

Legalities in Medical Abortions

Dear Readers,

Season's Greetings !

Research about safety of drugs during pregnancy has many limitations.

Therefore there is always a concern about prescribing drugs for pregnant women even for minor ailments . The article about pregnancy and drug use gives an in depth understanding of pharmacokinetics of drugs in pregnant women. It can be used as a reference document in antenatal clinic.

Medical abortions has revolutionized and simplified abortion process. But practitioners must be careful not to overlook the legalities involved.

Lastly , the article about MVA syringes attempts to give tips regarding care and maintenance of MVA syringes .

Happy Reading !

Your feedbacks and suggestions are always welcome at shamala@fpaindia.org

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Medical abortion has simplified abortion services delivery to merely an outpatient procedure. But as per MTP act amendments in 2003, legalities and responsibilities of an Abortion provider are same as for other abortion procedures. Simplicity of the procedure may cause overlooking the legal fulfillments which should be strictly avoided.

The important legal issues not to be missed in the FPAI SDPs while providing medical abortion services are as follows:

- A registered medical practitioner (RMP as defined by MTP act) only can prescribe medical abortion drugs.
- The procedure site needs to display a certificate of approval from the owner of an MTP certified site that acts as a backup in case of a referral.
- The consent form for MMA needs to have following points clearly mentioned
 - The names of drugs, regime and number of visits required .
 - Need to go for surgical evacuation in case of incomplete abortion.
- During counseling , the following points need to be clearly conveyed to the client in language she clearly understands.
 - The course of treatment and her role in it.
 - Events that will occur during the abortion process and when she must contact doctor as a routine step or as emergency measure.
 - Risk of taratogenesis in case of treatment failure and if client wishes to continue pregnancy
 - Expected side effects and complications
- Client Records required to be maintained at the SDP
 - Consent form signed by the client or her parent/ guardian in case she is a legal minor or mentally ill.
 - Written statement of refusal of surgical evacuation if client refuses surgical evacuation
 - Records of all the procedures and complications if any



Introduction:

No drug can be considered 100% safe to use during pregnancy. Both pregnancy and drugs affect each other. The physiological changes in body because of pregnancy alter the drug metabolism either increasing or decreasing its effect. At the same time the drug may cross the placental barrier and may have teratogenic effects of the fetus. The effect of drugs on the fetus depends on the stage of development of fetus, the dose of the drug, the properties of drug like lipid solubility, molecular weight, pH etc. This article takes a glance at the important issues about prescribing drugs in pregnancy.

Physiological changes during pregnancy and pharmacokinetics:

Two most important physiological changes in body during pregnancy that occur are weight gain and alteration in the metabolism. The weight gain is due to increase in the breast tissue, blood, water in the form of extravascular and extracellular fluid. Body fat and proteins are also increased. The increase in the plasma volume is 20 – 30 % which increases cardiac output and glomerular filtration rate. This actually hastens the clearance of the drugs from the system. Increase in the fats in body increase volume of distribution of fats soluble drugs like carbamazepine. Increase in the plasma albumin levels increase distribution of high protein bound drugs. Due to high progesterone levels in blood, gastric emptying time is decreased particularly in third trimester of pregnancy. This delays the onset of drug effect. Increased blood flow enhances drug absorption through intra muscular route.

Transfer of drugs to fetus:

Placenta is connection between the mother and fetus. Function of the placenta includes nutrition, supply of oxygen, metabolism, hormone secretion and excretion. To have an effect on the fetus, drugs need to cross the placental barrier. The rate of transfer depends on the properties of blood like pH, lipid solubility, molecular weight and protein binding. The transfer rate is relatively lower in first trimester but increases in third trimester because of increase in the size of placenta and blood flow from mother to fetus. The drugs can harm the fetus in various ways. Some drugs act directly on the fetus by interfering the organogenesis and causing birth defects. They alter the function of placenta by constricting blood vessels thus restricting the blood supply and oxygen to the fetus. This causes intrauterine growth retardation or death. Some drugs act on uterus muscles causing forceful contractions which may injure the fetus and cause premature expulsion.

