Parenthood with Exposure to Mycophenolic Acid Products
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**Abstract**
Successful pregnancy outcomes have been reported in all solid-organ transplant recipients on a variety of immunosuppressive medication regimens. In October 2007, the FDA pregnancy category of mycophenolic acid products (MPA) was changed from category C to D, based on registry and post-marketing data which revealed a higher incidence of spontaneous abortions and structural birth defects. The purpose of this abstract is to describe pregnancy outcomes with exposure to MPA and pregnancies fathered by male transplant recipients conceived while taking MPA. Data were collected by the National Transplantation Pregnancy Registry (NTPR) via questionnaires, telephone interviews, and medical records. There were 152 conceptions in female recipients with exposure to MPA (discontinued <6 wks prior to conception or with use during pregnancy). Outcomes included: 78 live births, 70 spontaneous abortions, 3 stillbirths and 1 therapeutic abortion. Among the live births, there were 14 malformations reported for an incidence of 18%, compared to the incidence of malformations in transplant recipients not exposed to MPA, which is approximately 4.9%. There were 146 male recipients who had fathered 199 pregnancies with 202 outcomes (including twins). Outcomes included: 168 live births, 14 spontaneous abortions, and no therapeutic abortions or stillbirths. Among the live births there were 6 malformations reported, for an incidence of 3.2%.

**Conclusions:** Reports to the NTPR reveal an increased incidence of non-viable outcomes and a pattern of structural malformations in pregnancies exposed to MPA in female transplant recipients compared to those without exposure to MPA. Those pregnancies fathered by male recipients appear similar to that of the general population.

**Background**
In October 2007, the FDA pregnancy category of mycophenolic acid products (MPA) was changed from category C to D, based on registry and post-marketing data which revealed a higher incidence of spontaneous abortions and structural birth defects.

**Purpose**
The purpose of this study was to describe pregnancy outcomes with exposure to MPA and pregnancies fathered by male transplant recipients conceived while taking MPA.

**Methods**
Data were collected via questionnaires, telephone interviews, and medical records.

**Abbreviations**
WMP = mycophenolic acid
TAC = tacrolimus
Pred = prednisone
EC-MPS = enteric coated mycophenolate sodium
CsA = cyclosporine

**Table of Pregnancy Outcomes**

<table>
<thead>
<tr>
<th>Case</th>
<th>Malformations</th>
<th>Infant Death</th>
<th>Maternal Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Complete heart defects</td>
<td>N</td>
<td>TAC, Pred</td>
</tr>
<tr>
<td>2</td>
<td>Congenital heart defects</td>
<td>Y</td>
<td>TAC, Pred, Prednisone</td>
</tr>
<tr>
<td>3</td>
<td>Microtia type III</td>
<td>N</td>
<td>TAC, Pred</td>
</tr>
<tr>
<td>4</td>
<td>Ventricular septal defect</td>
<td>N</td>
<td>TAC, Pred</td>
</tr>
<tr>
<td>5</td>
<td>Multiple anomalies (ventricular septal defect, underventilated left lung)</td>
<td>N</td>
<td>TAC, Pred</td>
</tr>
<tr>
<td>6</td>
<td>Multiple anomalies (cleft lip and palate, microtia, congenital heart defects)</td>
<td>Y</td>
<td>TAC, Pred</td>
</tr>
</tbody>
</table>

**Comparison of Structural Malformations**

- Among the live births born to female transplant recipients exposed to MPA, there were 14 malformations reported for an incidence of (18%), compared to the incidence of malformations in transplant recipients not exposed to MPA, which is approximately 4.9%.
- Among the live births fathered by male recipients there were 6 malformations reported, for an incidence of 3.2%.
- In the general population structural birth defects are reported in the range of 3-5%.