



IMPACT OF PHARMACEUTICAL USE DURING BREASTFEEDING ON INFANT HEALTH, OUTCOMES AND MATERNAL WELL BEING

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ABSTRACT

In the present study, the influence of pharmaceuticals consumption on pregnancy and the infant and the prevalence of use of these pharmaceuticals among pregnant and lactating women was evaluated through a cross sectional study conducted among 234 breastfeeding women who had consumed any kind of medication during their pregnancy or lactation. The study revealed that 75.2% of them were unaware about the adverse effects of the drugs used on the infant. Most of these medications were prescribed by the medical practitioners themselves, however only 44.9% of the women were made aware about the adverse effects by them. 70% of the women had taken the medication during the first trimester itself.

KEYWORDS: Pharmaceuticals, Lactation, Adverse Effect, Infant, First Trimester

There has been a consistent rise in the number of women entering pregnancy with preexisting comorbidities which only translates to more number of pregnant women with increased exposure to different pharmaceuticals. Evolution in obstetric practices and its knowledge has also contributed to an increase in medication use during pregnancy in general. However, there still remains a gap in our knowledge of the impact of different pharmaceuticals use on the pregnancy considering the change in pharmacokinetics and pharmacodynamics of the drugs during this phase. It is also proven that all the drugs enter breast milk in some or more amounts. It only seems reasonable to also mention here about the lack of awareness about the adverse effects of the drugs during pregnancy and lactation among the general population.

Consumption of unsafe or teratogenic drugs could result in multiple congenital defects such as warfarin is known to cause Disala syndrome, ACE inhibitors and ARBs causing oligohydramnios and NSAIDS are responsible for causing many developmental defects. The dosage and the timing of the medicine consumption also carries much significance as the first trimester is the period of organ development, hence the fetus is most susceptible to the teratogenic effects of any drug. At the same time insufficient or incorrect information about the side effects of the drugs which are actually safe enough to be prescribed during pregnancy or lactation could lead to discontinuation of the breastfeeding by these women. These factors could significantly affect the well being of both the mother and the infant.

Good antenatal care results in a favorable pregnancy outcome. Hence, the role of medical practitioners becomes the most important one in educating the people about the pharmaceutical use and their impact on the health of the baby. The healthcare practitioners are considered to be the most trusted source of information about the use of medications. Considering there are very few studies about the use of medications during lactation and their impact among Indian women and children, this study aims to fill those knowledge gaps and improve the outcome of pregnancy. This will also encourage the healthcare professionals to educate the mothers about the harmful effects of pharmaceuticals on the infant's health and motivate them to remain vigilant regarding the appropriate growth and well being of their children. (Devkota *et al.*, 2017; Kamuhabwa and Jalal, 2011; Lupattelli *et al.*, 2014)

MATERIALS AND METHODS

A cross sectional study was conducted among 234 breastfeeding women attending Primary Health Centres, Community Health Centres, and Tertiary Care hospitals of Mysuru, Karnataka. The study duration was of 3 months from April to July 2024.

Sample size was calculated

$$Z=1.96 \quad P=81.2 \quad Q=(1-P) \text{ which is } 18.8, \quad d=5\%$$

So $(1.96*1.96*81.2*18.8)/5*5$ is 234 breastfeeding women.

Criteria

The Inclusion criteria consisted of women with history of any pharmaceutical use during pregnancy or

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lactation. Pharmaceuticals such as Iron, calcium, folic acid supplements that are prescribed in every pregnancy were excluded from the criteria.

The data was collected through a Google form questionnaire which was then filled for the participants.

Questionnaire

The questionnaire comprised biographical details about the age, education attained, occupation, and monthly family income to determine their socioeconomic class. The important events during time of the pregnancy such as gravidity, parity, type of delivery and Caesarean section, assistance, anaesthesia, complications during pregnancy, gestational age were asked. The details about the infant such as gender, breastfeeding, use of formula, donor milk, any hospital admission, or death were also discussed. The time of the consumption of the medications was segregated into the different trimesters, and the type, the prescriber and the frequency of the medicine used, in each and its adverse effects were asked.

