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A PERSPECTIVE OF TRADITIONAL MEDICINE (TM) IN REDUCING TRANSPLACENTAL GENOTOXICITY CAUSED BY MODERN MEDICINES

Camellia Roy¹, Suvarna Jayothi Kantipudi¹ and V. Gayathri^{* 2}

Department of CEFTE, Faculty of Clinical Research¹, Department of Centre for Toxicology and Department of Centre for Toxicology and Developmental Research (CEFTE)², SRIHER (DU), Porur, Chennai - 600116, Tamil Nadu, India.

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Correspondence to Author:

Dr. V. Gayathri

Test Facility Management/Head,
Department of Centre for Toxicology
and Developmental Research
(CEFTE), SRIHER (DU), Porur,
Chennai-600116, Tamil Nadu, India.

E-mail: gayathriv@sriramachandra.edu.in

ABSTRACT: The contemporary generation utilizes specific pharmaceuticals to treat ailments, irrespective of their detrimental effects on genetic material. More specifically, the lifestyles of expectant mothers and the medications they come across during pregnancy, such as antiemetic, antacid, antihistamine, analgesic, antibacterial, diuretic, sedative, and other medications, exert a significant influence on the utilization of these drugs. Certain pharmaceuticals require a period of 30 to 60 minutes to reach equilibrium in maternal and fetal circulation, albeit at different concentrations and under varying conditions. Variables, including placental potency, dosage, maternal characteristics, drug efficacy, and gestational age at the time of exposure, contribute to the impact of drugs on the fetus. Notably, during the initial three weeks of pregnancy, a developing fetus is more susceptible than the mother. The National Institutes of Health (NIH) has documented spontaneous abortion, allergies, preeclampsia, gestational diabetes, hypertension, depression, and anxiety, as well as mild to severe functional or metabolic abnormalities as commonly reported complications during pregnancy. This review aims to ascertain the transplacental genotoxicity associated with medications employed for treating allergies and high blood pressure during pregnancy, along with the potential preventive measures using single or polyherbal formulations.

INTRODUCTION: More than half of pregnant women use prescription and over-the-counter (OTC) medications, and the prevalence is rising lately. Absolute necessary medications should only be used during pregnancy, as they may harm fetuses too. Treating diseases with medications is responsible for 2% to 3% of birth defects, probably due to the easy availability of drugs coupled with inadequate health services, self-medications for common complaints, and infective conditions than the prescribed drugs resulting in adverse drug reactions and drug interactions.

Medication prescribed to pregnant women reaches the fetus primarily through the placenta, which serves as the functional link between fetal and maternal blood. The placenta delivers nutrition, respiration, metabolism, excretion, and endocrine activity to maintain the well-being of both mother and fetus. Only unbound drugs can pass through the placenta. Maternal plasma albumin level falls while fetal albumin level rises. As a result, the concentration of free drugs rises, crossing the placenta and reaching the fetus. Drugs are being required frequently for the health of the mother and fetus².

According to the Food and Drug Administration (FDA), drugs classified as A, B, C, D, and X are based on available data from *in-vitro* and animal studies, which frequently may not be favorable to humans until 2015 PLLR came into effect¹. As per

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the NIH report, common complications reported during pregnancy are hypertension, allergies, gestational diabetes, preeclampsia, preterm labor, depression, anxiety, and many more. During organogenesis, drugs that reach the embryo can be a probable cause for subtle or permanent functional or metabolic abnormalities. Estrogen and progesterone influence hepatic enzyme activity, which can affect drug accumulation or elimination³. The most commonly used medications for treating the above-mentioned conditions are anti-hypertensives, antacids, antihistamines, analgesics, antibacterial drugs, diuretics, sedatives, social and illegal drugs, and their usage seems to be high. Hence, our research aims to identify the transplacental genotoxicity of the drugs commonly prescribed during pregnancy for treating allergies and hypertension and the possible preventive approach through traditional medicines. Our research also fills the lacunae in healthcare knowledge about a problem that exists in pregnancy that may be unnoticed because it is considered to have little impact.

