Drug Prescribing Pattern During Intranatal Period in a Secondary Care Hospital in South India: A Retrospective Study

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Deepasree Sukumaran¹, Anne George Cherian¹, Saibal Das¹,
Blessed Winston A¹, Aniket Kumar¹, and Margaret Shanthi FX¹

Abstract

Background: During delivery, drugs being prescribed cause concerns due to their harmful effects on lactation as well as potential adverse reactions on the mother. This retrospective study was performed to evaluate the drug prescribing pattern during normal delivery in a secondary care hospital in India. **Materials and Methods:** This cross-sectional retrospective study included 3 months of patient's medical records. **Results:** A total of 2222 drugs, comprising 51 different types of drugs were prescribed to 313 mothers undergoing normal delivery. Most of these drugs are safe in lactation. Ten types of drugs would have been better avoided, but they possibly did not cause harm because of their limited short-term use only during the intranatal period. **Conclusion:** This study reflects a good, safe, and rational medication practice during normal delivery for various common ailments in a secondary care hospital and can be cited as an example for similar settings.

Keywords

delivery, intranatal period, pregnancy, lactation, drug prescribing pattern

Introduction

In pregnancy, drug treatment presents a special concern. The physiological changes in the mother affecting pharmacokinetics of drugs, coupled with the threat of potential teratogenic effects determine the choice of drugs.^{1–3} Drugs prescribed during the intranatal period also warrant special concern as they directly impose risks on breast-feeding. Drugs used during normal delivery include analgesics, anesthetics, antacids, intravenous fluids, oxytocin, prostaglandin analogs, antibiotics, iron, folic acid, calcium, and so on.

The transfer of drugs into human milk is similar to the transfer of drugs across the placental barrier. It occurs mainly by passive diffusion. Certain properties of some drugs may cause them to be sequestered or actively excreted into breast milk. The most important factors involved in exposure of infants to drugs in breast milk are the amount of drug in the mother's serum and intrinsic properties of the drugs and the body such as bioavailability, molecular weight, protein binding, pKa, and lipid solubility. Milk to plasma ratio is a useful description of how much drug passes into milk and may be available as part of the drug literature supplied by drug companies.^{4,5} It is thus essential to monitor rational drug administration during the intranatal period.

There are very few kinds of treatment during which breast-feeding is absolutely contraindicated. However, there are some drugs that a mother has to take despite harmful effects to the baby (such as antiepileptics, immunosuppressants, etc). Several studies have confirmed that one of the factors that leads to early weaning is an infant's exposure to maternal drugs.^{6,7} Information and bibliographic references on drugs and breast milk have been available, but the information contained in drug package inserts and the scientific evidence regarding drug use during breast-feeding is often inconsistent.⁸

There are numerous studies looking into the drug prescribing pattern during pregnancy and/or lactation, but there is a dearth of articles exploring the drug prescribing pattern during delivery (ie, intranatal period). This is of paramount importance as drugs administered during delivery may influence the duration of hospital stay and also have an

¹Christian Medical College, Vellore, India

Corresponding Author:

Saibal Das, Department of Pharmacology, Christian Medical College, Vellore 632002, India.
Email: saibaldas123@gmail.com

impact on lactation, thus affecting both the mother and the newborn.²

Pharmacoepidemiological studies can help minimize the use of potentially dangerous drugs in pregnancy by establishing a profile of drug consumption, by monitoring the health services, and by investigating interventional measures.⁹ This is especially relevant for rural, primary and secondary care hospitals in a developing country where resources are limited.

With this background, the present study was conducted with the following objective: to evaluate the drug prescribing pattern during the intranatal period retrospectively among all the mothers undergoing normal delivery for 3 months in the Community Health and Development Hospital, Christian Medical College, Vellore, a secondary care hospital. This hospital belongs to the second tier of health system, in which patients from primary health care are referred to specialists in district hospitals and community health center at the block level.¹⁰

Materials and Methods

This study was started after obtaining approval from the Institutional Review Board, Christian Medical College, Vellore.

Study design: Descriptive.

Study type: Cross-sectional survey.

Study tools: Preformatted forms and patients' charts obtained from the Medical Records Department.

Inclusion criteria: All the women who delivered (including episiotomy) normally from October 1, 2014 to December 31, 2014.

Exclusion criteria: Drug histories of the women who delivered by Cesarean section.

Data analysis: Microsoft Excel 2010 was used.

Results

A total of 313 antenatal record charts were surveyed during the study period; 0.65% mothers were younger than 18 years, 91.23% were from 18 to 30 years old, and 8.12% were older than 30 years. Episiotomy was required for 190 (60.70%) mothers. All the mothers started breast-feeding immediately after delivery. A total of 2222 drugs, comprising 51 different drug types were administered. Some of the drugs were continued throughout the pregnancy in patients with chronic diseases.

