**Therapeutic Drug Monitoring of Lopinavir/Ritonavir (Tablet Formulation) in Pregnancy**

Josianne Gauthier¹, Marc Boucher², Niamh Higgins³, Joanne Moreau², Hong Yang¹, Nancy L. Sheehan¹,³
¹McGill University Health Centre, ²Centre hospitalier universitaire Sainte-Justine, ³Université de Montréal

**CONTACT INFORMATION**
Josianne Gauthier, Quebec Antiretroviral Therapeutic Drug Monitoring Program
Montreal Chest Institute, 3650 St-Urbain, J3.07, Montréal, Québec, H2X 2P4, Canada
@ josianne.gauthier@muhc.mcgill.ca

**RESULTS**

**PLASMA SAMPLES**
- 45 plasma samples were reviewed
- 12 excluded since time post-dose < 4 hours or > 16 hours
- 1 excluded due to no time post-dose available
- 7 excluded since lopinavir/ritonavir dosage of 600/150mg (among 3 women)
- 25 samples were retained from 25 women

**POPULATION CHARACTERISTICS** (N=25)
- Age (years): Median: 33, Range: 23 – 42
- Body weight (kg): Median: 78.7, Range: 56.4 – 98.8
- Height (m): Median: 1.65, Range: 1.53 – 1.81
- Time of pregnancy at the moment of TDM (weeks of gestation): Median: 32.1, Range: 28.7 – 36.0
- CD4 at time of TDM (cells/mm³): Median: 548, Range: 133 – 1344

**CORRELATION WITH LOPINAVIR Cmin**

**RELATIONSHIP BETWEEN TDM INTERPRETATION AND VL**

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic and undetectable VL</td>
<td>17</td>
<td>68%</td>
</tr>
<tr>
<td>Therapeutic and detectable VL</td>
<td>3</td>
<td>12%</td>
</tr>
<tr>
<td>Subtherapeutic and undetectable VL</td>
<td>5</td>
<td>20%</td>
</tr>
<tr>
<td>Subtherapeutic and detectable VL</td>
<td>8</td>
<td>0%</td>
</tr>
</tbody>
</table>

**FACTORS ASSOCIATED WITH VL**

**DISCUSSION**

- Some VL were detectable despite therapeutic levels and no subtherapeutic levels were associated with detectable VL.
- Lower lopinavir Cmin tended to be associated with a detectable VL though the difference was not statistically significant.
- Detectable VL during the third trimester or at delivery did not lead to HIV transmission to the newborn in this small sample.

**CONCLUSIONS**

- We observed an important proportion of subtherapeutic concentrations in women receiving the tablet formulation of lopinavir/ritonavir 400/100 mg twice daily during the third trimester of pregnancy.
- Given the small number of detectable VL, no clear relationship between lopinavir Cmin and VL could be established.
- Until further data are available, we propose to do TDM in pregnant women receiving lopinavir/ritonavir.

**ACKNOWLEDGMENTS**

We would like to thank the patients, physicians and pharmacists who participate in the Quebec Antiretroviral Therapeutic Drug Monitoring Program. We also thank the Ministère de la Santé et des Services Sociaux du Québec for complete funding of the TDM program.