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Drug utilization in breast-feeding women. A survey in Oslo

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Summary. In a retrospective questionnaire survey of 885 women who had given birth 3–5 months before, fewer of those who were still breast-feeding at 4 months ($n = 645$) were using drugs than those who had stopped breast-feeding before 4 months ($n = 240$), during the 2 week period preceding registration.

The average number of doses (Defined Daily Doses/1000 women/day) was 166 and 307, respectively, in that period. The number of doses taken was significantly associated with the use of oral contraceptive agents ($p < 0.005$) and young maternal age ($p < 0.05$).

Most of the variation in drug use between breast-feeding and not breast-feeding mothers was probably due to the greater use of contraception by the latter. The number of drugs used per mother in the 4 month period seemed to be best predicted by her and her infant's disorders.

Long-term medication in breast-feeding women included many drugs for which there is incomplete or no data about milk transfer, e. g. salbutamol, clemastine, dexchlorpheniramine, phenylpropanolamine, cromoglycate and levomepromazine.

The disorders most extensively treated with drugs in this period were dyspepsia, haemorrhoids and inflammation of the breast. The finding that smoking was associated with early weaning and consumption of alcohol with prolonged breast-feeding calls for further investigation.

More information on these drug and health issues to the breast-feeding mother is highly desirable.

Key words: Drug utilization; breast feeding; smoking; alcohol; puerperium; pharmacoepidemiology

Concern about the hazards and adverse effects of drugs in pregnancy has lead to general warnings against drug use if not strictly necessary for maternal or fetal health. Similar precautions have been recommended, sometimes without reason, in breast-feeding mothers [1, 2]. Surveys from one region in Sweden have shown that mothers use a wide range of prescription drugs while they are breast-feeding [3]. Whether drug use among women is higher or lower during breast-feeding than in general is not known. The aim of the present study was to investigate the extent of and predictors of drug utilization in mothers during the first months after birth, and to identify those symptoms in women which led to drug use in this eventful period of life. The following questions were raised;

– To what extent is drug utilization (self-medication, prescription drugs or long-term medication) after birth related to breast-feeding?
– Which disorders are most often treated with drugs during the lactational period and which drugs are used by breast-feeding women?
– Is maternal intake of stimulants (nicotine, alcohol and caffeine) higher or lower in breast-feeding women? A validation of postal questionnaires as a tool in pharmacoepidemiological studies was also included.

Material and methods

The data come from a survey of drug utilization among mothers and infants during the first 3–5 months after birth. The infant data and a more detailed description of the study are reported elsewhere [4]. A questionnaire was mailed to a random sample of 20% ($n = 1131$) of women who gave birth in Oslo in 1985. 885 (78%) mothers responded to the postal questionnaire, which asked for specific information about disorders, drug treatment and sociodemographic variables, as well as all drug doses taken during the 2 weeks preceding registration. The intake of vitamins and iron was recorded but was not included in the drug calculations. The general attitude to drugs was tested by asking about drug taking behaviour when suffering from strong headache. The following variables were calculated:

– Disorders per mother, i. e. the sum of disorders in each subject during the period lasting from discharge from hospital until registration, on average 4 months.
– Drugs per mother, which was the number of drugs (prescription and self-medication) used during the same period.
– Defined Daily Doses (DDD) per 1000 mothers per day [5] was the sum of DDD of all types of drugs used during the 2 week-period.

The concomitant consumption of stimulants was estimated as follows:

Table 1. Rates of breast-feeding 3 months after birth in various subgroups of mothers ($n = 885$)

	n	% of mothers	$P(\chi^2)$
Age			
< 25 years	240	67	
> 25 years	630	85	< 0.001
Parity			
Primiparas	513	78	
Multiparas	353	83	NS
Sex of infant			
Girls	423	84	
Boys	442	77	< 0.001
Prematurity			
> 3 weeks pre-term	54	63	
< 3 weeks pre-term	813	81	< 0.01
Co-habiting status			
Living without the father	60	57	
Living with the father	811	82	< 0.001
Employment outside home			
Yes	754	81	
No	124	75	NS
Duration of maternity leave			
< 4 months	103	79	
4–9 months	239	86	
> 9 months	394	79	< 0.05
Years of education			
< 9 years	76	53	
10–12 years	316	71	
13–16 years	369	90	
> 17 years	106	94	< 0.001
Social class[a]			
4 = Workers, skilled/unskilled	34	53	
3 = Employees, lower level	149	69	
2 = Employees, medium level and self-employed	394	88	
1 = Employees, higher level and liberal arts	230	95	< 0.001

