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Original Research Article

Prescription pattern for pregnant and lactating mothers, and attitude towards the safety of medicines in a tertiary hospital in Bangladesh

Madhabi Lata Shuma[1], M. A. K. Azad[2], M. Abdul Muhit[3], Shimul Halder[4]*

[1]Department of Pharmacy, Stamford University Bangladesh, Siddeswari Dhaka, Bangladesh
[2]Department of Pharmacy, BRAC University, Mohakhali, Dhaka, Bangladesh
[3]Department of Clinical Pharmacy and Pharmacology, Faculty of Pharmacy, University of Dhaka, Dhaka, Bangladesh
[4]Department of Pharmaceutical Technology, Faculty of Pharmacy, University of Dhaka, Dhaka, Bangladesh

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***Correspondence:**
Dr. Shimul Halder,
E-mail: shimulpht@du.ac.bd

ABSTRACT

Background: Prescription pattern of drugs particularly in the special physiological conditions, e.g., pregnancy and lactation have an impact on the mothers as well as the newborns. More specifically, the evaluation of the pattern can play a pivotal role to minimize their economic burden as well as improving their quality of life by reducing drug related toxicity. This study aims at the evaluation of the prescription pattern for the pregnant and lactating mothers for the first time in one of the largest tertiary hospitals in Bangladesh. Moreover, the perception of the patients about the safety of the medicines has also been enlightened.
Methods: Data collected from 500 pregnant women and 335 lactating mothers were analyzed in the context of demographic characteristics, drug use pattern, USFDA drug risk category, and clinical complications to understand their attitude towards the safety of medicines.
Results: The study suggests that the majority of the participants were aware of the safety and usage of medications during pregnancy and lactation. Moreover, the linear regression analysis clearly indicates that pregnant women were significantly associated with a higher attitude score compared to that of the lactating mothers.
Conclusions: This study necessitates the requirement to implement the relevant WHO recommended core interventions and to develop a healthcare system by incorporating clinical pharmacists about the dispensing and sale of medicines in ensuring the rational use of medicines more efficiently.

Keywords: Pregnancy, Lactation, Drug utilization, Safety, Perception

INTRODUCTION

The prescription trends of physicians related to pregnancy and lactation has always been of attraction and important to gratify the issue of safety and efficacy.[1] Medication use during pregnancy and lactation has been an issue of serious concern and therefore requires to maintain a fine balance between the risk and the benefit, so that no harm should take place to the fetus and the inborn, and to the mother as well, hence needs strict monitoring.[2-4] Despite the lack of adequate clinical and epidemiological studies on the drug use during pregnancy and lactation, it has been reported that at least 86% of the pregnant women requires at least one medication during their pregnancy.[5,6] The majority of the prescription arises due to minor problems during pregnancy and lactation and the prevalence of using different categories of medicines differs ranging from 12.4% to 75.9%; among them dietary supplements (38.7-65.2), traditional nutritional supplements (7.8-47.5), antibiotics (1.7-34.3) and hormonal drugs (3.7-7.2).[1,4,7] In spite of having tremendous changes in physiological, pharmacokinetic and pharmacodynamic conditions during pregnancy and lactation, still these phenomena is considered therapeutic

orphans due to majority of the commonly prescribed drugs have very limited clinical information.[5,8,9] Additionally, pregnant women have been often excluded from clinical trials and extrapolation of pharmacokinetics and pharmacodynamics data from clinical studies performed in non-pregnant subjects and evidence generated from animal studies are not often suitable for clinical application.[6,10] On the other hand, most drugs can cross the placental barrier. Therefore, careful considerations of the risk benefit ratio to the mother and fetus are required before prescribing. Moreover, world health organization (WHO) recommends minimizing the use of drugs to the lactating mothers unless required to save the life of the inborn.[11] In 1979, the united states food and drug administration classified the drugs used in pregnancy into five categories; A, B, C, D, and X; based on the safety to the fetus.[12] Among them category A and category X are considered as the safest and the most teratogenic, respectively; and thus drugs of category X should not be used unless life threatening to the expecting mothers.[13] In addition, Thomas Hale's has become the standard for safety reference of drugs during lactation into five categories named L1 to L5; where L1 is the safest and L5 is contraindicated.[14]

A large number of studies have already been conducted to evaluate the prescription pattern of medicines during pregnancy and lactation using pharmaco-epidemiological surveys.[3,12,15-18] Additionally, few attempts were made to identify the sociodemographic characteristics of pregnant women correlated with attitudes and beliefs regarding medications.[19] From these studies, a substantial number of drugs was found unsafe for the pregnant and lactating mothers. Since there are numerous gaps in knowledge about deleterious consequences for the fetus, prescription drug use by pregnant women should be viewed as a public health issue and to the best of our knowledge very few studies were made to spot the problems in Bangladesh.[20] The present study was aimed to analyze the prescribing pattern of doctors during pregnancy and lactation and to evaluate the perception of patients about the safety of medications in one of the largest tertiary government hospitals in Bangladesh.

