



DRUG USE PATTERN AMONG LACTATING WOMEN IN A TERTIARY CARE TEACHING HOSPITAL

Pallavi Priya P^{*1},
Rajesh K¹,
Purushothama Reddy K¹,
Ravindra Reddy K¹,
Rama Devi V²

1. Department of Pharmacy Practice,
P. Ramireddy Memorial College of
Pharmacy, KADAPA-516003,
A.P, India.

2. Assistant professor,
Department of Obstetrics and
Gynaecology, RIMS, Kadapa.

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ABSTRACT

The present study was to analyze the prescribing pattern of drugs in lactating women. A Prospective, Observational study was conducted in department of obstetrics and paediatrics at 750 bedded multi-disciplinary tertiary care teaching hospital. 90 lactating women were followed during their hospital stay. A total of 452 drugs are prescribed to lactating women, which are classified based on WHO, UNICEF classification and the prescribing frequency of drugs was studied based on Pharmacological class. Majority of the drugs prescribed are safer, compatible with breast feeding such as nutritional supplements followed by antibiotics. Pharmacist should play an important role in surveillance programme, should collect extensive information on drugs safety and its effects and provide the information to prescribers.

Keywords: Prescribing pattern, Obstetrics, Paediatrics, Breastfeeding, Compatible.

INTRODUCTION:

The study of prescribing pattern is a component of medical audit which seeks monitoring, evaluation and necessary modifications in the prescribing practices of the prescribers to achieve rational and cost effective medical care. Thus the monitoring of prescription and drug utilization studies can identify the problems and provide feedback to prescribers so as to create awareness about irrational use of drugs.¹ WHO recommends mothers worldwide to exclusively breastfeed infants for the child's first six months to achieve optimal growth, development and health.² Breast feeding is the best method of feeding neonates and young infants. Many mothers are likely to need to take medications of some point during lactation.³

Prescribing medicines to a breastfeeding mother may lead to untimely cessation of breastfeeding or a breastfeeding mother may be denied medicines due to the possible risk to her infant. Both of these situations may lead to poorer outcomes for mother and/or child.⁴ Several studies confirm that among the factors that lead to early weaning are problems related to the risk of infant exposure to maternal medications. Moreover, the information contained in drug package inserts and the scientific evidence regarding medication use during breastfeeding is often inconsistent.⁵ Often there is a need to decide whether a mother who is breastfeeding and who needs treatment with drugs can take the necessary medication and still continue breastfeeding safely. There are very few kinds of treatment during which breastfeeding are absolutely contraindicated. However, there are some drugs which a mother may need to take which sometimes cause side-effects in the baby.⁶

Address for correspondence

P. Pallavi Priya
Pharm.D (P.B-Intern),
P. Ramireddy Memorial College of Pharmacy,
KADAPA-516003, A.P, India.
E-mail:pallavipokkalla@gmail.com
Contact-09676301357

ACCORDING TO WHO & UNICEF CLASSIFICATION OF DRUGS FOR BREASTFEEDING:

1. **Compatible with Breastfeeding:** Drugs are classified as compatible with breastfeeding if there are no known or theoretical contraindications for their use and it is considered safe for the mother to take the drug and continued breastfeed.

2. **Compatible with breastfeeding & Monitor infant for side-effects:** Drugs are classified in this way if they could theoretically cause side-effects in the infant but have either not been observed to do so or have only occasionally caused mild side-effects. Inform the mother about any possible side-effects, reassure her that they are unusual and ask her to return if they occur or if she is worried, if side-effects do occur, stop giving the drug to the motherland if necessary find an alternative. If the mother cannot stop taking the drug, she may need to stop breastfeeding and feed her baby artificially until her treatment is completed. Help her to express her breast milk to keep up the supply so that she can breastfeed again after she stops taking the drug.

