Posology 2

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Recognize the clinical importance of factors affecting drug dosing.

Rationalize importance of pharmacokinetic changes in hepatic patients.

Identify factors affecting drug dosing in renal patients.

Enumerate teratogenic drugs.

Drugs In Pregnancy

Teratogenic Drug:

Crosses Placenta

&

Causing Fetal Malformations

Drugs In Pregnancy

- **Five** categories were established suggesting the potentiality of causing birth defects according to FDA.
- Drug categories run from the "**category A**" (safest) to "**category X**" (known danger- never used).
- In general, most drugs are contraindicated **unless the potential benefits** of taking the drug outweigh the risks to the fetus or the infant.

Table 1. FDA Drug Risk Classification

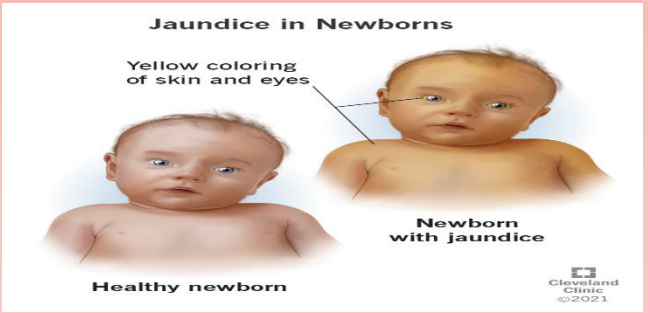
Category	Description
A	Controlled studies in humans show no risk to the fetus
B	No controlled studies have been conducted in humans; animal studies show no risk to the fetus
C	No controlled studies have been conducted in animals or humans
D	Evidence of human risk to the fetus exists; however, benefits may outweigh risks in certain situations
X	Controlled studies in both animals and humans demonstrate fetal abnormalities; the risk in pregnant women outweighs any possible benefit

Source: References 4-7.

Regardless of the pregnancy category or the presumed safety of the drug, **no drug should be administered during pregnancy unless it is clearly needed and the potential benefits outweigh potential harm to the fetus

Fluroquinnolones→ Joint abnormalities& reverse arthropathy.

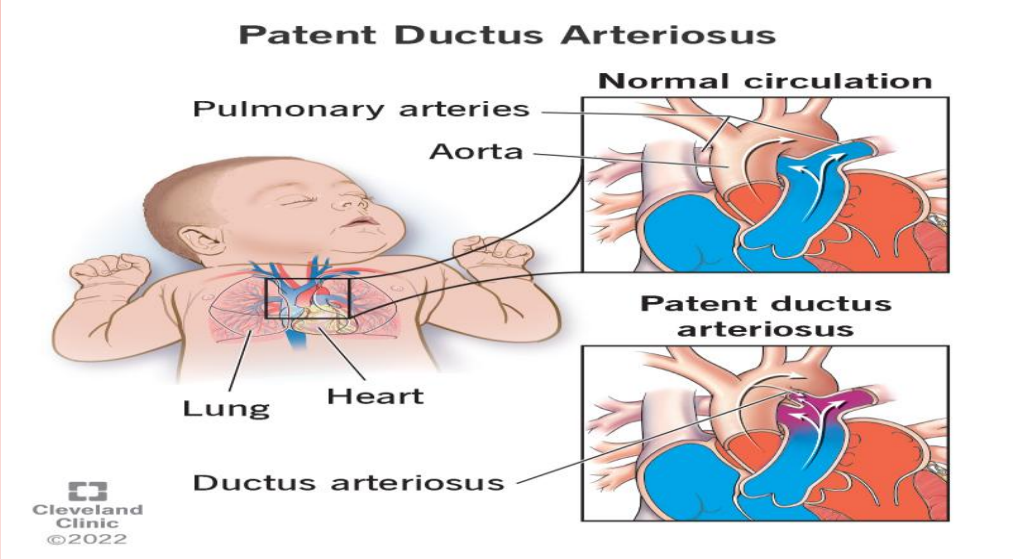
Streptomycin→ Deafness.



Sulfonamides → Jaundice and Kernicterus.

Tetracyclines→Permanent yellow brown discolouration and dysplasia in teeth, deformity and inhibition of bone growth.

Salicylates , Ibuprofen →Bleeding to mother during the delivery and if taken in late pregnancy causing premature closure of ductus arteriosus.

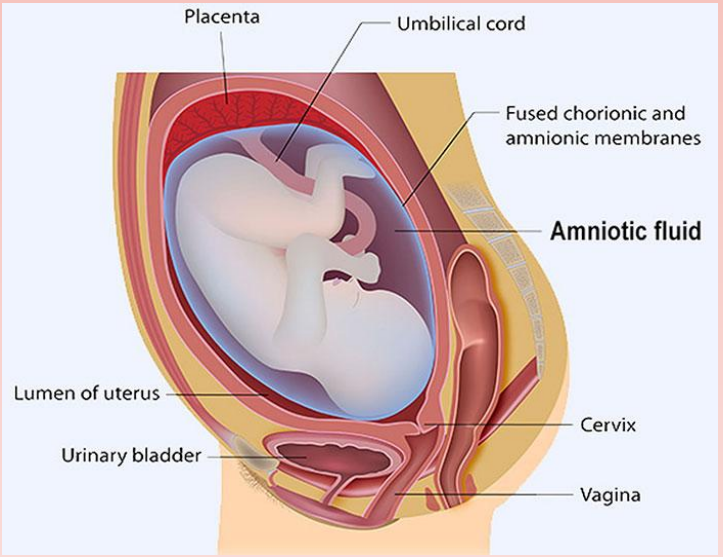


Examples of drugs that may cause teratogenicity :