Trans-placental Drug and its Prevalence Rate:

During the third trimester, transplacental drug transmission increases due to increased maternal and placental blood flow; decreased thickness, and increased surface area of the placenta⁴. The rate of transfer depends on the chemical properties of the drug such as 5: Protein binding, pH difference, lipid solubility, and molecular weight of the drug (less than 500g/mol). The prevalence rates of various drugs used during pregnancy are figured below³⁸⁻⁴¹:

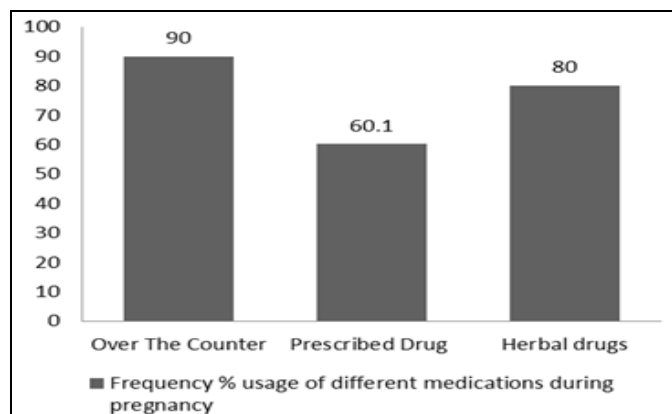


FIG. 1: PREVALENCE RATE OF DIFFERENT DRUGS

In this review, we focused mainly on allergies and hypertension, frequently reported complications

during pregnancy. It has been treated by the patients by their own or rarely through practitioners without considering its complications. Drugs prescribed by practitioners for the ailment of allergies and hypertension during pregnancy are Loratadine (antihistamine) and labetalol (antihypertensive).

According to reports, both drugs have a slight chance of crossing the placenta and are also reported to be found in breast milk because of low molecular weight with a contraindication, that they are not teratogenic^{6, 7}. In other words, it may not cause severe birth defects that are visible to the naked eyes, but it may cause minor defects in the genetic level which may not visible to the naked eyes.

Loratadine (LOR) Treatment: Second generation antihistamine drug falls under category B of FDA for pregnancy with the molecular weight of 382.9 g/mol. According to surveys, the global market of LOR tends to grow by 0.8 percent between 2021 and 2027, reaching USD 148.8 million by 2025, up from USD 144.3 million in 2019, and the Asia Pacific is the fastest-growing market^{8, 9}. However, it has excellent safety data and recommendations in multiple guidelines for other allergic conditions such as asthma and chronic urticaria, so physicians advise the patients to take loratadine during pregnancy. According to reports, Loratadine has inhibited cell cycle arrest in the G2/ M phase of human colon cancer xenografts⁷, was also found to have tumor-inhibiting effects on the human colon carcinoma cell line, eradicating leukemic cells^{10, 11}, causing birth defect of the urethra possibly in sons. As its molecular weight is less than 500g/mol, it diffuses through the placenta. Earlier it has been reported that antihistamines are likely to cause significant DNA damage^{12, 13, 14, 15, 16}. It has kindled us to study that there is a possibility of causing less significant damage to the fetus by Loratadine.

Labetalol Treatment: Labetalol, an antihypertensive beta-blocker with a low molecular weight of 328.406 g/mol used to treat maternal hypertension. According to the FDA label, it has been reported to cross the placental barrier in humans and a small amount in animal studies across the blood-brain barrier. According to the

estimation from surveys, the global market of Labetalol in 2019 has been valued at some USD Billion and is expected to reach some USD Billion by 2027¹⁷. El-Borm *et al.* reported that Labetalol induces histological, ultrastructural changes, severe DNA damage, and apoptosis in fetal heart tissue of pregnant female albino rats when treated orally during the organogenesis phase of gestation from the 6th to 15th day⁶.

Mechanism of Drugs While Pass through Placenta: The blood vessels in the fetuses are in the form of villi (hairlike projections) of the placenta extended into the uterine wall. Mother's blood flows through the space surrounding the villi (intervillous space).

The thin placental membrane separates the mother's blood from the fetus's blood in the villi. Drugs circulating in the mother's blood can cross the transplacental membrane into blood vessels in the villi and diffuse through the umbilical cord to the fetus and the drugs that do not go across the placenta have the probable possibilities to harm the fetus by affecting the uterus or placenta.

