Application a new terminology based on International Conference on Harmonisation to fetal therapy: adverse events of thoraco-amniotic shunting

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Introduction

"Adverse Events" seemed to be related with procedures

Unexpected harmful events that has not always relation with interventions

Methods

Established terminology; Apply to fetal therapy; re-evaluation; Thoraco-amniotic shunting

Results

Total adverse events of thoraco-amniotic shunting for 24 cases with 37 procedures during the entire pregnancy period (Postoperative day 1 to delivery) Takahashi Prenat Diag 2012

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Grade 0</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
<th>Grade 4</th>
<th>Grade 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROM</td>
<td>184</td>
<td>0</td>
<td>6</td>
<td>5</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Threatened preterm delivery/delivery</td>
<td>47</td>
<td>43</td>
<td>101</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Catheter displacement</td>
<td>180</td>
<td>7</td>
<td>2</td>
<td>11</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Conclusion

• Newly developed ADVERSE EVENTS criteria (table) is available for fetal therapy.
• From now, we should note not only effectiveness but also AE for all prospective fetal therapy.

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