ACE inhibitors →**Renal failure and oligohydramnios.**

Beta blocker → **Decrease heart rate and hypoglycemia in fetus.**

Thiazide diuretics →↓ **in o2, Na, K and the number of platelets in fetus.**

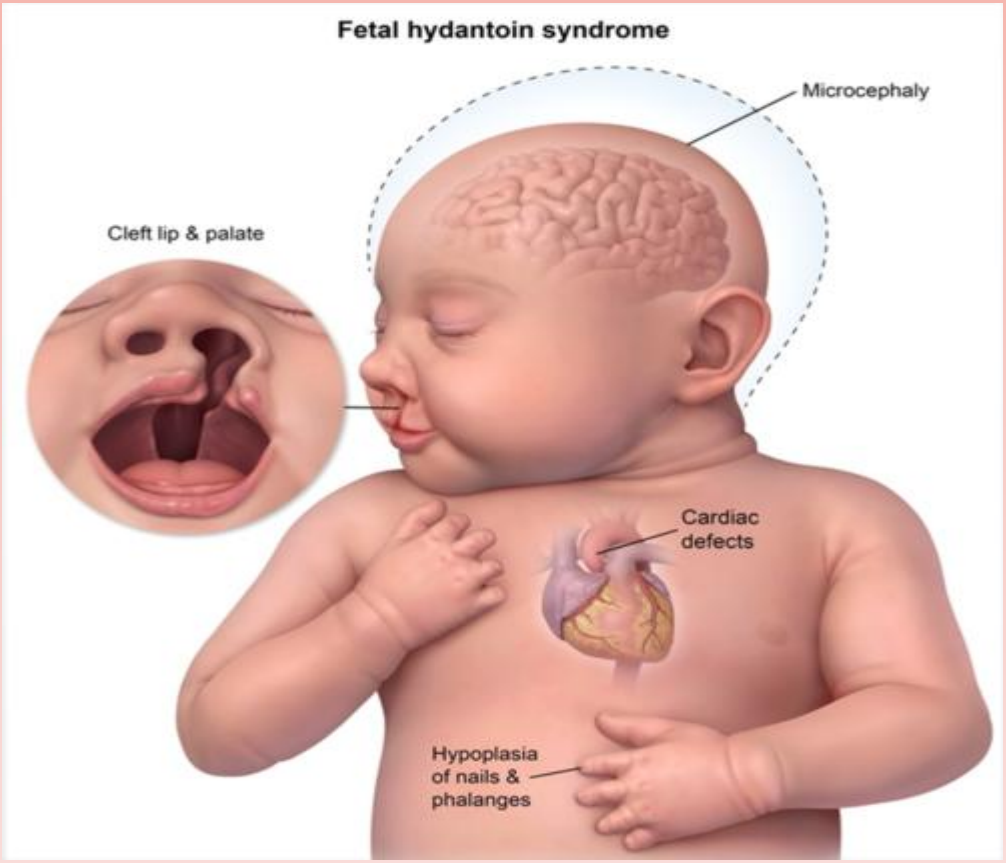


Examples of drugs that may cause teratogenicity :

Warfarin → abnormal bone formation, cutaneous necrosis , haemorrhage in fetus.

Examples of drugs that may cause teratogenicity :

Phenytoin → Fetal Hydantoin Syndrome (Hare lip & cleft palate).



The pregnancy &lactation labelling rule(PLLR)

The Pregnancy & Lactation Labelling Rule (PLLR) - Part 1

- Dec 2014 - Published by FDA to improve the current pregnancy category labelling system.
- Pregnancy category will be gradually phased out for affected drugs.
- Applicable to prescription drugs and biological products (to include in product information)

Source: fda.gov

Factors modifying dosage and action of drugs

Factors modifying dosage and action of drugs

1)Age
2)Sex
3) Body weight and SA
4) Route of administration
5) Super sensitivity

Factors modifying dosage and action of drugs

6) Tolerance:

Decreased or failed response to drugs.

Either ↑ dose of the drug or stop the drug for some time.

7)Hypersensitivity (allergic) reaction:

The drug may act as antigen or combine with hapten and becomes antigenic.

It does not occur on first exposure, and is not dependent on dose.

If allergic reaction occurs **do not use the drug** as this reaction **is not dose-dependent**

Factors modifying dosage and action of drugs

8) Idiosyncrasy = pharmacogenetics:

Definition: Abnormal reaction to drug due to genetic or enzyme defect.

How to avoid: Use low dose or not use the drug, according to the genetic condition.

9) Drug dependence: include:

a- Habituation:	b- Addiction:
- Psychic dependence.	- Psychic and Physical dependence.
- Sudden stop of the drug →Psychic craving for the drug.	- Sudden stop of the drug → Withdrawal (Abstinence) syndrome . Usually the reverse of what the addicting agent does.

Factors modifying dosage and action of drugs

11) Cumulation:

It occurs when the rate of drug administration exceeds that of metabolism and excretion (i.e., elimination). e.g., digoxin.

12) Emotional State (Placebo effect):

-Placebo effects are reactions which are unrelated to the pharmacologic effects of the administered drug.

-They are used to distinguish the pharmacodynamic effects of a drug from the psychological effects of the act of medication.

Factors modifying dosage and action of drugs

13) Drug Combinations:

a. Addition or summation

b. Synergism

c. Potentiation

d. Antagonism

14-Biological variations:

Patients may vary in their response to drugs, affected by Race, Nutritional state, Environmental factors. So, start by low dose and increase gradually.

Questions

Explain:

Warfarin is contraindicated in pregnancy.

Penicillins are classified as category A in pregnancy.


Thank You!