How a drug affects a fetus is determined by:

1. The developmental phase of the fetus
2. The strength and dosage of the drug
3. Placental permeability
4. The genetic structure of the mother, which determines the effectiveness of the drug

5. Other aspects like throwing up

The genetic setup and acknowledgment of drugs depend upon variations among individuals that what the body will do to a drug and what the drug will do to the body. Due to their genetic setup, some people metabolize drugs gradually. As a result, the accumulation of drugs in the body causes toxicity. Others metabolize drugs so quickly that even after taking a standard dose, drug levels in the blood never rise sufficiently to make the drug effective¹⁸.

Genetic Alterations/Toxicity caused by Drugs Passing Transplacental Barrier: As mentioned above, genetic composition plays a vital role and, that is why the term genotoxicity is being used to describe the existence of a substance that destroys the genetic material (DNA, RNA) of the cell and thus damages the integrity of the cell. Genetic toxicology is the study of agents or substances that can damage cells, DNA, and chromosomes. It has been noted that the terms genotoxicity and mutagenicity are often confused. All mutagens are genotoxic, but not all genotoxic substances are mutagenic¹⁹. According to their role, gene toxins are divided into the following categories²⁰:

Carcinogens: Substances that cause cancer.

Mutagens: Substances that cause mutations, and

Teratogens: Factors that cause birth defects.

The genotoxicity risk is shown in the figure below²¹:

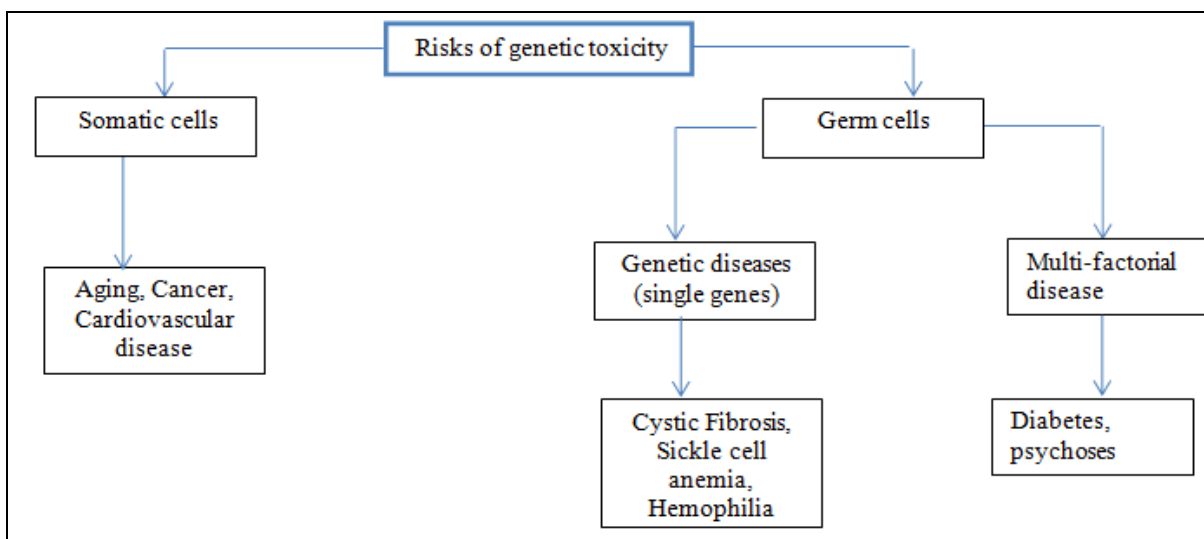


FIG. 2: RISK OF GENETIC TOXICITY

Importance of Genotoxicity Studies and its Mechanism of Action: Genotoxicity studies are conducted to assess the safety of one or more compounds, which can directly or indirectly damage the genetic material through various drugs or new compound mechanisms. There are many *in-vitro* and *in-vivo* tests that can be used to identify hazards associated with DNA damage and immobilization. These changes can be manifested as genetic mutations, chromosomal structural aberrations, recombination, and quantitative changes. When positive, these tests help predict whether the compound has the potential to cause genotoxicity and carcinogenicity^{21, 22}.

