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## A prospective study in a Southern Indian hospital on the prescription of medication during the lying in period following childbirth

### Summary

*The awareness of the inherent risks attached to medication use during pregnancy is increasing. There is, however, a paucity of available following childbirth. We have conducted a prospective study in women who gave birth in hospital with the objective of analysing the use of medication in this lying in period. The results show that, in addition to the vitamins and minerals routinely prescribed for every young mother and the antipyretics administered as required, the following medications were most often used: analgesics (by approx. 9%), anti-inflammatory agents (49%) and antibiotics (38%). The antibiotics were either used prophylactically or, in cases of proven infection, administered therapeutically. The use of antibiotics appears more intensive compared to western countries, presumably due to the greater risk of infection in this group in India. On the other hand, the use of sleep inducing medication and tranquillizers during the lying in period appears, in comparison to other studies, almost negligible. The majority of the women were unaware of the potential side-effects of medication during breastfeeding.*

Although there is an increasing awareness regarding the possible side-effects of the use of medications in pregnancy, there is very little information on the use of drugs during the immediate puerperium. A prospective study done on women admitted for delivery designed to assess drug intake during the puerperium showed that apart from routine vitamin and mineral supplements, which every

mother received, and antipyretics prescribed as and when necessary, the following drugs were used: analgesics (13.9%), anti-inflammatory (49.2%), antibiotics (37.8%). Antibiotics were used either prophylactically, or therapeutically in cases of proven infection. The use of antibiotics appears to have been higher than in western countries, probably owing to the greater risk of infection. The use of hypnose-

datives during the puerperium was negligible compared to findings of studies done elsewhere. Most women were ignorant about the effects of drugs during lactation.

The problem of drug excretion in breast milk, and the associated adverse effects in suckling infants, has received increasing attention over the last ten to fifteen years. Though a large number of drugs are commonly used, their harmful effects on the breast-fed infant have not been conclusively proved. Information on drug use in lactation has been published in many review articles<sup>1-3</sup>. Although there is increasing awareness regarding the possible risks of the use of medications in pregnancy, there is no hesitancy in prescribing them during the lactating period. Several authors have expressed the need for a more thorough study of drugs during lactation, and their effects in the breast-fed infant<sup>1,2</sup>.

This study was designed to determine the prescribing patterns prevalent in a hospital in Vellore, India, during the puerperium, as well as adverse effects of the drugs, if any, in the mother and the breast-fed infant, and to assess the attitudes of women to drug use during lactation and their awareness of possible effects.

## Patients and Methods

The department of Obstetrics and Gynecology at the Christian Medical College Hospital has 3 units, and 6000 deliveries are conducted yearly. A post partum programme is also carried out. The hospital is situated in a district headquarters and caters for the needs of a large town in addition to being a major referral and teaching hospital. The proportion of high risk to low risk patients is 15/85. This hospital is representative of most obstetric hospitals in India.

A prospective survey of all women admitted to the second unit of this hospital for a period of four months (June–Sept. 1989) was carried out. During this period, there were 539 deliveries. The women were interviewed individually by the same person. Using a pretested questionnaire and chart review, information was obtained on vital data, obstetric score,

details of the present delivery, complications in the immediate puerperium, breast feeding, problems related to the baby, details of drug intake, indications and side effects, awareness regarding drug intake during lactation, and drugs taken during previous deliveries. The study was planned to assess drug intake during the puerperium, that is, up to six weeks after delivery. Patients were interviewed post partum on the day of discharge from the hospital and reinterviewed on subsequent post partum visits, which were planned one week after delivery for those who came for suture removal, and 6 weeks later.

## Results and Analysis

Of the 539 patients, 327 (60.7%) had a normal delivery. 110 deliveries were assisted by forceps application and 2 by vacuum

extraction (20.7%). 100 patients underwent a caesarean section (18.6%). 230 (42.7%) patients had episiotomy.

The women's ages ranged from 18 to 40 years, with two-thirds being less than 25 years old. 118 were primigravida.

Of the 539 mothers interviewed, 516 (95.7%) had chosen to breast feed their infants. The remaining few had not breast fed, mainly owing to prematurity of the infants. Pyridoxine was used to suppress breast milk whenever this was required (e.g. cases of intra-uterine death or early neonatal death). Table 1 gives a list of drugs taken by mothers; these medications are classified according to their major action and the type of delivery.

All patients in the study received vitamins and minerals. 369 (68.5%) had 3 or more drugs.