METHODS

Study area and design

This hospital based cross-sectional study was carried out to investigate the pattern of prescription during and post pregnancy period among the patients who came for treatment and consultation in a tertiary medical care hospital in the Chittagong division in Bangladesh. To conduct the study, the sampling area was selected in the gynecology and obstetrics, and neonatology department in the Chittagong Medical College Hospital (CMCH), one of the largest tertiary care hospitals in Chittagong region in Bangladesh. This study was conducted in accordance with the International Conference of Harmonization (ICH) guideline for Good Clinical Practice (GCP).[21]

Study participants

The medical and healthcare related documents of pregnant women and lactating mothers who visited the CMCH at the study period were considered as study population and the patients were considered as the participants. The participants were clearly informed about the type and purpose of this study and a written consent was taken from the participants and notified them about the confidentiality of their identity in this study.

Participants' eligibility criteria

The pregnant and breastfeeding mothers who visited the CMCH during the study period and reported at least one complication were included in this study. Any associated complications diagnosed by the physicians were considered as the complications. Both in-patient and out-patients were included and their prescriptions were evaluated. The patients were not forced to participate in the study; only those who were willing to participate were included.

Exclusion criteria

All administrative and non-administrative staff who belongs to pregnant and breastfeeding; patients who did not present with any complications and those who had complications before the time of study duration were excluded from this study.

Sampling and sample size

A stratified simple purposive population proportion based technique was used to determine the sample size in both pregnant women and lactating mothers.[22] The sample size was calculated for pregnant women was 467, however, to ensure more representative data, we selected a larger sample size of 500 for pregnant women in this study. In case of lactating women, the calculated sample size was 630, hence the total number of populations during this study was <1000, therefore the sample size was adjusted to 335 in this study. All patients approached responded to this study and thus the response rate was 100%.

Data collection

Data were collected by means of a semi structured questionnaire over six months of period and also data were abstracted from the medical records of the individual patients file including socio-demographics, drug related variables, safety profile of drugs and also the medical condition of the patients. Data on self-medications and/or any other medication being taken besides those prescribed by the physicians were not collected. Any doubts and queries by the data collectors were communicated through telephone or face to face by either the supervisor and/or investigator. The questions were prepared in such way that can be easily understandable to the participants.

Statistical analysis

This study employed primarily univariate and multivariable regression data analyses. Univariate analysis was used to tabulate the frequency of social and demographic statistics. The collected data were coded, checked manually for completeness, recorded and analyzed. The graphs were plotted using Graph pad, Prism 6.0, (GraphPad Software, LaJolla, CA). A value of $p<0.05$ was considered statistically significant at 95% confidence interval. Data were presented in tables. In the section on attitudes, scores were calculated based on the respondents' answers to each attitudinal statement; 1, strongly disagree; 2, disagree; 3, undecided; 4, agree; and 5, strongly agree; respectively. Scores were calculated by averaging respondents' answers to the six statements. Total scores ranged from 6.0 to 30.0, with high scores indicating positive attitudes. The Likert scales were assessed for internal reliability, using Cronbach's a. Cronbach's alpha coefficient was 0.78, indicating internal reliability. A multivariable linear regression analysis was performed, to identify the difference between pregnant women and lactating mothers related to the attitudes towards the safety of medicine.

Ethical considerations

This study is anonymous and didn't involve any risk to the patients, therefore this study didn't require a review board approval. However, the experimental protocols were approved by the Institutional Ethical Review Committee of the department of Pharmacy, Stamford University of Bangladesh. In addition, a written permission was obtained from the respective head of the departments to collect the prescriptions and survey questionnaire. In order to prevent sampling bias, the prescribers were kept unaware about the collection of prescriptions.

RESULTS

Sociodemographic characteristics

A total of 500 pregnant women and 335 lactating mothers' medical record along with structured questionnaire were reviewed. From these data it showed that the mean age of the pregnant women and lactating mothers were 23.4±4.34 years and the majority were in the range of 21-25 years. The larger proportion of pregnant women 250 (50%) were multigravida and the mean parity was found 2.03±1.05. According to trimester distribution, 219 (45.63%) of the populations were from third trimester. It also revealed that majority of them are housewives and live-in rural areas. In Table 1 and Table 2, the detailed socio-demographic data on pregnant women and lactating mothers have been presented. It is also noticed that the mean random blood glucose level (in mmol/l) and blood pressure (in mmHg) of the respondents are closed to upper-level limit of the normal adult, 6.37±0.52 and systolic 125.2±9.49 and diastolic 82.4±4.97, respectively.