The distribution of drugs with lactation risks^{11,12} has been itemized in Table 1. Of all the 51 types of drugs, most are safe. However, some prescribed drugs were not recommended for use during lactation including tramadol, cetirizine, phenobarbitone, metoclopramide, betamethasone, nifedipine,

furosemide, amlodipine, metronidazole and doxycycline due to potential risk of adverse reactions.

Discussion

This study was undertaken to find out the drug prescribing patterns during normal delivery and screen for possible drug errors. The most common indications for drug prescription included stabilization of vital signs, pain during delivery, to promote uterine contraction and stop postpartum hemorrhage, hypertension, urinary infections, respiratory infections, vaginal infections, Rh isoimmunization, vomiting, hypothyroidism, diabetes, gastritis, constipation, asthma, diarrhea, epilepsy, and cough. Along with these, routine supplementation of iron, folic acid, and calcium was continued. Some of the mothers were already on concomitant medications for chronic diseases like diabetes, hypothyroidism, and asthma.

The World Health Organization¹¹ has classified drugs into different categories based on safety during lactation:

- A. Compatible with breast-feeding: no monitoring required
- B. Compatible with breast-feeding: monitor infant for side effects
- C. Avoid if possible: monitor infant for side effects
- D. Avoid if possible: may inhibit lactation
- E. Avoid
- F. No data available

The safety of certain drugs also depends on the age of the infant. Premature babies and neonates have a different capacity to absorb and excrete drugs than older infants. Thus, in general, extra caution is needed for these infants.¹²

In our study, most of the prescribed drugs are safe. Although some drugs are best avoided, their limited use only during delivery might not affect the breast-feeding infant. For some drugs, the lactation status is not available. Tramadol can increase prolactin levels, but discontinuation of breast-feeding following a single dose is not necessary.¹² Cetirizine is excreted into human milk and the manufacturer does not recommend its use in nursing mothers.¹² Diazepam is excreted into human milk because of which sedation, lethargy, and weight loss have been reported in nursing infants.¹² With phenobarbitone, sedation and lethargy have been also reported in breast-fed infants. Some investigators have recommended close therapeutic drug monitoring of infant blood concentrations if a nursing mother takes phenobarbital.¹² Metoclopramide is best avoided during lactation, although there is insufficient data on long-term adverse reactions (possible defects in neural development in newborn animals and increased breast milk production).¹¹

Table 1. Distribution of Drugs Administered During Delivery With Their Lactation Risks (n = 313).

Groups of Drugs/ Indications	Names of Drugs	Duration of Use	Proportion (%) of Patients Prescribed	Status in Lactation
Supplements	Iron	From first trimester to few months after delivery	97.44	Compatible with breast-feeding
	Calcium		97.44	Compatible with breast-feeding
	Folic acid		97.44	Compatible with breast-feeding
Nonopioid analgesics	Multivitamins	1-2 months	0.96	Compatible with breast-feeding
	Ibuprofen	3-7 days	90.73	Compatible with breast-feeding
	Paracetamol		12.14	Compatible with breast-feeding
Opioid analgesics	Diclofenac	3 days	0.32	Compatible with breast-feeding
	Pentazocine	1-2 days	3.51	No data available
	Tramadol		6.07	Avoid if possible. monitor infant for side effects
	Pethidine	1 day	0.32	Compatible with breast-feeding
Antitussives and antiallergics	Promethazine	3-5 days	9.58	No data available
	Chlorpheniramine	3 days	0.32	Compatible with breast-feeding: monitor infant for side effects
	Cetirizine	3-5 days	0.64	Avoid if possible
	Pseudoephedrine	3 days	0.32	No data available
Laxatives	Bisacodyl		0.64	No data available
Oxytocic	Oxytocin	1 day	97.12	Compatible with breast-feeding during short term use
Anti-epileptics	Diazepam	1-2 days	11.18	Compatible with breast-feeding in single dose
	Phenobarbitone		9.58	Avoid if possible. monitor infant for side effects
	Phenytoin	Continued	0.32	Compatible with breast-feeding
For asthma	Terbutaline	1 month	0.64	Compatible with breast-feeding
Antiemetics	Metoclopramide	1-2 days	0.96	Avoid if possible
	Ondansetron		0.64	No data available
For stabilizing vitals	Intravenous Ringer lactate	1 day	72.52	No data available
	Intravenous 5% dextrose		0.32	No data available
	Intravenous dextrose normal saline		0.32	No data available
	Intra venous normal saline		0.32	No data available
	Oral rehydration solution	3 days	0.32	Compatible with breast-feeding
To prevent postpartum hemorrhage	Misoprostol	1 day	37.06	Compatible with breast-feeding
	Methergine		10.22	Compatible with breast-feeding for at least 12 hours after administration of the last dose
	Carboprost		1.60	No data available
To prevent Rh iso- immunization	Anti-D immunoglobulin		2.23	Compatible with breast-feeding
Steroid	Betamethasone	2 days	0.32	Avoid if possible. monitor infant for side effects
Hypothyroidism	L-thyroxine	Continued	1.28	Compatible with breast-feeding

