Use of Tenofovir Disoproxil Fumarate (TDF) in Pregnancy: Findings from the Antiretroviral Pregnancy Registry (APR)

B Omscheidt and S Zhang
Gilead Sciences, Inc., Foster City, CA, USA

Introduction

• Tenofovir disoproxil fumarate (TDF), a nucleoside reverse transcriptase inhibitor (NRTI), has been widely used in combination with other antiretroviral drugs for the treatment of chronic HIV infection in adults.
• TDF is available in the following products:
  - TDF (Truvada®)
  - FTC (emtricitabine)/TDF (Truvada®)
  - FTC/emtricitabine/TDF (Truvada®) •
  - TDF was recently approved for the treatment of chronic hepatitis B infection (HBV) in the EU region in April 2008 and in the U.S. in August 2008.

Methods

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Gilead Sciences, Inc.
Findings from the Antiretroviral Pregnancy Registry (APR) •
H-456
Foster City, CA 94404
48th Annual ICAAC / IDSA 46th Annual Meeting
Tel: (650) 574-3000

Table 4. Birth Defect Prevalences for First Trimester Exposure to Antiretroviral Therapy Class

<table>
<thead>
<tr>
<th>APR VI Subclass</th>
<th>Birth Defects/Non-Live Births</th>
<th>Prevalence % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>tenofovir</td>
<td>0/114 (0.0 - 2.3)</td>
<td>0.0% (0.0 - 2.3)</td>
</tr>
<tr>
<td>emtricitabine</td>
<td>0/114 (0.0 - 2.3)</td>
<td>0.0% (0.0 - 2.3)</td>
</tr>
<tr>
<td>TDF</td>
<td>0/114 (0.0 - 2.3)</td>
<td>0.0% (0.0 - 2.3)</td>
</tr>
</tbody>
</table>

Results

Comparison to a Population-Based Birth Defect Rate

• CDC's population-based birth defects surveillance system, the Metropolitan Atlanta Congenital Defects Program (MACDP) reported total prevalence of birth defects of 2.7% of live births (1989-2003).
• MACDP always excludes cases among all births in five counties of metropolitan Atlanta area with approximately 50,000 annual births.

Figure 1. Birth Defect Rates for First Trimester Exposure by Antiretroviral Therapy Class

APR Advisory Committee Consensus

Primary Registry Analysis (Prospective Reports)

In analyzing individual with substances to watch a separate analysis was performed for frequency of birth defects has been detected for childbirth only.

For allergic reactions, includes laboratory numeric, non-immune, transient, idiopathic, and benign. sufficient numbers of first trimester exposures have been monitored to detect at least a 1.5-fold increase in risk of overall birth defects. No such increases have been detected to date.

For convivence and avoid or does not require that those with earliest exposure in the second or third trimester

Birth Defect Rates By Trimester of Earliest Exposure to TDF and All ARV Medications

Table 5. Birth Defect Rates By Trimester of Earliest Exposure to TDF and All ARV Medications

<table>
<thead>
<tr>
<th>Trimester of Earliest Exposure</th>
<th>TDF</th>
<th>All ARV Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st trimester</td>
<td>2.5%</td>
<td>2.5%</td>
</tr>
<tr>
<td>2nd trimester</td>
<td>2.7%</td>
<td>2.7%</td>
</tr>
<tr>
<td>3rd trimester</td>
<td>2.9%</td>
<td>2.9%</td>
</tr>
</tbody>
</table>

Conclusions

• APR overall birth defect prevalence (2.5%) was comparable to that of other large prospective cohort studies of newborns with prenatal exposure to ARVs (2.5% and 1.5%) and to general population-based surveillance data (2.7%).
• Birth defect prevalence with 1st trimester exposure to NRTI Class (TDF) is similar to that of other ARV classes.
• Monitoring of birth defects among infants born to women should be encouraged during ARV therapy.

APR Contact Information

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References