

Leukemia therapy with imatinib during pregnancy may cause infant abnormalities

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While doctors already face many challenges in treating patients with cancer, treating pregnant women with the disease, in particular, can be quite difficult as studies suggest that certain therapies can harm developing fetuses. According to the results of a study prepublished today online in *Blood*, the official journal of the American Society of Hematology, expectant women treated with imatinib, a commonly used therapy for chronic myeloid leukemia (CML), may be at moderate risk of developing fetal abnormalities.

Imatinib was introduced for the treatment of CML in 1998 and has become a primary therapy for most patients, turning the previously fatal disease into a mostly chronic condition in the last decade. The drug's label warns that women of child-bearing age should avoid pregnancy while taking the drug based on earlier studies that suggested it may penetrate the placenta and cause damage to developing cells.

The retrospective study reviewed records of 180 cases of CML treatment during pregnancy reported to Novartis, the Hammersmith Hospital in London, or The University of Texas M. D. Anderson Cancer Center to determine the real risks of imatinib therapy. Specific outcomes data were available for 125 of the cases, as 55 cases had incomplete pregnancy-related data.

Half of the pregnancies resulted in the birth of normal live infants (n=63). Thirty-five women underwent elective terminations, three following the identification of fetal abnormalities. At least 18

pregnancies resulted in miscarriage. The remainder of the births resulted in infants with congenital abnormalities (n=9, one still birth). In total, 12 pregnancies resulted in infants with fetal abnormalities (9.6 percent) and of those, there were eight live births, one still birth and three terminations (mentioned above). Some of the abnormalities in the infants were similar, including exomphalos (umbilical hernia), renal agenesis (undeveloped kidney), and hemivertebrae (underdeveloped spine). The stillborn child suffered from meningocoele (cerebral hernia).

The study showed that a significant proportion of pregnancies exposed to imatinib result in a normal outcome and a healthy infant. The miscarriage rate in the study was 14.4 percent, which is within the expected range for the general population. However, the fact that some of the abnormalities seen in the 12 infants were similar to results found in early animal studies with imatinib suggests the possibility of an imatinib-induced effect.

"Our study suggests that a concern about conceiving a child while taking imatinib is justified and that patients should be advised to avoid conception while on treatment," said Dr. Seonaid Pye, of the Department of Hematology, Imperial College of London and lead author of the study. "In those patients who do become pregnant, balancing the risk of the fetus from taking therapy to the risk of the mother from interrupting therapy will be an individual decision."

The majority of women in the study were being treated for CML at the time of conception; just four cases were exposed after the first trimester. The dose and the exact duration of imatinib therapy are unknown for most cases, with insufficient information to assess a dose-related relationship. There were no reports of maternal exposure to alcohol, drugs, or tobacco addiction during pregnancy, and none of the mothers had received other high-dose chemotherapy prior to their pregnancies.

"The risks and benefits to an expectant woman fighting cancer and her fetus are challenging and must be evaluated on an individual basis with careful counseling," said Dr. Pye. "Ultimately, the treatment of CML during pregnancy clearly remains a considerable clinical challenge."

Source: American Society of Hematology

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