All mothers routinely received vitamin and mineral supplements

Drugs	ND (n=327)		ID (n=112)		CS (n=100)		Total (n=539)	
	n	%	n	%	n	%	n	%
Vitamins & Minerals	327	(100.0)	112	(100.0)	100	(100.0)	539	(100.0)
Antipyretics	98	(30.0)	108	(96.4)	80	(80.0)	286	(53.1)
Antiinflammatory	149	(45.6)	85	(75.9)	31	(31.0)	265	(49.2)
Antibiotics	68	(20.8)	40	(35.7)	96	(96.0)	204	(37.8)
Analgesics	2	(0.6)	3	(2.7)	70	(70.0)	75	(13.9)
Antihypertensives & CVS drugs	8	(2.4)	10	(8.9)	9	(9.0)	27	(5.0)
Anticonvulsants	3	(0.9)	3	(2.7)	1	(1.0)	7	(1.3)
Laxatives	6	(1.8)	11	(9.8)	4	(4.0)	21	(3.9)
Anti-TB drugs	–	–	–	–	3	(3.0)	3	(0.6)
Sedatives	–	–	–	–	1	(1.0)	1	(0.2)
Miscellaneous – (antitussives, antihistamines, bronchodilators, antiemetics etc.)	19	(5.8)	10	(8.9)	11	(11.0)	40	(7.4)

ND – Normal Delivery  
ID – Instrumental (Forceps & Vacuum extraction)  
CS – Caesarean Section.

**Table 1.** Drugs used during delivery & puerperium.

	ND (n = 327)		ID (n = 112)		CS (n = 100)	
	n	%	n	%	n	%
Iron & Folic acid	327	(100.0)	112	(100.0)	100	(100.0)
Calcium lactate	327	(100.0)	112	(100.0)	100	(100.0)
Multivitamin	2	(0.6)	4	(3.6)	47	(47.0)
Vitamin C	–	–	2	(1.8)	–	–
B-Complex	3	(0.9)	2	(1.8)	–	–
Folic acid	1	(0.3)	–	–	1	(1.0)
Pyridoxine *	10	(3.1)	10	(9.0)	–	–

\* Pyridoxine was given to suppress breast milk secretion.

**Table 2.** List of vitamins and mineral supplements used.

Drugs	ND (n = 327)		ID (n = 112)		CS (n = 100)	
	n	%	n	%	n	%
Aspirin/paracetamol	98	(30.0)	108	(96.4)	80	(80.0)
Pethidine	2	(0.6)	3	(2.7)	64	(64.0)
Ibuprofen	149	(45.6)	85	(75.9)	31	(31.0)
Propoxyphene	2	(0.6)	4	(3.6)	–	–
Pyridium	–	–	–	–	1	(1.0)

**Table 3.** Analgesics used.

	ND (n = 327)		ID (n = 112)		CS (n = 100)		Total (n = 539)	
	n	%	n	%	n	%	n	%
Cephaloridine 3 doses	23	(7.0)	12	(10.7)	36	(36.0)	71	(13.2)
Cephaloridine >3 doses	2	(0.6)	2	(1.8)	11	(11.0)	15	(2.8)
Pencillin/ gentamicin	6	(1.8)	5	(4.5)	7	(7.0)	18	(3.3)
Cephaloridine/ metronidazole	5	(1.5)	5	(4.5)	16	(16.0)	26	(4.8)
Pencillin/ metronidazole/ gentamicin	5	(1.5)	1	(0.9)	14	(14.0)	20	(3.7)
Ampicillin	10	(3.1)	4	(3.6)	2	(2.0)	16	(3.0)
Ampicillin/ metronidazole	3	(0.9)	1	(0.9)	3	(3.0)	7	(1.3)
Ampicillin/ gentamicin	5	(1.5)	4	(3.6)	–	–	9	(1.7)
Cotrimoxazole/ metronidazole	5	(1.5)	2	(1.8)	1	(1.0)	8	(1.5)
Other combinations	4	(1.2)	4	(3.6)	16	(16.0)	24	(4.5)

**Table 4.** Nature of antibiotics used during delivery & puerperium.

(Table 2). The commonest drugs used were a combination of iron and folic acid as haemetinic, and calcium lactate. These were followed up from the antenatal period.

