ABSTRACT

Background: In ARV-naive patients, NVP liver toxicity is related to high CD4+ cells. It is not clear whether this also happens in simplification or substitution strategies.

Methods: Retrospective analysis of 221 patients treated with NVP due to simplification (n=141) or substitution for toxicity (n=43) or bad tolerability (n=37). Liver toxicity was defined as increase in 5 times the upper normal level of AST or ALT. CD4+ cell counts defined as high if greater than 250/µL in women and 400/µL in men. Summary statistics for describing variables, relative risk for prevalence, and logistic regression model for liver toxicity associated factors were performed.

RESULTS

Baseline Characteristics (n=221 patients)

- **Gender**: 164 (74.1%) male, 57 (25.9%) female.
- **Risk factors for HIV infection**: - None
- **CD4 Count, cells/mm3**:
  - Low (women <250/µL, men <400 µL) 166 (75.1%)
  - High (women >250/µL, men >400/µL) 54 (24.9%)

Liver toxicity and CD4+ cell counts

<table>
<thead>
<tr>
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<th>Yes</th>
<th>All</th>
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<tbody>
<tr>
<td>#</td>
<td>%</td>
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<tr>
<td>Baseline CD4+</td>
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<tr>
<td>High</td>
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<tr>
<td>Low</td>
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</tbody>
</table>

Liver toxicity

- Male: 164 (74.1%)
- Female: 57 (25.9%)

CD4+ cell counts

- Low: 166 (75.1%)
- High: 54 (24.9%)

Risk factors for liver toxicity

- None

CD4+ cell counts

- Low (women <250/µL, men <400 µL) 166 (75.1%)
- High (women >250/µL, men >400/µL) 54 (24.9%)

NVP therapy durability and reasons of NVP discontinuation

- Withdrawal: 24 (10.9%)
- Failure: 101 (45.7%)
- Toxicity: 29 (13.4%)
- Rash: 3 (1.4%)

Factors associated to liver toxicity

- HCV co-infection: 3.530 (95% CI: 1.198, 10.399)
- Rash: 3.833 (95% CI: 0.919, 16.976)

CONCLUSIONS

- In our cohort, incidence of liver toxicity was low and not related to high CD4+ cell counts.
- The only factor related to liver toxicity was hepatitis C co-infection.
- Liver toxicity presented mainly after six months of NVP therapy, was mild to moderate in intensity and always reversible upon suspension of NVP.

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