RESULTS

48.3% of participants in this study belonged to the age group of 26-30 years and 58.1% participants belonged to the upper lower class according to the Modified Kuppswamy scale.

Among these participants, 47.4% of the women were primigravida. 34.2% of the women suffered from some type of pregnancy related complication out of which 9% had preeclampsia.

66% of the women had a cesarean delivery, most of them (44.8%) secondary. 55.1% of the babies

delivered were female. The range of the gestational age varied from 36 weeks to 41 weeks with average being 37-38 weeks. The average weight of the babies born varied from 3.2 kgs to 4 kgs. 20.9% of the babies born were admitted. Neonatal deaths accounted for 0.4%.

64.5% of the women started taking the medication during pregnancy itself. 13.7% had been taking the medicine before more than 1 year of pregnancy. 8.5% of the participants started taking medicine after the delivery. 52.6% continued the medication throughout the lactation while 29.5% of these people stopped taking the medication before starting with breastfeeding, rest stopped while they were breastfeeding their babies.

Maximum amount of medications prescribed were by the obstetricians- 53.8% to the patients who developed some kind of pregnancy related complications or other medical conditions during pregnancy, followed by the general practitioners -39.3% who prescribed the medicines to the women who had been suffering from some time of medical illness before pregnancy.

3% of the women did not start breastfeeding shortly after delivery due to extreme weakness or mostly to avoid any side effects of the medication they took during pregnancy or lactation. Use of the medication influenced 14.1% of the women’s decision to breastfeed their babies. 4.3% of the infants were fed formula. 1.7% of the babies were also fed donor milk.

1.7% of the mothers reported some kind of ill effects of the medication on their child.

Table 1: Medications taken and their side effect known to the participants on the baby during pregnancy/lactation

Medication Taken	Medical Condition	Side Effect Known
Thyronorm	hypothyroidism	no side effects
Labetalol	hypertension	no side effects
Promethazine	Hperemesis gravidarum	Drowsiness
Paracetamol	Fever and headache	Developmental defects
Metformin	Diabetes	No side effects
Aspirin	HELLP syndrome	Kidney defects
Hydrocortisone cream	Rash	no side effects
Propylthiouracil	Hyperthyroidism	Birth defects
Loperamide	Constipation	Birth defects
Domperidone	Hyperemesis gravidarum	No side effects
Pheniramine	Hyperemesis gravidarum	Drowsiness
Metoclopramide	Hyperemesis Gravidarum	no side effects
Cetizine	Cold	Drowsiness
Glimiperide	diabetes	no side effects
Ursodeoxycholic acid	cholestasis of pregnancy	no side effects
ciplox	conjunctivitis	birth defects

Ranitidine	acid reflux	no side effects
Amoxicillin	UTI, throat infection	low birth weight
Ondansetron	Hyperemesis gravidarum	no side effects
Ofloxacin	Stomach infections	low birth weight
Azithromycin	throat infection	birth defects
Pantoprazole	acid reflux	no side effect
Cefuroxime axetil	UTI	diarrhoea
Salbutamol	Asthma	no side effects
Clomiphene	infertility	structural malformations
Flavoxate	frequent micturition	poor weight gain
Carbimazole	hyperthyroidism	congenital malformation
Enoxaparin	HELLP syndrome	no side effect
Prednisolone	infection	low birth weight
Nifedipine	hypertension	no side effects
Levocetirizine	cold	drowsiness
Metronidazole	bacterial vaginosis	low birth weight
Diclofenac	backache	premature birth
Warfarin	HELLP syndrome	birth defect
Cefixime	UTI	no side effect
Levetiracetam	epilepsy	birth defects
Escitalopram	Depression	heart defects
Fluoxetine	Depression and anxiety	no side effect

Table 2: Side effects of the medications known to the participants

Side Effects Known	Percentage
Congenital defects	14.4%
Breathing difficulty in baby	1.8%
Poor feeding	1.8%
Diarrhea	1.8%
Drowsiness in baby	14.4%
Heart defects	1.8%
Hiccups in baby	1.8%
Kidney dysfunction in baby	1.8%
Poor weight gain	1.8%
Rash	7.2%
No side effects	52.6%