Analgesics were mostly given post-operatively, following caesarean sections and puerperal sterilization. In the immediate post-operative period they were given at regular intervals, and later, on demand. Both narcotic and non-narcotic analgesics were used. Narcotic analgesics were given mainly for the operative cases and for forceps delivery. Two normal delivery patients had pethidine for pain relief. Table 3 lists the analgesics used. Ibuprofen was the most commonly used antiinflammatory drug given after episiotomy. Paracetamol was prescribed on demand for fever and mild pain. Pyridium was given to one patient who developed dysuria.

204 (37.8%) patients received antibiotics either alone or in combination. Table 4 describes the various antibiotic combinations used. As previously shown in table 1, 96% of the women who had had a caesarean section received antibiotics, as compared to 35.7% of those with instrumental delivery, and 20.8% of those who had a normal delivery. Since this group of drugs was found to be one of the most frequently prescribed, the indications for which they were prescribed were analysed. Antibiotic use could be broadly classified into prophylactic (one dose before delivery and two doses after delivery) and therapeutic. 150 women (73.5%) received antibiotics prophylactically and 54 (26.5%) as a therapeutic measure. Cephaloridine was the single most frequently used antibiotic drug. The other popular combinations were penicillin/gentamicin/metronidazole and cephaloridine/metronidazole (Table 4).

Antibiotics were given prophylactically for perioperative prophylaxis in cases of caesarean section,

premature rupture of membranes, obstetric complications and heart disease complicating pregnancy. In 37% of cases, the course of antibiotic treatment was extended to 5 to 7 days because patients either developed infection or fell into the high risk group for infection, e.g., post-operative urinary tract infection (in 7 cases of caesarean section) or 3rd degree perineal tear. In the therapeutic group, there was definite evidence of infection proved by microbiological investigations, such as urinary tract infections, intrauterine infections, fever with localising signs and positive cultures and respiratory infections. Antibiotics were used alone or in combinations – e.g. Furadantin/co-trimoxazole alone for UTI, penicillin/gentamicin/metronidazole or co-trimoxazole/metronidazole for other infections. All drugs were given in the standard accepted doses and for the duration of treatment.

Only one mother was given a hypnotic, diazepam. Two patients known to have convulsive disorder were on prophylactic anticonvulsants. Phenobarbitone was given to 5 patients who had pregnancy-induced hypertension.

Laxatives were the most commonly used gastrointestinal drugs. Tablet forms were more often used than liquid preparations. Eight patients received antiemetics and one had antacids.

Cardiovascular drugs included digoxin and furosemide for heart disease and  $\alpha$ -methyl dopa, hydralazine and nifedipine for hypertension. Heparin and dipyridamole were prescribed along with digoxin and furosemide to a mother who developed deep vein thrombosis. Mothers who had bronchial asthma were given theophylline combinations: Salbutamol, Aminophylline or Terbutaline. Antitussives were given for upper respiratory infection. No drug-related adverse experiences were reported by the patients.

One mother was diagnosed to have acute myelomonocytic leukaemia at 34 weeks gestation. Pregnancy was terminated and she was given anticancer drugs.

All newborns had normal Apgar scores. There was no evidence of any drug-induced effects except in one child. One primipara mother reported that she and her baby developed diarrhoea while she was taking Ampicillin. Symptoms subsided on stopping the drug.

All mothers were asked specific questions regarding their awareness concerning drug intake during lactation. Only 4 (all doctors) knew that drugs had to be avoided during lactation. These included tetracycline, trimethoprim and steroids. Seven patients (5 doctors and 2 nurses) suggested that iron and calcium should be given to all breast-feeding mothers. There were 88 (16.3%) mothers who were aware that drugs taken by a lactating mother would affect the baby, and of these, 85 knew that drugs are secreted in breast milk. Of the 306 mothers who had delivered more than once, 91 (29.7%) knew the names of at least some of the drugs prescribed to them during the previous deliveries. None of them had noticed any side-effects on themselves or their babies.

17 (3%) informed that they self-prescribed for minor ailments like headache, fever and backache. Paracetamol was the most commonly self-prescribed drug.

530 (98.3%) of the mothers preferred to give allopathic treatment, 7 (1.3%) ayurvedic and 2 (0.4%) homeopathic medicines to their babies. Traditional medicines are held to be relatively harmless for the baby.

## Discussion

The use of drugs during the puerperium requires a fine balance. No harm should be allowed to befall the baby because of the drug. But it

is equally important that no harm should come to the mother or baby because of a disease inadequately treated.