(continued)

Table 1. (continued)

Groups of Drugs/ Indications	Names of Drugs	Duration of Use	Proportion (%) of Patients Prescribed	Status in Lactation
Antihypertensives	Nifedipine	1 day	1.59	Avoid
	α -Methyl dopa	From diagnosis of gestational hypertension to few days after delivery	0.96	Compatible with breast-feeding
Diuretic	Magnesium sulfate	1 day	0.32	Compatible with breast-feeding
	Amlodipine	3 days	0.32	Avoid
	Furosemide	1 day	0.64	Avoid if possible: may inhibit lactation
	Metformin	Continued	0.95	No data available
	Insulin		0.32	Compatible with breast-feeding; dosage may need to be reduced
For gastritis	Ranitidine	1-2 months	93.93	Compatible with breast-feeding: monitor infant for side effects
	Famotidine		2.87	No data available
	Liquid antacid (dimethicone, magnesium hydroxide, aluminum hydroxide, magnesium aluminum silicate hydrate)	3 days	0.32	Compatible with breast-feeding
Antibiotics	Gentamicin	5-7 days	4.15	Compatible with breast-feeding: monitor infant for side effects
	Ampicillin		18.85	Compatible with breast-feeding
	Amoxicillin		4.47	Compatible with breast-feeding
	Metronidazole	5 days	4.15	Avoid if possible
	Cotrimazole	3 days	0.32	No data available
	Doxycycline	5 days	0.32	Avoid if possible
	Nitrofurantoin	10 days	3.20	Compatible with breast-feeding
	Cloxacillin	5 days	0.96	Compatible with breast-feeding
	Normal saline nasal drops	3 days	0.32	No data available
	Glycopyrrolate	1 day	0.32	No data available
Miscellaneous	Lignocaine		60.70	Compatible with breast-feeding

Mothers should not breast-feed during treatment with methergine for at least 12 hours after administration of the last dose and milk secreted during this period should be discarded.¹² The manufacturer recommends that because beta-methasone has the potential for serious adverse reactions in breast-fed infants, it should be used with caution.¹² Nifedipine is excreted into human milk and although there is insufficient data on long-term adverse reactions, the manufacturer warns it could cause serious adverse reactions in nursing infants.^{11,12} Use of amlodipine is not recommended during lactation.¹² Although compatible with breast-feeding, ranitidine should be used with caution.¹² Frusemide inhibits lactation and is also best avoided.¹¹ Insulin is compatible with breast-feeding but dose adjustment may be required.^{11,12} With gentamicin, the neonate needs to be monitored for thrush and diarrhea.¹¹ Animal data suggest that metronidazole may be carcinogenic and if given in a single dose of 2 g, breast-feeding should be discontinued for 12 hours and the baby should feed on expressed breast milk ejected in advance.¹¹ With doxycycline, there is a possibility of staining the infant's teeth, although a single dose is probably safe.¹¹

Thus, in our study, most of the various drugs prescribed during delivery appear safe in lactation. So also were the concomitant medications. Although some of the drugs would have been best avoided, they did not cause any harm possibly due to their limited use only during the time of delivery. In a study done previously, drug prescribing pattern in pregnancy to antenatal mothers in the same secondary care hospital was also very safe and rational.¹³ The limitation of our study was that detailed demographic data of all mothers were not available at the time of data collection.

Conclusion

This study reflects a good, safe, and rational medication practice during normal delivery for various common indications in a secondary care hospital and can be cited as an example for similar primary and secondary care hospitals in India.

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Declaration of Conflicting Interests

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Author Biographies

Deepasree Sukumaran is a PG registrar.

Anne George Cherian is an assistant professor, Department of Community Health and Development, Christian Medical College, Vellore, India.

Saibal Das is a PG registrar.

Blessed Winston A is an assistant professor.

Aniket Kumar is a lecturer.

Margaret Shanthi FX is an associate professor, Department of Pharmacology, Christian Medical College, Vellore, India.