[a] According to the parent with the highest status using Nordic Occupational Classification, Central Bureau of Statistics, Norway

– Cigarettes smoked per day, assuming a nicotine content of 1.1 mg per cigarette
– Alcoholic drinks per week, where 1 drink (16–18 g alcohol) = 1 longdrink = 1 glass of wine = $^1/_2$ l of beer
– Cups of coffee/tea per day, where 2 cups of tea = 1 cup of coffee = 70 mg caffeine

Two categories of breast-feeding were defined; those mothers who were still breast-feeding at registration, i.e. on average 4 months after birth, and those who had weaned their children before registration. The latter group had breast-fed for a median time of 8 weeks. In this context breast-feeding means giving at least two meals of breast milk daily. The relative dose of each drug excreted in breast milk was calculated from the following formula:

$$\frac{\text{Average milk concentration} \times \text{average milk intake} \times 100}{\text{maternal dose/kg}}$$

assuming a daily milk intake of 0.15 l/kg in the infant and a maternal body weight of 60 kg [6].

To validate the reliability of the written answers, interviews were carried out with 96 (11%) of the respondents, selected at random. Statistical analyses included 95% confidence intervals of proportions, the Chi-squared test, Spearman correlation, Student's t-test, Mann Whitney U test and stepwise regression analysis, as described in the DDPP (University of Oslo) and SPSS-programmes (SPSS Inc., Chicago, USA). Permission to establish the data base was obtained from the relevant official bodies.

Results

The representativeness of the respondents was checked with regard to infant sex (48.9% girls), pre-term deliveries (6.1%), infant birth weight (3513 g (560), mean (SD)) and site of residence in Oslo. The distribution of birth weights and prematures in the sample corresponded well to official birth statistics for Oslo. Response rates calculated for different areas of residence indicated, however, that the highest and lowest response rates (84% and 67%) came from the areas with the highest and lowest socioeconomic conditions in Oslo.

Breast-feeding

Answers from 885 women showed that 98% were breast-feeding on discharge from hospital, 88% wholly and 10% partially. At the time of registration the rate of breast-feeding was 73%. Breast-feeding characteristics at 3 months when 80% (77–83%) of all mothers were lactating, are shown in Table 1. No clear difference in maternal perception of milk yield was found between breast-feeding mothers taking and those not taking contraceptive pills.

Disorders

The occurrence of disorders in the 4 month period following birth was assessed by a check list. In total 81% (78–84%) of the mothers reported at least one disorder during this period. The frequency of disorders and drug intervention are shown in Fig. 1. The predominant disorders requiring treatment for more than 1 week were haemorrhoids, cracked nipples and genito-urinary disorders. 4% of the mothers took drugs without indicating a symptom. About 10% of the mothers also reported other symptoms than those given in the check list. Chronic diseases included 6 cases each of migraine, 4 of asthma, 3 of diabetes, 2 of epilepsy, 1 of psoriasis and 1 of thyrotoxicosis. When psychiatric symptoms, such as nervousness/stress, depression/weeping and sleep problems were added in, there was a higher frequency among primiparas and single mothers.

Drug use during the 4 month period

In total 69% (66–72%) of the women had taken at least one drug during the 4 month period surveyed. The therapeutic groups most frequently reported are shown in Table 2. There were only small differences between mothers who breast-fed for a period shorter ($n = 240$) or longer ($n = 645$) than 4 months, except for contraceptive pills (25 versus 9%), antacids (0.8 versus 2.2%) and neuro-