During the past two decades, there has been a considerable increase in the number of mothers breast-feeding their newborn babies<sup>4-7</sup>. Though no exact figures are available, most Indian mothers elect to breast-feed<sup>8,9</sup>. In our study, 516 mothers (95.7%) breast-feed their babies. As a number of drugs are secreted into breast milk, the use of drugs during the puerperium should be carefully monitored.

Studies conducted by Passmore et al.<sup>10</sup> and Matheson<sup>11</sup> found that during the puerperium 99% and 90% of mothers received at least one drug. In the present study, all patients received at least one drug and 68.5% of the patients had 3 or more. The average number of drugs per prescription was 3.4, which is higher than the figures quoted for hospitals elsewhere<sup>12</sup>.

Except vitamins and iron, few drugs were taken routinely by mothers over a prolonged period. About 5.8% of the study population required long-term treatment for organic diseases such as epilepsy, cardiovascular or respiratory disorders. The corresponding figure for Belfast was 7.3%<sup>10</sup>. Steroids, including oral contraceptives, were used by 4.8% in the Belfast group, whereas these drugs were not used by the Indian patients. In India, oral contraceptives are still not a popular form of family planning.

All mothers in the present study received vitamins and mineral supplements, as it is the hospital's practice to give iron and folic acid to all pregnant women admitted and continue it even after delivery. Moreover, the use of iron and folic acid supplementation during pregnancy is ensured at all levels of health care through a national programme. No unwanted effects of these were noted either in the mothers or in the newborn babies.

Our data indicates that, with the exception of antibiotics, there seems to be no significant difference in the prescribing patterns among women who have had various types of deliveries.

Antipyretic (53.1%) and anti-inflammatory drugs (49.2%) were most frequently prescribed, followed by antibiotics (37.8%). Studies from Northern Ireland<sup>10</sup> and Norway<sup>11</sup> showed that only 15.5% and 4.2% of women received antibiotics. However, these figures cannot be compared with the present study as the profile of patients receiving antibiotics in relation to the type of delivery is not available for the western studies.

In the present study, antibiotic use among women who had had normal deliveries was 20.8%, which is higher than the total antibiotic utilisation figures quoted for either Northern Ireland<sup>10</sup> or Norway<sup>11</sup>. However, it could be that our patients have a higher risk of infection. No adverse effects due to the use of antibiotics were observed in either mothers or children, except for a case of ampicillin-induced diarrhoea in one mother and child. Although most antibiotics are found in the breast milk in low concentrations, they are unlikely to affect the baby because no appreciable amounts are absorbed from the infant's gastrointestinal tract. However, a few antibiotics like chloramphenicol and tetracycline have been incriminated as being harmful to the infant<sup>2,4</sup>. Adverse effects attributable to drugs in milk vary in severity and include diarrhoea, irritability, sedation, convulsions, metabolic acidosis, anaemia and allergic sensitisation to antibiotics<sup>13,14</sup>. The concentrations of many antibiotics in milk have been estimated both theoretically and experimentally and although these amounts have been found to be subtherapeutic, they may cause sensitivity reactions<sup>1,13,14</sup>.

37.8% of the mothers who breast fed in this survey received anti-

biotics. Though metronidazole and erythromycin are contraindicated in the new born according to some authors<sup>2</sup>, 63% of the mothers in this study who received antibiotics had received metronidazole, probably because of a high risk of anaerobic infections. However, no adverse effects due to these drugs were observed in the neonates.

Hypnosedative drugs were used much less (0.2%) in our study than in Northern Ireland (36.0%) or Norway (65.3%)<sup>10,11</sup>. This significant difference could reflect a cultural difference, with Indian patients not demanding drugs against insomnia.

Antipyretic (53.1%) and anti-inflammatory drugs (49.2%) were the major groups used. These were used as occasional medicines given "as required" and the information was obtained by referring to the nursing records. The most commonly used was paracetamol for patients with episiotomy wounds. Ibuprofen was given initially after episiotomy for 1 to 2 days followed by paracetamol as required. The Belfast study reports the use of 37.8% of anti-inflammatory drugs<sup>10</sup>. However, in their study he analgesics used were formulations containing aspirin, paracetamol and codeine, whereas no analgesic formulations were given to the sub-

jects in this study. A number of patients in Belfast received phenylbutazone, which was not used in the group surveyed here. No evidence of NSAID-induced adverse drug reactions were noticed in the mothers or the babies. A significant number of women in Belfast received trypsin and chymotrypsin but this was not prescribed to any of the Indian patients. A comparison between the surveys done in India, Norway & Ireland is shown in Table 5.