Drug use in pregnancy

Use of drugs in pregnancy should be restricted. But sometimes it becomes necessary to prescribe drugs in case the pregnant women is already on the medications for some pre existing condition or if the woman develops some a new condition for which some medication is needed. Women may experience some morbidities related to pregnancy like vomiting and may need a medicine. In such cases, it is absolutely necessary to know about the drug safety during pregnancy.

Since clinical trials conducted in pregnant women are very few for ethical reasons, the trial based evidences about the safety of drugs are very limited. Many of the drugs are assessed based on indirect evidence based on the studies conducted in the animals.

US Food and drug administration has published categories for labeling medications for potential teratogenic effects.

Category A: Studies in pregnant women show no risk. Examples: Levothyroxine, Potassium Chloride, Folic Acid

Category B: Animal studies show no risk but human data insufficient OR animal data shows toxicity but human studies show no risk. Examples: Ampicillin, Insulin, Budesimide, Vancomycin

Category C: Animal studies show toxicity, human data are insufficient, but clinical benefit may exceed risk. Examples: Albuterol, Heparin, Miconazole, Digoxin

Category D: There is evidence of human risk, but clinical benefits may outweigh risk. Examples: Lithium, Diazepam, Vincristine, Imipramine, Doxycycline

Category X: There is evidence of fetal abnormalities in humans, and risk exceeds benefits. Examples: Ribavirin, Estradiol, Isotretinoin

In India, in spite of many cultural practices commonly seen about prohibiting consumption of certain foods during pregnancy, over the counter or prescription medication is also commonly seen. This is particularly dangerous because India is a hub for diseases like malaria and infectious diseases like gastroenteritis, typhoid, TB etc. It is the responsibility of not only doctors but also pharmacists to counsel any pregnant patient about intake of medicines and give correct and accurate information about drugs clearly mentioning the risks involved. Due precautions must be taken while prescribing medicines to the pregnant clients. The tables following will help while treating any morbidity in pregnant clients in antenatal clinics. Strictly avoid using drugs in C, D and X category for any pregnant woman.

References :

1. Drugs to avoid in pregnancy, H. A. Shehata and C. Nelson-Piercy, Current Obstetrics & Gynaecology (2000) 10, 44-52
2. http://www.clinfowiki.org/wiki/index.php/Medications_to_be_avoided_during_pregnancy
3. Drug Use in Pregnancy; a Point to Ponder, P Sachdeva, B. Patel, and B. Patel Indian J Pharm Sci. 2009 Jan-Feb; 71 (1): 1-7.
4. <http://www.merckmanuals.com/>

FDA categorization of the common drugs

Antibiotics	FDA Category	Anti TB drugs	FDA Category
Amoxicillin	B	Ethambutol	B
Aztreonam	B	INH	C
Cefadroxil	B	Rifampicin	C
Cefazolin	B	Pyrazinamide	C
Cefotaxime	B	PAS	C
Cefoxitin	B	Cycloserine	C
Cefprozil	C		
Ceftazidime	B	Anthelmintics	
Ceftriaxone	B	Piperazine	B
Ciprofloxacin	C	Albendazole	D
Clindamycin	B	Mebendazole	D
Erythromycin	B		
Gentamicin	C	Hormones	
Kanamycin	D	Androgens	X
Nitrofurantoin	B	Estrogens	X
Ofloxacin	C	Progestogens-	
Penicillin	B	Hydroxyprogesterone	D
Streptomycin	D	Medroxyprogesterone	D
Sulfisoxazole	C	Norethindrone	X
Tetracycline	D	Norgestrel	X
Trimethoprim/sulfamethoxazole	C	Thyroxin	A
Antivirals		Antifungal drugs	
Acyclovir	C	Griseofulvin	D
Interferon-alpha	C	Terbinafine	D
		Ketoconazole	D
Asthma drugs		Fluconazole	D
Deriphylline	C	Triazoles	D
Terbutaline	B		
Theophylline	C	Antiemetics	
		Doxylamine	B
Decongestants		Meclizine	B
Pseudoephedrine	C	Cyclizine	B
		Dimenhydrinate	B
Antimalarials		Metoclopramide	B
Chloroquine	C	Domperidone	C
Hydroxychloroquine	C		
Pyrimethamine	C	Amoebicides	
Quinine	D	Metronidazole	B
		Tinidazole	C
Antihypertensives			
Captopril	D	Steroids	
Diltiazem/Diltiazem HCL	C	Methylprednisolone	C
Enalapril/Enalapril Maleate	C (1st trim.) D (2nd, 3rd trim.)	Prednisolone	C
Hydralazine	C		
Methyldopa	C	Antacids drugs	
Metoprolol	B	Alluminium and Magnesium salts	A
Nifedipine	C	Cimetidine, Ranitidine, Famotidine	B
Propranolol	C	Omeprazole	C
Sotalol	B		
Timolol	C	Antimigraine drugs	
Verapamil	C	Sumatriptan	C
		Ergometrine	C

