDS-defining conditions (HAART-controls: 27; IL-2 patients: 15, p = 0.1). Rapid HIV-RNA decrease with no rebounds was observed in both IL-2 and HAART-patients. Major results are shown in Table 1. Compared to HAART-controls, IL-2 resulted in a more significant and rapid CD4 rescue after 3 months (p = 0.01). However, response to IL-2 was not equally persistent among patients: IL-2R displayed a higher and more sustained CD4 recovery up to month 18 respect to IL-2NR (p = 0.01) and controls (p = 0.04). Three additional cycles in IL-2NR did not result in any further significant CD4 recovery. During study period, AIDS-defining events were diagnosed in six (15%) HAART-controls and in one (3%) IL-2+HAART patient (p = 0.06).

Conclusion

In advanced naïve patients, IL-2 adjuvant therapy is efficacious in inducing a rapid and significant CD4 reconstitution, in most cases sustained up to 18 months. The finding of a reduced prevalence of patients developing AIDS-defining conditions suggests a possible efficacy in functional immune enhancement which may translate into earlier clinical benefit.

Table 1:

Group	Median CD4/μL change from BL (T3 mths)	Median CD4/μL change from BL (T6 mths)	Median CD4/μL change from BL (T18 mths)
IL-2+HAART patients (n = 33)	+145	+59	+107
IL-2R (n = 23/33)	+161	+91	+135
IL-2 NR (n = 10/33)	+95	+28	+74
HAART controls (n = 40)	+20	+59	+97