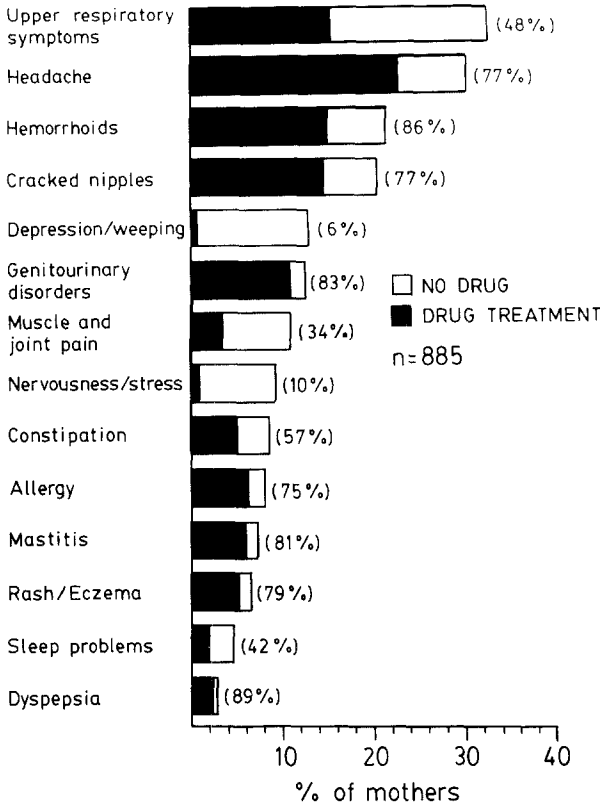

Fig. 1. Percentage of mothers with reported disorders and reported drug treatment during the 4 month period. Percentage (in brackets) of each disorder treated with drugs

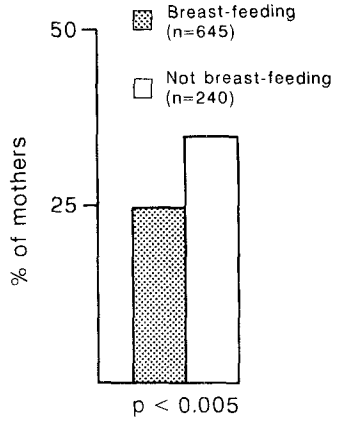

Fig. 2. Percentage of mothers who took medicines at least once in a 2 week period according to breast-feeding at 4 months

leptics (2.5 versus 0.2%). Vitamins and iron preparations were taken more frequently by those still breast-feeding. The mean number of drugs per mother was 1.5 (range 0–9), and it increased with the level of education, but it did not differ between the breast-feeding groups. Half of the drugs were claimed to be used upon advice from a physician or a nurse. The relationship between drugs per mother and possible predictors, such as length of breast-feeding, attitude to drugs, years of education, social class, maternal age, parity, marital status, employment outside home, as well as disorders per mother and infant, was analysed using a stepwise linear regression model. The numbers of disorders, drugs and doses were transformed logarithmically. Drug use was associated with disorders in the mother ($\beta = 0.57$, $P < 0.001$) and infant ($\beta = 0.19$, $P < 0.05$), as well as the attitude to drugs ($\beta = 0.16$, $P < 0.05$), accounting, respectively, for 35,2 and 2% of the variance in the model. Maternal age and education had some influence on drug use, but were not entered into the equation. A weak but significant positive correlation was found between the number of drugs and educational level in mothers working outside the home, both for drug use in mothers (Spearman $r = 0.10$, $P < 0.005$) and infants (Spearman $r = 0.09$, $P < 0.005$), as opposed to drugs taken by housewives.

As regards the 54 mothers using long-term medication, Table 3 shows that for several drugs used by lactating mothers data about milk transfer were not available.

The perceived risk of drug use during lactation in relation to that during pregnancy was assessed. 36% of the mothers had less, 33% similar and 17% had more doubts about drug use during lactation than during pregnancy, whereas 13% answered "Don't know". An association was found between the number of drugs per mother and doubts about drug use during lactation ($P < 0.001$).

Drug use during the 2 week period

During the 2 week recall period preceding registration, the percentage who took drugs at least once (28%) was significantly higher amongst mothers who had weaned (35% [29–41%]) than in those who were still breast-feeding (25% [22–28%]; Fig. 2). Estimated average drug intake behaved similarly (DDD/1000 mothers/day; 307 versus 166, $P < 0.001$). In a multiple regression analysis the DDD/1000 mothers/day seemed to be best predicted by the use of contraceptive agents ($\beta = 0.41$, $P < 0.005$) and maternal age ($\beta = -0.31$, $P < 0.05$), which accounted for 23 and 9% of the variance. The $^1/_4$ of breast-feeding mothers who took drugs had an average intake of 665 DDD/1000 mother/day in the period. The types of drugs used are shown in Table 4.