75.2% of the study population was unaware about the side effects of the medicine they consumed. According to 52.6% of the people there were no side effects of the medicine they took on the baby. 65% of the women claimed that they were advised on medication use during pregnancy by the medical practitioners, mostly the obstetricians-97.4%. ASHA, ANM, AWW did not play a significant role in offering the same advice to pregnant women. 0.9% had taken some unknown ayurvedic medicines.

Table 3: Medications taken before pregnancy by the participants

Medication Taken (Before Pregnancy)	Percentage
Amlodipine	1.6%
Carbimazole	4.8%
Clomiphene	1.6%
OCP	1.6%
Epilive	1.6%
Escitalopram	3.2%
Glimiperide	1.6%
Levetiracetam	1.6%
Metformin	9.7%
Nicardia	1.6%
Nifedipine	1.6%
Propylthiouracil	4.8%
Salbutamol	1.6%
Thyronorm	62.5%

26.9% of the women had been taking some kind of medicine before pregnancy out of which thyronorm alone accounted for 62.5% taken for hypothyroidism, followed by Metformin (9.7%) for Diabetes mellitus and then Labetalol-4.8%.

Table 4: Medications taken during first trimester by the participants

Medication Taken (1st Trimester)	Percentage
Amoxicillin	1.2%
Ampicillin	0.6%
Aspirin	3%
Carbimazole	1.8%
Cefuroxime	1.8%
Cetirizine	1.2%
Ciplox eye drops	1.2%
Diclofenac	1.2%
Domperidone	2.4%
Fluoxetine	0.6%
Escitalopram	1.8%
Glimiperide	0.6%
Labetalol	15.7%
Levatoracetam	1.2%
Levocitrazine	0.6%
Loperamide	0.6%
Metformin	9%
Metoclopramide	1.8%
Metronidazole	0.6%
Nifedipine	0.6%
Ofloxacin	1.2%
Ondansetron	1.8%
Paracetamol	4.8%
Promethazine	3.6%
Propylthiouracil	1.2%
Ranitidine	2.4%
Salbutamol	0.6%
Terbutaline	0.6%
Thyronorm	34.3%
Ursodeoxycholic acid	1.2%

70.9% of the women took some medicine in the first trimester. Thyronorm for hypothyroidism was the most consumed medicine out of all (34.3%) followed by labetalol by 15.7% for pregnancy induced hypertension. Other common medications consumed were Metformin, Paracetamol, Promethazine, Aspirin and Domperidone.

Table 5: Medications taken during and after the second trimester by the participants

Medication Taken (2nd Trimester)	Percentage
Amoxicillin	0.15%
Amoxiclav	0.15%
Aspirin	0.15%
Azithromycin	0.30%
Carbimazole	0.45%
Cefixime	0.15%
Cefuroxime axetil	0.15%
Cetirizine	0.45%
Ciplox eye drops	0.15%
Warfarin	0.15%
Diclofenac gel	0.15%
Escitalopram	0.45%
Flavoxate	0.45%
Fluoxetine	0.15%
Glimiperide	0.15%
H.Mixtard injection	0.15%
Hydrocortisone cream	0.45%
Labetalol	20.6%
Levatoracetam	0.30%
Levocitrazine	0.15%
Loperamide	0.45%
Metformin	11.6%
Nifedipine	0.15%
Ofloxacin	0.15%
Ondansetron	0.15%
Pantoprazole	0.45%
Paracetamol	1.2%
Propylthiouracil	0.45%
Ranitidine	0.30%
Salbutamol	0.30%
Thyronorm	37.6%
Ursodeoxycholic acid	0.30%

80.3% of the study population consumed medication after the second trimester. Most common again being Thyronorm, taken by 37.6% of the population, labetalol by 20.6%, Metformin by 11.6%, Paracetamol by 4.2%, and after that Carbimazole, Propylthiouracil, Loperamide, Flavoxate, and Hydrocortisone cream, all accounted for 1.6% each of the medication consumed. They were mostly prescribed by the obstetricians (66.1%) followed by the General practitioners (43.4%).