3. **Avoid if possible & Monitor infant for side-effects:** Drugs are classified in this way if they have been reported to cause side-effects in the infant, especially if the side-effects could be serious. Use these drugs only when they are really essential for the mother's treatment and when no safer alternative is available. Allow the mother to continue breastfeeding but give her clear instructions about observing the baby and arrange for frequent follow-up. If side-effects occur, stop the drug. If it is not possible to stop giving the drug, stop breastfeeding and feed the baby artificially until treatment is completed. Help her to express her breast milk to keep up the supply so that she can be breastfeed again after stops taking the drug.

4. **Avoid if possible & May inhibit lactation:** Drugs classified this way may reduce breast milk production and if possible they should be avoided. However if a mother has to take one of these drugs for a short period, she does not need to give artificial milk to her baby. She can offset the possible decrease in milk production by encouraging her baby to suckle more frequently.

5. **Avoid:** Drugs are classified in this way if they can have dangerous side-effects on the baby. They should not be given to a mother while she is breastfeeding. If they are essential for treating the mother, she should stop breastfeeding until treatment is completed. If treatment is prolonged, she may need to stop breastfeeding altogether. There are very few drugs in this category apart from anticancer drugs and radioactive substances.⁶

For various reasons, antibiotics are one of the commonest groups of drugs prescribed to postpartum mothers. This trend is noticeable both in developing and developed countries. Besides the obvious immediate side effects and adverse reactions of inadvertent medication to babies, some drugs also have long term effects on infant growth and development. Premature babies, with more vulnerable renal and hepatic systems, are at greater risk than term babies. Thus, when viewed as a whole, administration of drugs to breast feeding mothers is an important issue and merits a closer look.⁷

OBJECTIVES:

- To evaluate the safety category wise prescribing pattern of drugs in lactating women (according to WHO & UNICEF).
- To study the prescribing frequency of drugs in lactating women according to pharmacological class.

RESEARCH METHODOLOGY:

Place of Study: A Prospective observational study was carried out in the 'Department of Obstetrics and Paediatrics' IP and OP at Rajiv Gandhi Institute of Medical Sciences (RIMS), Kadapa, a 750 bedded multi-disciplinary tertiary care teaching hospital. The study was approved by the Institutional Ethics and Research Committee of Rajiv Gandhi Institute of Medical Sciences, Kadapa (RC.No. 413/Acad./2011-12).

Period of study: 6- months.

Study population: 90 lactating women.

Patient enrollment: Patients are enrolled in the study based on inclusion and exclusion criteria,

a. Inclusion criteria: Lactating women's who visited IP & OP departments of the obstetrics and paediatrics along with their nursing infants were included in the study.

b. Exclusion criteria: Lactating women's who are not following regular medications and with significant systemic failure (hepatic and renal) disease, HIV, Hepatitis were excluded from the study.

METHOD OF STUDY:

The data for the present study was collected by “**Patient interview/OP sheet verification**” and “**Chart Review Method** “. All the necessary and relevant baseline information was collected on a “**Patient data collection proforma**”, which includes patient demographic like age, socio-economic status, family income, educational status, past and present medical / medication history, lab investigation data, physician medication order sheet and any other verbal communication data with patients.

STATISTICAL ANALYSIS:

Different categories of drugs prescribed for lactating women based on safety categories (WHO & UNICEF) was observed based on column statistics by using software Graph pad prism.

RESULTS:

During the study period the following results are analyzed. On age distribution in 90 lactating women, 17 members were below 20 years, 42 were between the ages of 21-25 years, 27 were between the age of 26-30 years and 4 were between the age of 31-35 years.