Table 2. Drugs taken at least once by mothers ($n = 885$) during 4 months after birth, according to therapeutic class

	% of mothers
Analgesics/antipyretics[a]	32
Dermatologicals[a]	19
Antihaemorrhoidals	15
Oral contraceptive agents	13
Respiratory agents	11
Systemic antiinfectives	11
Oxytocics	10
Uro-/gynaecologicals excl. hormones	8
Herbal medicine	7
Antiallergics	5
Laxatives	5
Antacids	2
Sedatives/hypnotics	2
Antirheumatic agents	1
Eye drops	1
Cardiovascular agents	1
Others	3

[a] According to the validation interview underreporting in the mothers exceeded 10%

Table 3. Numbers out of all the mothers surveyed ($n = 885$) and breast-feeding (BF) mothers ($n = 645$) on long term medication, and relative infant dose through breast milk obtained from the literature

	No of mothers	No of BF mothers	Relative infant dose
Cromoglycate	7	7	nd
Topical corticosteroids	6	5	nd
Salbutamol	5	4	nd
Insulin	5	4	nd
Theophylline	5	0	15%
Clemastine	4	3	nd
Thyroxine	4	4	nd
Dexchlorpheniramine	3	3	nd
Phenylpropanolamine	3	3	nd
Naproxen	3	2	2%
Phenytoin	2	0	7%
Carbamazepine	2	1	10%
Phenobarbitone	1	1	30–100%
Warfarin	1	0	< 1%
Methyldopa	1	1	< 1%
Levomepromazine	1	0	nd
Carbimazole	1	0	3–16%
Tetracycline	1	1	1–4%

nd = no or insufficient data on breast milk transfer

Table 4. Drugs taken at least once by mothers ($n = 885$) during a 2 week period preceding registration, according to therapeutic class

	% of mothers
Analgesics/antipyretics	12.7
Oral contraceptive agents	11.9
Antiallergics	4.1
Respiratory agents	3.4
Uro-/gynaecologicals excl. hormones	3.2
Dermatologicals	2.5
Systemic antiinfectives	1.9
Psychotropic agents	1.1
Thyroid hormones and insulin	1.0
Antihaemorrhoidals	0.9
Eye drops	0.6
Antiepileptics	0.6
Antimigraine agents	0.5
Antirheumatic agents	0.3
Cardiovascular agents	0.2
Others	0.4

Consumption of stimulants

The overall picture is shown in Fig. 3. 40% (37–43%) of the mothers smoked at registration. 35% (31–39%) of the breast-feeding mothers smoked daily as did 65% (59–71%) of those not breast-feeding at 4 months. Only 7% of all mothers (21% of smokers at registration) claimed they had stopped smoking because of the pregnancy and/or lactation. There was no difference between breast-feeding and not breast-feeding mothers with regard to abstinence from alcohol (17 and 16%), but significantly more of those not breast-feeding were abstainers from coffee.

Data validity

In Fig. 4 the answers obtained by mailed questionnaires are compared with those obtained in subsequent interviews. The number of drugs/mother and DDD/1000 mothers/day were underreported in the written answers by 22% (14–31%) and 6% (1–11%), respectively. Underreporting showed no systematic variation with maternal age, education or breast-feeding.

The additional disorders most frequently reported at interview were muscle and joint pains, headache, nervousness/stress and respiratory tract symptoms (11%). The proportion of those taking medicines was not increased, but 44 mothers (46% [36–56%]) recalled taking more drugs in the 4 month period than previously stated, e.g. mild analgesics (18% of mothers), topical preparations and dermatologicals (15%), systemic antiinfectives (3%) and antiallergics (3%).

Discussion

Representativity and validity

The mothers included appear to have been reasonably representative of those giving birth in Oslo, except for a somewhat lower response rate from the area with the lowest socioeconomic status, consistent with other studies using postal questionnaires [7, 8]. This may have resulted in underestimation of the use of psychotropic drugs, tobacco and alcohol. A retrospective method was chosen, because a prospective survey might have lead to different drug behaviour as compared to normal practice and a higher rate of refusal. The finding that on average 22% of the drugs taken during a 4 month period, and 6% of the doses taken during the 2 week period preceeding the survey, were not recalled in the questionnaire may indicate that direct interview is more reliable than mailed questionnaires. However, those mothers interviewed were exposed to the same questions twice, thus their recall received additional stimulation. A major part of the drugs forgotten were either one dose of a mild analgesic or sporadic use of dermatological preparations. As regards prescription drugs and the total number of doses, valid answers were given in the questionnaires. The fact that underreporting was less for the 2 week recall period also illustrates the difficulty of recalling drug intake and related events over a longer period.

The association seen between higher education and the number of drugs per mother vanished upon inclusion of maternal and infant disorders in the multivariate analysis. Further analysis did not prove that higher education was correlated with many self-reported disorders, as discussed previously [9]. It is known from other studies that usage of prescription drugs is more prevalent in the lower social classes; while self-medication with "over the counter"-drugs (and vitamins) is found in the higher classes [10, 11].