The genotoxic substances interact with the DNA structure at a specific location or base sequence, resulting in lesions, breakage, fusion, deletion, mis-segregation, or nondisjunction, and thus causing damage and mutation. The combination of placenta and genotoxicity results in transplacental genotoxicity, a rare route of exposure investigated for drugs or compounds. One of the classic problems in medical treatment is that certain drugs or medication prescribed during pregnancy may be harmful to the unborn child directly or indirectly, which can be witnessed later in lifespan.

Alternative/Preventive Approach: According to World Health Organization (WHO), traditional medicine (TM) refers to health practices, methods, knowledge, and beliefs, including plant, animal, and mineral-derived medicines, psychotherapy, manual techniques, and exercises, used alone or in combination to treat, diagnose, and prevent diseases or maintain health. As we all know, 65% to 85% of the world's population use herbal medicine as their main form of healthcare. The prevalence of herbal use during pregnancy ranges from 12% to 82.3%. Some of the commonly used herbs during pregnancy are Ginger, garlic, raspberries, blueberries, valerian, chamomile, peppermint, and fenugreek. Use of herbal medicine during pregnancy may be mild harm to the fetus at first three months and the end of the third trimester but there were no relevant supporting evidence for this controversial statement^{23, 24, 25}. Purpose of this review is to inform the healthcare system about TM and conventional medications used to treat certain pre-existing conditions or diseases that occurred during pregnancy (such as high blood pressure).

Traditional Medicines for Treating Allergies during Pregnancy: Sneezing, sniffing and itchy eyes began during pregnancy. TM like haldi, cinnamon, black pepper etc., having an anti-allergic effect. It helps to stop sneezing and reducing nasal congestion and postnasal drip. Some of the ayurvedic drugs prescribed, are commercially available and approved by physicians for treating allergies during pregnancies²⁶⁻²⁸.

Haridrakhand is an Ayurvedic medicine that is highly effective for allergies such as allergic skin diseases, itching skin diseases, blisters, pruritis, allergic hives, allergic rhinitis, and other similar conditions. During pregnancy and lactation, practitioners advise taking a lower dose. Haridra Khand contains the following ingredients: turmeric, cow ghee, and milk, sugar candy mixed with pepper, long pepper, ginger, cinnamon, cardamom, tej patta, Emelia Ribes, Indian Jalap, haritaki, baheda, Indian gooseberry, nagakesar, nutgrass, and Loha Bhasma³¹.

Sitopladi churna /shithopala an effective ayurvedic medicine for the treatment of respiratory diseases, digestive problems, and allergic disorders. Antihistaminic properties in sitopaladi churna have been shown to inhibit the release of inflammatory mediators and control various allergy symptoms. The sitopladi churna is made by combining the right proportions of ingredients such as Mishri, Vanshalochan, Indian long pepper, cardamom, and cinnamon³².

Phala sarpi is an ayurvedic classical medicated ghee given throughout the pregnancy to maintain pregnancy as well to fulfill nutritional demands³³.

Chawanprash rasayana is a delicious and nutritious jam that is high in nutrients. Chawanprash contains sesame oil, ghee, honey, sugar, amla, and a few other herbs, and it is high in Vitamin C. Although sufficient scientific evidence is lacking, Chyawanprash may be beneficial in the treatment of allergic reactions. It is because antioxidants with anti-allergic properties are present^{34, 35}.

Cinnamon contains antioxidants like polyphenols, which help your body fight free radicals, which damage cells and cause illness. Antioxidants can strengthen your immune system and protect you

from bacterial and fungal infections³⁶. Black pepper has medicinal properties and is beneficial for health. It is probably safe to consume in moderate amounts during pregnancy. Black pepper is high in vitamins C and K, as well as minerals like iron, calcium, magnesium, potassium, and copper. It also contains a lot of antioxidants. Having a cold or cough during pregnancy and taking cold and cough medications is not advised because they may interact with pregnancy medication and cause side effects. However, adding pepper to food can help relieve cold symptoms³⁷.

Traditional Medicines for Treating Hypertension During Pregnancy: Pregnant women can use TM as a supplement or alternative medicine to lower blood pressure such as *Rauwolfia serpentina* (L.), buchu *Agathosma betulina*, garlic (*A. sativum* L.), black or green tea *Camellia sinensis* (L.) or Roselle (*Hibiscus sabdariffa* L.). In the human body, labetalol undergoes extensive metabolic changes in the gut and liver.

