
Non-AIDS serious adverse events are as important as AIDS events in patients with advanced multi-drug resistant HIV disease

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Background: Both AIDS and non-AIDS events adversely affect clinical outcomes and quality of life (QOL) for HIV+ patients. We compare the type, frequency and QOL consequences of AIDS vs. non-AIDS events in patients having advanced AIDS when treatment options are limited. **Methods:** OPTIMA is a tri-national trial (UK, Canada, USA) of alternate treatment strategies for patients with advanced HIV disease (CD4 \leq 300 cells/mm³) and evidence of resistance to 3 classes of antiretroviral (ARV) medications. Groups of patients AIDS-related events (AIDS), non-AIDS serious adverse events (SAE's), or no serious clinical event were identified. Scores from the Medical Outcomes Study HIV (MOS-HIV) QOL instrument, both physical health status (PHS) and mental health status (MHS), were calculated at baseline, pre-event, and post-event. Concurrent SAE's and AIDS events and those with missing MOS-HIV data were excluded. **Results:** As of December 2003, 255 patients were enrolled, median CD4 = 111 cells/mm³, median follow-up = 11 months. Of 23 deaths, 9 were HIV related, 5 unrelated, and 9 to be adjudicated. There were 167 non-AIDS SAE's in 67 patients and 65 AIDS events in 35 patients, of which 79 were evaluable. There were no differences in pre-event scores between groups. Compared to patients without events, the decrease in PHS scores was greater for SAE's (p = .006) and the decrease in MHS scores was greater for both SAE's (p = .013) and AIDS events (p < .003). PHS and MHS declines from pre-event to post-event status did not differ between AIDS events and non-AIDS SAE's. However, significant decreases in pre-event to post-event scores occurred in PHS following SAE's (p = .002) and in MHS following AIDS events (p = .033). **Conclusion:** Non-AIDS SAE's are more common than AIDS related events in patients with advanced multi-drug resistant HIV. Non-AIDS and AIDS events have comparable serious adverse effects on quality of life in this population.