Breast-feeding

The almost 100% breast-feeding rate upon discharge shows that the potential for breast-feeding in women is very high. The 80% breast-feeding rate after 3 months is compareable to recent data from Norway [12]. That

breast-feeding is more prevalent in well educated, cohabiting mothers delivering at term (Table 1) is already firmly established [13]. A significantly shorter duration of breast-feeding for sons than for daughters was also reported in a Swedish breast cancer study [14]. One possible explanation might be that behavioural differences exist between the sexes, exemplified by the stronger nutrition reflex and weaker motility (activity) reflex postulated in females [15].

Disorders

The "disorders" in this study were perceptions of illnesses rather than specific diagnoses. This fact may partly explain why more illnesses, especially back pain and headache, were reported at interview. The discrepancy may either be due to underreporting in the questionnaires or overestimation of symptoms at the interview. Few data are available that describe maternal disorders after birth. However, respiratory symptoms and headaches are generally known to be prevalent in women [16]. The high frequency of haemorrhoids and cracked nipples was not unexpected. Further, a substantial fraction of the breast inflammations claimed might have been due to milk stasis or non-infectious mastitis [17]. The high proportion of subjects (81%) receiving antibiotics (penicillin V and erytromycin) may reflect an overestimated risk of bacterial infection, as found in a subsequent study [18].

Drug use

In the present study, drug usage (proportion of drug takers; number of drugs and doses) was assessed in different ways (questionnaire; interview) and over different periods (4 months; 2 weeks). Control interviews indicated that non-prescription drug usage in the 4 months was markedly underestimated by the questionnaire technique, so they are not further discussed.

In a national health survey in 1985, in a 2 week period drugs were taken by 26% of women aged 25–44 y [16], a value with which the present data are in fair agreement. It is less than the prevalence reported from Tromsø [19]. The present study showed that non-breast-feeding mothers used more drugs and doses than breast-feeding mothers in the 2 week-period. This could not be fully (32%) explained by the greater need for contraception and the younger age of the former, and may reflect some variation derived from uncontrolled factors.

The number of drugs per mother in the 4 month period seemed to be best predicted by her disorders. The result may also reflect greater drug usage in mothers who reported many symptoms in their infants. Employment outside the home seemed to influence drug use both in mothers and infants, possibly indicating a lower threshold for illness or drug taking in working mothers.

The finding that 50% of the mothers either had the same doubts or were more reluctant to take medicines during lactation than during pregnancy may reflect the

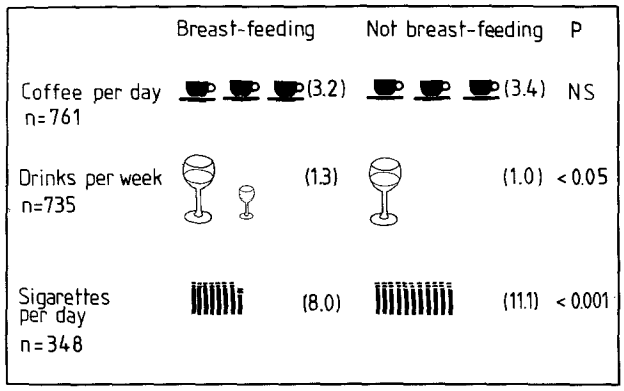

Fig. 3. Average consumption (units) of cups of coffee, alcoholic drinks and cigarettes in mothers according to breast-feeding at 4 months

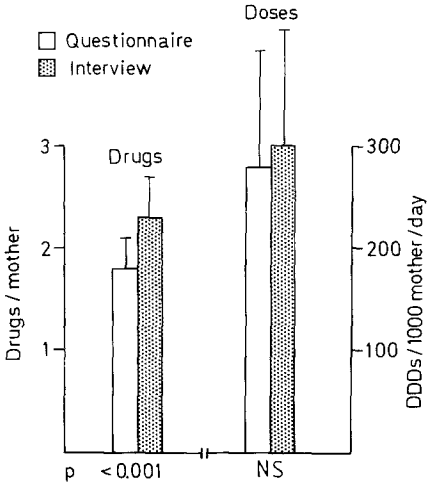

Fig. 4. Comparison of number (m and (2 SEM)) of drugs taken during a 4 months period and doses used during a 2 week period obtained from questionnaires and subsequent interview of a random sample of 96 mothers