Taking care of MVA syringes

Manual Vacuum Aspirations (MVA) are on rise as they have a distinct advantages over Electric Vacuum Aspirations, especially in limited resource settings. Though advised to use only once, MVA syringe can be used many times if it is very well maintained. The manufacturers allow reuse up to certain number of times proper care of syringes is taken.

- ☞ The cannulae when are in sterile unopened pack can be used till three years after the date of manufacturing provided the packing is kept dry and intact.
 - ☞ New MVA aspirators could be reused from 25- 50 times and new cannulae can be reused for 10 - 20 times if they are properly sterilized and stored after each procedure.
 - ☞ After procedure, aspirator and cannulae must be kept wet for ease to remove the contaminants. They must be completely immersed in 0.5 % sodium hypochlorite solution after procedure . Make sure that the cannulae and syringe is filled completely with the solution
 - ☞ First disassemble aspirator and then clean each part separately.
 - ☞ Use bleach and glutaraldehyde (Cidex) for sterilization as they do not cause any change in the flexibility of cannulae and alteration of markings.
 - ☞ Avoid boiling and steam sterilization changes durability and quality of MVA syringe.
 - ☞ Use soft brushes to clean the instrument. Metal brushes may cause groves which invite contaminants.
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- ☞ If tissue or dried blood is trapped inside the cannulae, flush it with water repeatedly or use a cotton-tipped probe or soft cloth to remove it. Don't use a metal brush.
 - ☞ If all visible matter cannot be removed from inside the cannulae, discard and replace it.
 - ☞ After sterilization or HLD process in Cidex, wash with sterile water. Don't use tap water.
 - ☞ For HLD in 0.5 % chlorine solution, don't use a metal container.
 - ☞ Cannulae should be stored in dry, sterile or HLD containers with tight-fitting lids and protected from dust and other contaminants.
 - ☞ When assembling the aspirator, push the cylinder straight into the valve. Do not twist the barrel or valve when assembling as this will cause the liner to dislodge and may lead to device failure.
 - ☞ When using chlorine to disinfect devices, briefly rinse unassembled parts in clean water after the disinfection process. When chlorine is allowed to dry on the devices, the plunger does not move easily in the cylinder. It may also cause the valve hinges to wear out prematurely.
 - ☞ When a layer of mineral appears on the instrument, Soak it briefly in vinegar and brush with a soft brush as needed; rinse with clean water.
 - ☞ Don't use flash settings in the Autoclave. The instrument may get mis-shapen.
 - ☞ Make sure that the o-ring is properly lubricated each time before use and properly positioned in the groove on the plunger head.
 - ☞ Replace MVA syringe in case of disappearance of markings, non removable tissue, Alteration in shape, grooves on instrument etc.

These tips will help in keeping instrument use to optimum and reducing any chances of infection

*(Taken from Performing Uterine Evacuation with the
Ipas MVA Plus® Aspirator and Ipas EasyGrip® Cannulae: Instructional Booklet)*