

Why poison your baby?

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IN 1961, A GERMAN NEWSPAPER drew the attention of the public to the harmful effects of a newly introduced sleeping pill - thalidomide - used during pregnancy. It warned of the possibility of foetal deformities, especially phocomelia, or more popular known as "flipper-babies".

Phocomelia is a very rare type of inborn malformation, but following the use of thalidomide, about 10,000 cases were found in many countries, particularly in Europe. Thalidomide was later classified as a teratogen and was eventually banned.

But it was too late. Its traumatic effects extended far beyond the victims' families. It was a bitter lesson for society at large.

When thalidomide was first introduced in the late 1950s in Germany, it was reported to be non-toxic in experiments conducted both on animals and humans. In fact, it was proclaimed safe because the ingestion of more than 10 times its normal dose did not result in death.

Unfortunately, it led to one of the worst man-made "foetal poisoning" tragedies in history. Since then, thalidomide has been reported to cause abnormalities of the limbs, skull, heart, liver, gastrointestinal tract, kidney, lung and uterus.

As a consequence, the use of medicines for expectant mothers today is rigidly regulated. Pregnant mothers are advised not to take medications unnecessarily even though under normal circumstances, they are generally regarded safe.

Today, many countries have developed a system that categorises risks associated with the use of drugs during pregnancy. This is intended to avoid any potential incidence of birth defects.

A medicinal drug may have more than one harmful effect on foetuses, depending on when they are exposed to the drug, even in therapeutic doses. Thus, it is essential to know the types of drugs to be used, especially the dose level, and the stages of pregnancy involved.

This is because expected incidences of malformation of different organs and systems vary in susceptibility according to the stages of pregnancy. Drugs with than one active substance may even result in a greater risk.

Below is an example of the various categories prepared by the Congenital Abnormalities Sub-committee of the Australian Drug Evaluation Committee with respect to the categorisation of risks in pregnancy:

Category A: Drugs which have been taken by a large number of pregnant women and women of childbearing age without an increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

Examples are pain killers (paracetamol), anti-asthma drugs (theophylline derivatives, sodium cromoglycate), anti-histamines (meclizine, cyclizine, hydroxyzine), antibiotics (cephalexin, cephalothin, amoxycillin, ampicillin, carbenicillin), anti-TB drugs (ethambutol, isoniazid), anti-Parkinson drugs (digoxin, other cardiac glycosides, guanethidine, methyl dopa), gastrointestinal drugs (antacids, suphasalazine), sleeping pills (chloral hydrate) and the vaccine for tetanus.

Category B: Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed.

Examples are anticonvulsants (carbamazepine), antibiotics (amoxycillin with clavulanic acid, ticacillin, peperacillin, acyclovir), antimalarials, anti-TB drugs, anti-Parkinson drugs (benserazide, biperiden, carbidopa, benzhexol), antipsychotic drugs (pizotifen) and vaccines for cholera, BCG, hepatitis B, typhoid and influenza.

Category C: Drugs which, owing to their pharmaceutical effects, have caused or may be suspected of causing, harmful effects on the human foetus or neonate without causing malformations. These effects may be reversible.

Examples include anti-TB drugs (rifampicin), antihypertensives (metoprolol, propranolol, reserpine), antipsychotic drugs (chlorpromazine, fluphenazine, haloperidol), diuretics (thiazides, frusemide), heart drugs (amiodarone, verapamil, nifedipine), migraine drugs (ergotamine, methysergide), narcotic analgesics (pentazocine, morphine, pethidine), non-steroidal anti-inflammatory drugs (ibuprofen, ketoprofen) and sleeping pills.

Category D: Drugs which have caused an increased incidence of human fetal malformations or irreversible damage. They may also have adverse pharmacological effects.

Examples include anticonvulsants (phenytoin, sodium valproate), antibiotics (gentamicin, kanamycin),

antimalarials (chloroquine), antihypertensives (captopril, enalapril), antipsychotic drugs (lithium), cancer drugs and vaccines for measles, mumps, rubella and poliomyelitis.

Category X: Drugs that have such a high risk of causing permanent damage to the foetus that they should NOT be used in pregnancy or when there is a possibility of pregnancy. Two main examples are skin drugs (etretinate, isotretinoin) and hormones (stilboestrol).

As seen from the above discussion, the number of drugs shown to cause foetal deformities with certainty (Category X) is rather small compared with other categories. However, the rule of thumb of drug use in pregnancy still applies.

But because the examples mentioned can never be exhaustive, it is therefore advisable to check with your doctor before taking any drugs if you are pregnant or planning to have a baby.

In some of these categories where the experience of effects of the drugs in humans are limited, for example in Category B, results of toxicological studies, including reproduction studies in animals are also considered.

However, there may be some variations in the effects of drugs given to pregnant animals compared to that in humans. As such, it cannot be said for certain that drugs tested "safe" in animals will be so in humans. Conversely, a drug may have a teratogenic effect in animals but not in humans.

Thus, the use of drugs in pregnancy and the unborn must be exercised with great care. Also, it is worthwhile to extend this to all types of medications, be it modern or traditional.

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