Abstract category: B29 Intermittent or pulsed therapy, CD4 guided therapy
Optional category: B21 Clinical trials - phase III/post-licensing

Abstract title:
The effect of episodic CD4-guided antiretroviral therapy on quality of life: results of the Quality of Life substudy of SMART

Author(s): Burman W.[1], for the SMART Study Group
Institute(s): [1]*Denver Public Health, University of Colorado Health Sciences Center, Denver, United States*

Abstract text:
Background: The SMART study is an international, randomized trial with 5,472 participants comparing an episodic CD4-guided antiretroviral treatment (ART) strategy (drug conservation, or DC arm) with continuous ART (viral suppression, or VS arm). It was hypothesized that episodic ART might improve quality of life (QOL) by reducing time spent on ART.
Methods: A subset of SMART study participants enrolled in 64 U.S. sites had QOL assessments (current health state, assessed by visual analog scale, and SF-12) at baseline, months 4, 8, and 12, and annually thereafter. The DC and VS strategies were compared longitudinally for changes in the visual analog scale, each of the 8 SF-12 dimensions, and physical (PCS) and mental (MCS) health components.
Results: 1,225 patients participated in the substudy. Most (76%) were on ART at enrollment; 25% women; and median CD4 count was 575 (IQR, 455 – 784) cells/mm^3. At study entry, mean current state of health scores was 75 (out of 100). Fifty percent rated their health as very good or excellent on the SF-12 general health question. Mean follow-up was 2.4 years. During follow-up, current health state and general health perception declined in the DC group and increased in the VS group ($p=0.09$ for difference in current state of health and $p=0.02$ for general health perception). DC patients also scored lower on the physical summary score (PCS; $p=0.005$) and in the energy dimension of the SF-12 (baseline = 60 out of 100 and average change of -1.7 versus +0.2; $p=0.05$). Differences in other SF-12 dimensions and the MCS between groups were small and not statistically significant.
Conclusions: Episodic use of ART as in SMART did not improve quality of life. Physical functioning, general health perception, and energy scores worsened among patients in the DC group compared to the VS group.