DISCUSSION

From this study, out of a sample size of 234 women who had used a medication during pregnancy or lactation, 64.5% of the participants had started taking the drug during pregnancy itself. 26.9% of the participants had been taking the medication before pregnancy due to some chronic illness, most commonly being hypothyroidism. Hypothyroidism was also one of the major reasons for the women who had started taking medication during pregnancy. Other reasons being pregnancy related complications such as Pregnancy induced Hypertension, HELLP syndrome, Gestational Diabetes Mellitus and Hyperemesis gravidarum. This is in contrast to the study conducted by A Lupattleli *et al.*, which mentioned that 68.4% of the participants used medication for an acute illness during pregnancy and only 17% used it for some chronic disorder. (Banzal *et al.*, 2017)

In this study, the study population mostly comprised women in the age group of 26-30 years. Majority (31.2%) had attained a high school certificate whereas 12.8% of the population was illiterate. It was found that most of the women who were aware about the side effects of the medication they were using, belonged to upper middle or lower middle class according to modified Kuppuswamy scale and had attained either a graduate certificate or a post high school diploma. (Ogechi and Chibueze, 2023)

75.2% of the participants were unaware of the side effects of the medicine that they were using. According to the people who knew about the side effects, they claimed there were no side effects of the medication as per what the prescribing medical practitioners told them. This is in line with some similar conducted by others. Banzal *et al.*, 2017 had conducted a study on assessment of awareness amongst pregnant women about effects of pharmaceutical use on fetus and reported that 91% of the women out of the study population of 200 were unaware about the impact of pharmaceutical use on the pregnancy and the fetus and they did not even inquire from the prescribing physicians about the same. (Patel *et al.*, 2016; Rangwala *et al.*, 2021)

In this study only 44.9% of the people were informed about the side effects of the pharmaceutical use during pregnancy. This highlights the urgent need to address this problem. The medical practitioners should be encouraged to rightly inform all the patients about the side effects of the medicine they are prescribing and should also educate the women about harmful effects of pharmaceutical use during pregnancy. A similar study by Rangwala *et al.*, 2021, reported that 95.7% of the

participants out of the 303 women were not familiar with the harmful effects of pharmaceutical use during pregnancy on infants.

1.7% of the women took the medicine by self while the rest relied on medical practitioners for the prescription. This is in contrast to the study conducted by Banzal N *et al.*, where they claimed that 8.5% out of the study population of 200 had practiced self medication. In another study on medication use during pregnancy in Nigerian women, conducted by Ogechi C.Obi, it was found that 73% of the women relied on the medical practitioners for the prescription of the drugs. Every woman should be advised against self medication during pregnancy on the first antenatal visit itself. A thorough medication history should be taken and the impact of the medication on the fetus as well as the mother's well being should be considered before proceeding further. Pregnant might demand a change in dose or the class of drug being used or it might become imperative to stop with it altogether before continuing the pregnancy. (Soussan *et al.*, 2014)

14.1% of the women's decision to initiate breastfeeding was influenced by the history of pharmaceutical use by them during the pregnancy. 1.7% out of the 97% women who initiated breastfeeding claimed that they stopped breastfeeding in the middle due to medication use but resorted to resumption after some time. This is in contrast to the study by Maria de Ward where one third of the participants did not initiate breastfeeding out of the fear of suspected side effects of the drugs. Since breastfeeding forms a very integral part of any good antenatal and postpartum care given, it becomes all the more important to give accurate information about the drugs administered to the patient to avoid unnecessary discontinuation of breastfeeding. Women and their family should also be encouraged to inquire about the side effects of every medication they are prescribed. (Waard *et al.*, 2019)

1.7% of the women reported that there were some kind of ill effects on the infant due to exposure to the medication they used. Common ill effects mentioned were poor weight gain and poor feeding.

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