Clinical prediction guide

A simple scoring system predicted clinical progression in HIV patients receiving highly active antiretroviral therapy


QUESTION: In patients with HIV who are receiving highly active antiretroviral therapy (HAART), does a scoring system predict clinical progression?

Design
Prognostic scoring system developed in 1 derivation cohort and validated in 2 cohorts of patients.

Setting
60 centres in Europe and Israel.

Patients
2027 patients (median age 37 y) formed the derivation set: inception cohort of participants in the EuroSIDA study who were ≥ 16 years of age and had started a protease inhibitor or non-nucleoside reverse-transcriptase inhibitor as part of a HAART antiretroviral regimen and had CD4 cell counts and viral loads measured within 6 months before starting HAART and ≥ 1 measurement after starting HAART. 2 cohorts of patients formed the validation set: 1946 patients in the EuroSIDA study who started HAART before recruitment to the study and 1442 patients from a clinic in Barcelona who had previously started HAART.

Description of prediction guide
Cox proportional hazards models were used to determine factors associated with clinical progression. The final prediction model comprised the latest CD4 cell count, viral load, haemoglobin concentration, and clinical status at the start of HAART (no AIDS, severe AIDS [progressive multifocal leucoencephalopathy and non-Hodgkin’s lymphoma], or other AIDS diagnosis). For CD4 cell counts, the cut points were 50 and 200 cells/mm<sup>3</sup>; for viral loads, the cut points were 500 and 10 000 HIV-RNA copies/ml. The normal haemoglobin concentration was defined as > 14 g/dl for men and 12 g/dl for women; severe anaemia was defined as < 8 g/dl for men and women. Logarithms of the relative hazards were used to derive a score for the variables with independent association with the risk for clinical progression. The score ranged from 0 to 17 points.

Main outcome measure
Clinical progression (new diagnosis of an AIDS defining event or death).

Main results
Among patients in the derivation cohort, 200 patients (9.9%) clinically progressed (death 30%, first AIDS defining illness 47%, and new AIDS defining illness 24%). For a 1 unit increase in score, a mean increase of 38% (95% CI 33% to 43%) occurred in risk for clinical progression. The incidence of clinical progression was 3.9/100 person years. In the EuroSIDA and Barcelona validation cohorts, the incidence of clinical progression was 4.2 and 4.6 per 100 person years, respectively. A single point increase in score was associated with an increased risk for clinical progression of about 40% among the 3 cohorts.

Conclusions
In patients with HIV who are receiving highly active antiretroviral therapy, a scoring system based on the latest CD4 cell count, viral load, and haemoglobin concentration and a previous severe AIDS diagnosis was predictive of clinical progression. The risk for disease progression of a 1 unit increase in score was about 40%.

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