Clinical complications

Table 1 and Table 2 showed the frequency of some complications which were found among the participants. On reviewing pathological data, it was found out that all pregnant women underwent ultrasonography. The frequency distribution of the complications revealed that 175 pregnant women (35%), 90 women (18%) and 110 women (22%) had been suffering from various types of pains (back, abdominal, lower abdominal, neck and pelvic pain), hypertension and diabetes, respectively. Pathological data of breastfeeding mothers also showed that the majority 230 (68.7%) had problems in breast milk quantity or milk production, most probably due to the breast engorgement followed by sore nipples or breast abscess.

Table 1: Socio-demographic characteristics of the pregnant women (mean±SD).

Characteristics	Sub-group	Frequency (N)	Percentage
Gestational period (trimester)	First	105	21.00
	Second	176	36.67
	Third	219	45.63
Occupation	Unemployed	328	65.6
	Employed	172	34.4
Education	Uneducated	40	8.0
	Below HSC	125	25.0
	Tertiary level	335	67.0
Residence	Rural	390	78.00
	Urban	110	22.00
Regular antenatal check-up	Yes	410	82.00
	No	90	18.00
Gestational complications/ co-morbidities	Hypertension	90	18.00
	Diabetes mellitus	110	22.00
	Epilepsy	15	3.00

Continued.

Characteristics	Sub-group	Frequency (N)	Percentage
	Chronic thyroiditis	5	1.00
	Uterine fibroid	55	11.00
	Gastro enteritis	5	1.00
	Chronic bronchitis	10	2.00
	Depression	25	5.00
	Eclampsia	10	2.00
	Pain	175	35.00
		Mean±SD	
Maternal age (years)		23.4±4.34	
Parity		2.03±1.05	
Blood glucose level (mmol/L)		6.37±0.52	
Body weight (kg)		47.3±7.33	
Blood pressure (mmHg)	Systolic BP	125.2±9.49	
	Diastolic BP	82.4±4.97	
Drugs per prescription		2.94±0.82	

Table 2: Socio-demographic characteristics of the lactating mothers (mean±SD).

Group	Sub-group	Frequency (N)	Percentage
Is the breast milk sufficient for the newborn?	Agreed	98	29.3
	Somewhat agreed	230	68.7
	Disagree	7	2.0
Mode of delivery	Normal	201	60.0
	Cesarean section	134	40.0
Is the baby a full-term baby?	Yes	303	90.5
	No	28	8.5
		Mean±SD	
Age of the newborn (months)		10.3±3.31	
Birth weight of the baby (Kg)		3.45±0.82	
Drugs per prescription		2.2±0.68	

Table 3: Commonly prescribed therapeutic category of drugs during pregnancy (according to gestational age and their chi-square statistics) and lactating women.

Therapeutics	During pregnancy (n=1477)					Lactating women (n=737)	
	1st trimester frequency (N)	2nd trimester frequency (N)	3rd trimester frequency (N)	χ^2 value	P value	Frequency (n)	%
Analgesics, antipyretic, anti-inflammatory	16	56	47			99	13.43
Anti-anemic/vitamin and mineral supplements	107	161	171			143	19.4
Anti-asthmatic	0	3	3			13	1.79
Anti-diabetic	6	8	5			9	1.19
Antiemetic	35	41	8			11	1.49
Antihistamine	26	15	29			68	9.25
Anti-infective	7	15	30	73.76	<0.01**	187	25.37
Anti-ulcerant	47	75	83			99	13.43
Cardiovascular drugs	2	18	9			–	–
Dermatological						26	3.58
Folic acid	112	159	166			79	10.75
Hormones	2	3	6			–	–
Prescribed milk inducing drugs	–	–	–			53	7.16
Others	2	3	1			16	2.09
Total	362	557	558	(1477)		737	100

**Indicates p value highly significant.

Table 4: Drugs prescribed during pregnancy according to USFDA risk category and gestational age.

USFDA risk category	Gestational age (trimesters)							
	First		Second		Third			
	Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)	Frequency (N)	Percentage (%)	χ^2 value	P value
A	108	7.31	256	17.33	261	17.67	59.15	<0.0**
B	132	8.94	187	12.66	196	13.27		
C	89	6.03	94	6.36	81	5.48		
D	24	1.62	10	0.68	13	0.88		
X	3	0.20	0	0.00	0	0.00		
Non- coded	6	0.41	10	0.68	7	0.47		

**Indicates p value highly significant.

Table 5: Patient's attitude towards the safety and adverse effects of prescribed medicines along with regression analysis.