UGT1A1 and UGT2B7, are the main route of the elimination of labetalol. The potential impact of TM on conventional drugs is not known yet. Few Traditional medicines prescribed are commercially available and approved by physicians for treating hypertension during pregnancy^{29,30}.

Arjuna Tab: Arjuna, also known as the "Arjun tree" in India, is known for its anti-inflammatory, antioxidant, and antimicrobial properties. In studies, it has been stated that it reduces the risk of cardiovascular disease and promotes proper heart function by strengthening and toning the heart muscles. The Arjuna tree also has potent anti-hypertensive properties that can help with hypertension treatment. Because there is a lack of reliable information about the use of Arjuna during pregnancy, it is best to consult a doctor before using it.

Lashuna: Garlic provides the body with a variety of nutrients, vitamins, and minerals, as well as acting as a natural antibacterial agent. It regulates blood flow and hormonal function in the body. It contains allicin, which effectively fights various germs and viruses in the vessels. Garlic's toxicity is determined by the amount consumed, so while garlic is completely safe to consume during the first

trimester, pregnant women should be cautious about the amount they consume during the later stages of pregnancy, particularly during the final months.

Brahmi: All over the world, the perennial herb '*Bacopa monnieri*' is used in traditional medicine. Many people call it water hyssop or herb of grace, but the most common name is Brahmi. Because of its high concentration of valuable triterpene saponins and alkaloids, which have powerful effects on the human body, and have numerous health benefits. There are many organic compounds and volatile constituents as well. Chewing 2-3 Brahmi leaves at a time is said to relieve stress and anxiety. Consumption of Brahmi lowers cortisol levels in the body, which is a stress hormone. Brahmi relieves stress and leaves you feeling relaxed and at ease. It can be consumed for a short period, ranging from 2-4 weeks during pregnancy.

Shankhapushpi: also known as *Convolvulus pluricaulis*, is a perennial plant native to India. This medicinal herb, also known as morning-glory, speed wheel, or Aloe weed in English, has arrowhead-shaped leaves and bulb-shaped blue or white flowers. The herb is extremely beneficial and is used from root to tip for a variety of therapeutic benefits. The magical herbal remedy contains a plethora of active constituents, including alkaloids such as shankhapushpine, convolvuline, convolidine, convolvine, convolamine, convoline, confoline, and convozine. Other ingredients include volatile oils, fatty acids, fatty alcohols, hydrocarbons, palmitic acids, linoleic acids, myristic acids, flavonoids, steroids-phytosterols, D-glucose, maltose, sucrose, starch, rhamnose, and other carbohydrates, proteins, and amino acids. Shankhapushpi's active ingredients make it an effective treatment for people who have high blood pressure or hypertension. It prevents artery hardening, or atherosclerosis, lowering the risk of strokes and heart disease. Shankhapushpi is an excellent natural remedy for hypertension.

Sarpagandha vati: It is an ayurvedic medication used to treat people with high blood pressure. Sarpagandha (Ghan Satva), Khurasani Ajavain (Ghan Satva), Jatamansi (Ghan Satva), Vijaya (Ghan Satva), and Pippali Mool are the main ingredients in sarpagandha churna.

Amalaki: When ripe, amla is a bright green fruit that looks like a lemon and has a sweet-and- sour flavour. Because the fruit is high in nutrients, especially Vitamin C, it is an excellent antioxidant. Amla is a key ingredient in many Ayurvedic medicines and should be consumed by pregnant women. Because of its high vitamin and fibre content, it is an excellent choice for pregnant women. Amla's high vitamin C content causes blood vessels to dilate, which aids in the maintenance of normal blood pressure.

CONCLUSION: In summary, this review details the transplacental genotoxicity caused by prescribed modern drug during pregnancy. In order to reduce its impact and achieve a greater impact on society, we recommended the traditional medicines or preparations together or separately with these medicines shall be considered, so as to fill the gaps in the knowledge about the genetic toxicity of medicines prescribed while pregnancy and to improve the quality of life of next generation.

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