Based on economic status, 11 were very poor of earning <Rs.2000/-per month, 45 were poor of earning Rs.2100-5000/-per month, 24 were moderate of earning Rs. 5100-7000/-per month, 9 were middle class of earning Rs.7100-10,000/-per month and 1 is upper middle class earning >Rs.10, 000/-per month. In the present study 32 were literates and 58 were illiterates. Out of 90 lactating women, (70%) of women had undergone elective lower segment caesarean section where (30%) with normal vaginal delivery. In which 48(53.33%) were primiparous, 40(44.44%) were multiparous, 2(2.22%) were Grand multiparous respectively. (Figure-1)

Among 90 lactating women, 65 were healthy women and 25 were with complications/diseases (Table-1). Out of 25 lactating women with complications, 40% with hypertension, 28% with eclampsia, 24% with mastitis, 4% with asthma and 4% with diabetes mellitus. (Table-2)

A total of 452 drugs are prescribed during the study period. In which (28.3%) are supplements as it includes Vitamin B-complex (10.17%), Iron folic acid (8.18%), Calcium (5.97%) and Vitamin-C (3.98%) followed by Antibiotics (27.65%), NSAIDS(16.15%), GI drugs(15.04%), Antihypertensives (5.08%), Antihistamines (1.76%), Antiepileptic drugs (1.54%), Antiemetics (1.1%), Laxatives (1.1%) and other drugs (2.21%). (Table-3) (Figure.2)

During lactation period, the effect of suspected drugs on nursing infants according to safety profile of WHO classification was observed. (20%) nursing infants had diarrhoea due to ceftriaxone and amikacin, (13.33%) had constipation due to amoxicillin, (2.22%) had blood stains in stools due to diclofenac and (64.44%) neonates had no effect due to drugs. (Table-4)

Based on WHO safety category wise prescribing frequency of drugs for lactating women, (50.44%) are safer-compatible with breast feeding, (32.52%) are compatible-but monitor for side effects, (14.16%) are unsafe-avoid if possible and monitor for side effects and (2.87%) are controversial.(Table-5)

DISCUSSION:

Even though the knowledge about medication use during breastfeeding has been largely expanded, the side effects of several drugs used by the mother in breast fed infants are still unknown. On top of that, the effects of many new drugs have not been sufficiently studied yet or controversy exists in the literature over their use during breast feeding.⁵ It should always be remembered that the infant is an innocent bystander. The possible risks to the child must therefore be considered carefully when a mother takes a drug while breastfeeding.⁸

Our study revolved that, among 90 lactating women, majority were between the age group of 21-25 years. 27.77% had complications in which the Hypertensive patients with (40%) was majorly admitted. In our study, majority of lactating women had undergone caesarean with primiparity.

In the present study, the most commonly prescribed drugs are supplements followed by antibiotics, NSAIDS, GI-drugs, antihypertensive, Antihistamines, Antiepileptics, Antiemetics, Laxatives which was supported by the study conducted by Uppal R et al⁹, in which apart from the use of nutritional supplements, such as iron, calcium, multivitamins etc., most commonly prescribed drugs were antibiotics (90% of the patients in the hospital settings, 86% of the patients in the postnatal clinic and 13% of the community based patients) followed by antihypertensive agents (2.5% of the patients).

According to WHO & UNICEF classification, the majorly prescribed drugs are safer (50.44%), followed by compatible but requires monitoring of infant for side effects (32.52%), unsafe-avoid if possible (14.16%) and (2.87%) may controversial. It was supported by the study done by Olesen C et al¹⁰, in which safer drugs followed by drugs with possible harmful neonatal effects and non-classifiable drugs accounted for 43.5%, 4.8%, and 35.8% of the prescription had observed with reference to the Swedish classification system in lactation which was similar to WHO classification respectively.

CONCLUSION:

Lactating women never be prescribed unnecessary drugs as it shows an adverse effects on neonates. Clinician's are encouraged to seek updated reference material such as drugs for lactating women according to safety categories classifications and refer to it frequently when making a prescribing decision.