One of the objectives of our study was to assess the attitudes and awareness of mothers regarding the effects of drug ingestion during lactation. It was found that even medical personnel, including doctors, did not know which drugs were safe during lactation. None of the other patients were aware of the problem of drug safety.

Successful "Self Administered Medication Programs" have been carried out in the West<sup>15</sup>. Unfortunately, most of the patients in our hospital are still too illiterate to participate successfully in such programmes. A model for the education of women about drug use is needed.

In conclusion, this study has documented the prescription of a wide range of drugs in the immediate post-partum period in a teaching

	Norway (n = 970)	N. Ireland (n = 2004)	India (n = 539)
No drug treatment	9.6%	<1.0%	nil
<b>Drug classes</b>			
Analgesics	81.6%	78.4%	13.9%
Antibiotics	4.2%	15.5%	37.8%
Hypnotics	65.3%	36.0%	0.2%
<b>Specific drugs:</b>			
<i>Benzodiazepines</i>			
Nitrazepam	60.0%	16.0%	nil
Diazepam	3.7%	2.3%	<0.02%

**Table 5.** Comparison between various surveys on drug use during puerperium-major drug groups prescribed.

hospital. The present study showed a large number of drugs being used during the post-partum period in a teaching hospital in India. These results are probably only the tip of the iceberg of drug use during pregnancy and the puerperium. In these situations, rational use of drugs is generally advocated. The majority of Indian women are attended by general practitioners, who may prescribe drugs without much restrictions<sup>9</sup>. Therefore similar surveys on drug use should be carried out in the community as well as in the hospital setting, to ascertain the levels of drug use during the puerperium, and to enable educational interventions to be planned.

### **Zusammenfassung**

#### **Prospektive Studie zur Verschreibung von Medikamenten im Wochenbett in einem süd-indischen Spital**

Das Bewusstsein der Problematik der Anwendung von Arzneimitteln in der Schwangerschaft nimmt laufend zu, doch findet sich wenig Information über den Gebrauch der Medikamente während des Wochenbettes. Wir führten eine prospektive Studie an zur Geburt hospitalisierten Frauen durch, um den Arzneimittelgebrauch im Wochenbett zu analysieren. Sie zeigte, dass neben routinemässig verabreichten Vitaminen und Mineralstoffen, welche jede junge Mutter erhielt, und neben Antipyretika, die für den Gebrauch bei Bedarf verschrieben wurden, vor allem folgende Medikamente gebraucht wurden: Analgetika (bei ca. 9%), Entzündungshemmer (49%) und Antibiotika (37,8%). Antibiotika wurden entweder prophylaktisch gegeben oder in Fällen gesicherter Infektion therapeutisch eingesetzt. Die Verwendung von Antibiotika scheint häufiger zu erfolgen als in westlichen Ländern, vermutlich wegen des erhöhten Infektionsrisikos dieser Gruppe in Indien. Der Gebrauch von Schlaf- und Beruhigungsmitteln während des Wochenbettes dagegen schien, im Vergleich zu anderen Studien, fast vernachlässigbar. Die meisten Frauen wussten über Wirkungen der Medikamente während der Stillzeit nicht Bescheid.

### **Résumé**

#### **Prescription pendant la période puerpérale dans un hôpital du sud de l'Inde**

Bien que l'intérêt concernant l'utilisation des médicaments pendant la grossesse augmente, il y a peu d'information sur cette utilisation pendant la période puerpérale immédiate. Une étude prospective des femmes ayant été hospitalisées pour accouchement évaluant les produits ingérés pendant la période puerpérale a montré à part des vitamines et sels minéraux habituellement prescrits et des antipyrétiques que les médicaments suivants ont été fréquemment utilisés: analgésiques (13,9%), anti-inflammatoires (49,2%), antibiotiques (37,8%). Les antibiotiques ont été utilisés soit de manière prophylactique ou thérapeutique dans les cas d'infection. L'utilisation des antibiotiques apparaît être plus importante que dans les pays occidentaux probablement à cause de plus grands risques infectieux. L'utilisation d'hypnotiques ou sédatifs durant cette période est négligeable en comparaison d'études similaires. La plupart des femmes ignoraient les effets des médicaments sur l'allaitement.

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