HIV-1-infected individuals starting their first-line antiretroviral regimen after 2008 in Italy: data from theICONA Foundation Study Cohort

Background

Rates and reasons for discontinuation or modifications of the first HAART regimens have been investigated in a number of recent study.

Data updated from the Italian Cohort of Antiretroviral-Naive Patients (ICONA) on 2008 highlighted a first cART stopping rate of 36.1%; Moreover it has been noticed that the incidence of discontinuation because of intolerance/toxicity has declined over time while simplification strategies have become more frequent in recent years.

Objective

The aim of this study was to analyze predictors associated with treatment interruption (TI) of first-line antiretroviral drugs and their evolution in more recent years, in a population of HIV-infected antiretroviral-naive patients starting their first cART regimen in Italy.

Patients and Methods

HIV-1-infected patients from the ICONA Foundation Study who had initiated their first-line HAART regimen after 01/01/2008 were included in this analysis. TI was defined as stop and/or switch of at least one drug contained in the regimen, with the exclusion of simplification of TDF/FTC/EFV plus EFV with a STR containing TDF/FTC/EVF. All causes of TI, were evaluated and cumulative risk of stopping was investigated according to age, gender, comorbidity, years since starting cART, CD4 cell count, HIV-RNA, third drug and backbone combined in the regimen.

Statistical analysis

Standard survival analysis was used to estimate the time to TI. Patients follow-up accrued from the date of starting their first cART-regimen from HAART was defined as up to the date of TI or last clinical visit. Kaplan-Meier (KM) curves were drawn using a competing risk approach such as follow-up of patients who discontinued for a reason different from that of interest was truncated at the date of last clinical follow-up (administrative censoring). Overall cumulative risk of stopping was estimated using the KM method and all curves stratified by reason for stopping were plotted on the same graph. Cox regression analysis was used to identify factors associated with the risk of TI.

Results

In this study 1759 patients, who started first antiretroviral regimen and had at least one month of clinical follow-up, were included. Male were 1,363 (77.5%), 419 patients (23.8%) were 18-30 years old, 1,113 (63.3%) were 31-50 years old and 227 (12.9%) were more than 50. Over a median follow-up of 12 months, 576 patients stopped their cART with an overall discontinuation rate of 32.7%. Demographic characteristics of population and differences between discontinuation and not discontinuation group are shown in Table 1.

Table 1. Main characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Discontinuation</th>
<th>Total</th>
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<tr>
<td>Median age (years)</td>
<td>41 (37-44)</td>
<td>41 (37-44)</td>
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<tr>
<td>Median CD4 count (cells/mm3)</td>
<td>500 (114-1146)</td>
<td>500 (114-1146)</td>
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<tr>
<td>HIV RNA (copies/mL)</td>
<td>3.8 (3.8-3.8)</td>
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<td>Gender, n (%)</td>
<td>Male: 1,363 (77.5%), 419 (23.8%)</td>
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The Kaplan-Meier estimates of drug discontinuation for any reason were those who initiated ATV/r 28.2%, 26.1% for DRV/r, 53.77% for LPV/r and 31.6% for other third agents (p<0.001) (Figure 2).

Conclusions

In a previously reported analysis of the ICONA data, the overall risk of discontinuation of first-line HAART was 36% with 21% due to intolerance/toxicity. In this updated analysis, the main reason for stopping is simplification (accounting for 32% of stops), reflecting the recent changes in recommendations aimed to minimize drug toxicity, enhancing adherence and quality of life.

References

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Contact information: Antonio Di Biagio; a.dibiagio@gmail.com