erroneous idea that the same or larger doses are transferred through the milk than through the placenta. Similarly, the fact that several drugs still not investigated to show the amount transferred to the baby through breast milk are used on a long-term basis in breast-feeding women may indicate insufficient attention to this issue due to inappropriate information. The authoritative Norwegian Drug and Therapeutic Formulary did not contain detailed guidelines on drugs and lactation until the 1986 edition [20], and data about milk transfer was not formally requested for New Drug Applications in the Nordic countries before 1984. From the study it is desirable that frequently used systemic drugs, such as dexchlorpheniramine, clemastine, fenoterol, salbutamol, phenylpropanolamine and levomepromazine, be studied in milk. Closer collaboration between clinicians, clinical pharmacologists and breast-feeding mothers is needed to provide the documentation.

According to current knowledge only phenobarbitone among the drugs used in this study carries a clear risk of adverse effects (somnolence, poor suckling) in the breast-fed baby [6]. Some caution is also required when prescrib-

ing other antiepileptics, thyrostatics, tetracyclines and theophylline to breast-feeding women [6]. Monitoring of T-3 and T-4 has been recommended in the infant during maternal treatment with carbimazole, although recent studies found no change in infant thyroid function during long-term treatment of the mother [21]. Tetracyclines are probably poorly absorbed from milk, but may accumulate in the breast-fed infant upon long-term treatment [6]. Irritability has been reported in a breast-fed child whose mother was on theophylline [22]. However, breast-feeding is probably reasonably safe if both the maternal dose of theophylline and the concomitant intake of coffee are moderate. None of the 5 mothers taking theophylline in the study were nursing.

Oral contraceptive agents were taken by 14% of American women in the early post partum period [23], which is similar to the incidence here (13%). The majority of the latter were not breast-feeding at registration. In addition, most of those who were breast-feeding preferred the so-called mini-pill with low oestrogen, which does not impair milk production [6]. Almost the same incidence of use (11% versus 9%) of systemic antiinfectives was found as in the 3 month study of Boethius [3].

Drugs for "nervous disorders" were reported to be taken by 6.2% of Norwegian women aged 25–44 y during a 2 week period in 1985 [16]. For unknown reasons the exposure to psychotropic drugs was very low (1.1%) among our respondents, whereas psychiatric symptoms were reported by 19% of the mothers. Extrapolation of prescription data from two Norwegian counties [24] indicates that the percentage of fertile women who take tranquillizers and hypnotics is 6-times higher than in our study.

Stimulants and breast-feeding

The finding that cigarette smoking, on average, was much more common in mothers who weaned their babies before 4 months than in those who weaned at a later stage might be due to sociodemographic factors, or it could be directly related to an effect of nicotine on lactation. Nicotine is concentrated in milk and the average serum concentration of nicotine in suckling infants corresponded to 6% of that in the mother [25]. The consequences of such doses of nicotine are not known but the passive smoking itself in young children increases the risk of many diseases (e.g. respiratory tract infections, asthma and atopic allergy). In this context the 40% prevalence of smoking among mothers after birth is alarming.

On the other hand, breast-feeding mothers had a slightly higher consumption of alcohol than non-breast-feeding mothers, most probably due to differences in social status among the groups. With an average intake of 2 drinks per week, the breast-fed infant is exposed to approximately 50 mg alcohol weekly, which is a small dose, probably without pharmacological effect [26, 27]. Neither does moderate maternal intake of coffee, e.g. 5 cups/day have any proven effect on breast-fed infants [28], although caffeine elimination is delayed in breast-fed infants [29].

Conclusions

1. Postal questionnaire surveys are useful tools to collect drug utilization data from women after birth, but problems of recall and comprehensiveness may require validation of the results.
2. The results indicate that in general breast-feeding mothers are no more cautious about drug taking than non-breast-feeding ones. Data about milk transfer are not available for several prescription drugs taken by breast-feeding mothers, sometimes on a long term basis. Priority should be given to appropriate studies on those drugs.
3. More appropriate and pertinent information about drugs and breast-feeding should be given to mothers, taking into account the erratic perception held by half of the mothers that the risk for the infant was the same as or even greater than during pregnancy.
4. Health personnel should reinforce warnings on smoking amongst breast-feeding mothers.
5. The relatively high percentages of mothers with haemorrhoids, cracked nipples, breast inflammation and psychiatric problems in the puerperal period should be better recognized in order to improve preventive, symptomatic and curative measures, whether based on drugs or alternative interventions.

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