

Abstract category: B10 Opportunistic infections (excluding TB)
Optional category: B29 Intermittent or pulsed therapy, CD4 guided therapy

Abstract title:

Severity and types of clinical events by proximal CD4 cell counts in the SMART study

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Abstract text:

Background: The SMART study demonstrated an increased risk of HIV disease progression (POD) and death in patients on CD4-guided antiretroviral therapy (ART) strategy (drug conservation, DC; stop ART CD4>350, (re)start ART CD4<250) compared to those on continuous ART (viral suppression, VS). We describe POD clinical events (CE) by severity and type, and by proximal CD4 cell counts prior to CE.

Methods: Non-fatal CE were classified as serious (SE) and non-serious (NSE). SE are those associated with mortality: DMAC, CMV, toxoplasmosis, histoplasmosis, cryptococcus, PML, AIDS dementia, wasting, lymphoma, and visceral KS. NSE are all other HIV-related CE. Rates are per 100PY.

Results: Of 5,472 patients (mean follow-up 14 months; 3200 PY in each arm), 90 patients had a CE: 70 in DC (rate=2.2) and 20 in VS (rate=0.6) [HR=3.57, P<0.0001]. Of patients in DC, 40 (57%), and VS 6 (30%), were off ART at time of CE. CE by severity and proximal CD4 were:

Study Arm	CD4<350 No. (rate)		CD4≥350 No. (rate)	
	SE	NSE	SE	NSE
DC	9 (0.9)	34 (3.4)	4 (0.2)	26 (1.2)
VS	0	7 (3.0)	2 (0.1)	11 (0.4)
Total	9 (0.7)	41 (3.3)	6 (0.1)	37 (0.7)

[CE by CD4]

SE (No. by arm, proximal CD4 range) were: lymphoma (DC=4 149-362, VS=1, 644); wasting (DC=4, 145-826); DMAC (DC=1, 338, VS=1, 646); CMV (DC=1, 339); toxo (DC=1, 50); crypto (DC=1, 274); dementia (DC=1, 1091). NSE occurred at all CD4 levels: esophageal/pulmonary candidiasis (DC=23, VS=7); PCP (DC=8, VS=2); recurrent bacterial pneumonia (DC=7, VS=2); chronic HSV (DC=7, VS=2); KS (DC=6, VS=1); TB (DC=4, VS=3); disseminated HZ (DC=5, VS=1).

Conclusions: The incidence of both SE and NSE was greater in the DC than VS arm. In patients with CE at proximal CD4 cells ≥350, the proportion of SE were similar in DC (13%) and VS (15%).