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Table 1: Health status-wise distribution of Lactating Women

Lactating Women	No. of Lactating Women (n=90)	%
Normal/Healthy	65	72.22%
Complicated/Diseased	25	27.77%
Total	90	100%

Table 2: Complications/Diseases of Lactating Women

Complications	No. of Lactating Women (n=25)	%
Hypertension	10	40%
Mastitis	6	24%
Eclampsia	7	28%
Diabetes	1	4%
Asthma	1	4%
Total	25	100%

Table 3: Prescribing frequency of drugs for Lactating Women

S. No	Class of drugs	No. of drugs prescribed	% distribution of drugs
1.	Supplements	128	28.3%
a.	Vit.B-complex	46	10.17
b.	Iron Folic Acid	37	8.18
c.	Calcium	27	5.97
d.	Vitamin-C	18	3.98
2.	Antibiotics	125	27.65%
3.	NSAIDS	73	16.15%
4.	GI-drugs	68	15.04%
5.	Antihypertensive	23	5.08%
6.	Antihistamines	8	1.76%
7.	Antiepileptic	7	1.54%
8.	Antiemetic	5	1.1%
9.	Laxatives	5	1.1%
10.	Other drugs	10	2.21%
	Total	452	100

Table 4: Distribution of nursing infants based on effect of Drugs

Suspected drug / Effect	No. of nursing infants	%
Ceftriaxone & Amikacin / Diarrhoea	18	20%
Amoxicillin / Constipation	12	13.33%
Diclofenac / Blood stains in stools	2	2.22%
No effects	58	64.44%
Total	90	100

Table 5: Safety category wise prescribing frequency of drugs for lactating women with reference to WHO eleventh model list of essential drugs

Safety Profile	No. of Drugs prescribed	%
Compatible with breast feeding (Safe)	228	50.44
Compatible (but monitor for side effects), Probably safe.	147	32.52
Avoid if possible (monitor for side effects), Un-safe.	64	14.16
Avoid if possible (it may inhibit lactation), Controversial.	13	2.87
Avoid	-	-
Total	452	100

Figure 1: Parity wise Distribution of Lactating women

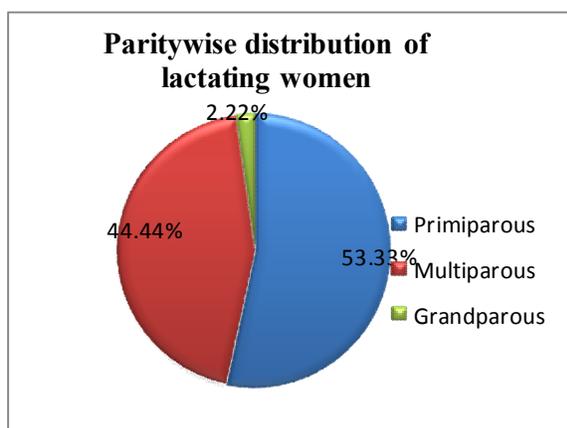
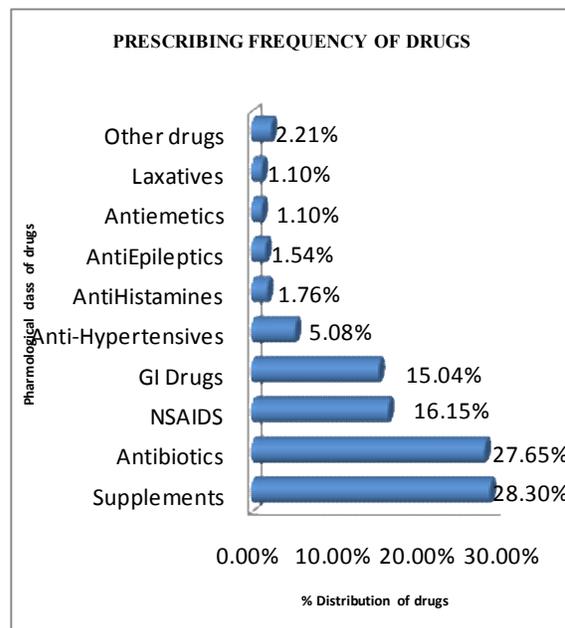


Figure 2: Prescribing frequency of drugs according to Pharmacological Class



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