Questionnaire	During pregnancy (n=500)					During lactation (n=335)				
	Strongly Agree	Agree	Undecided	Disagree	Strongly disagree	Strongly Agree	Agree	Undecided	Disagree	Strongly disagree
Too many medicines in a prescription	277	89	44	61	29	164	59	31	57	24
Natural remedies are safer than medicines	304	74	43	32	47	156	50	45	43	41
Medicines are more beneficial than harmful	249	58	65	79	49	146	39	44	69	37
If doctor had more time with patients; he would have prescribed fewer medicines	256	102	38	77	27	171	68	26	52	18
Medicines can be harmful to the fetus/inborn	269	99	32	56	44	151	67	30	48	39
Avoid medicines if possible (side effects/inhibit lactation)	323	71	41	29	36	159	58	46	39	33
Mean ±SD	24.1±1.27					22.5±1.88				
Multiple linear regression output of the attitude score										
Factors	β			Standard error		t			P value	
Intercept	21.33			1.906		106.5			<0.01**	
Pregnancy vs lactation	0.7889			0.1738		3.387			<0.01**	

Drug use pattern in prescriptions

From the total 500 pregnant women everyone took at least one drug. A total of 1477 drugs were prescribed to the pregnant women, among which supplemental drugs and folic acid accompanied majority; 29.63% and 29.47%, respectively. The average number of drugs prescribed per pregnant women was found to be about 3 per prescription (2.94±0.82) where as in lactating mothers 2.2±0.68. A detail data on prescribed drugs during pregnancy was presented in Table 3. Beside the supplemental drugs; anti-ulcerants and analgesics were more predominant in prescriptions to the pregnant women. Antiemetic drugs (9.68%) have the large proportional used during first trimester to prevent the morning sickness. According to trimester, the drug use per prescription is higher in frequency during the third trimester followed by second and third trimester. In addition, drugs used during lactation period based on the therapeutic class were presented in Table 3. Anti-ulcerant, nutritional supplements, analgesics and anti-infective are more commonly prescribed medicines during lactation.

FDA pregnancy risk categories

For the analysis of FDA pregnancy category of drugs and identification of teratogenic drugs were used. Majority of the prescribed drugs were from pregnancy category A, 42.31%, followed by 34.84% from category B. Very limited number of category D and X drugs were used based on the risk benefit ratio to the pregnant women. The detailed data on USFDA pregnancy category dugs observed in this study are presented in Table 4. The Chi-square value shows highly significant means there is significance in drug using in different trimesters of pregnancy (p value <0.01).

Attitudes towards the risk

The attitude towards the safety and adverse effects of medicines has been analyzed based on the data of the participants during pregnancy and lactation. Table 5 represents the pregnant and lactating mothers' attitude towards the prescribed medicines using Likert scale. Every participant was marked upon the range of 6 to 30 score. From the data, it was found that the majority of the participants were aware about the safety and usage of medications during pregnancy and after birth up to a certain period of time. The mean score for the pregnant and lactating mothers found 24.1±1.27 and 22.5±1.88, respectively**.** From the linear regression analysis, we see that the pregnant women (*vs*. lactating mothers, β=0.7889; p<0.01), were significantly associated with a higher attitude score.

DISCUSSION

Rational use of drugs, particularly in pregnancy and lactation is of utmost importance considering the matter of fact that the benefits outweigh the potential risks; most importantly when the development of the fetus as well as the recovery of maternal health is necessary. Moreover, there are some unprecedented events, e.g., abortions, premature births and embryopathies which could be avoided by managing diabetes, infections etc. with proper treatment.[17,23]

In this study, data were analyzed for demographic characteristics, drug use pattern, FDA (Food and Drug Administration) drug risk category and trimester wise drug use pattern (Table 1-5). Overall drug use pattern was found rational with a few exceptions. Trimester wise distribution of the drugs was found logical in accordance with the common practice except a prescription in pregnancy category X and more encounters of prescribed drugs in second trimester (Table 4). FDA pregnancy category A constitutes the majority of the drugs prescribed, the safest category during pregnancy, followed by other classes of the drugs, B, C, D and X, respectively. However, the average number of drugs per prescription in an encounter was much higher (>3) than the standard set by World Health Organization (1.6-1.8) that represents the practice of poly pharmacy in the hospital.[24] The drug prescription pattern showed that the prophylactic use of folic acid, multivitamins and minerals were frequently recommended (Table 3) which is in accordance with some studies done in many other countries, e.g., Australia, Finland, Ethiopia and India.[25] It seems that this has been a very common practice worldwide. However, the presence of antibiotics in the prescriptions of that specific duration of the study period was relatively lower in comparison to other studies that seemed very positive and in line with the standard recommended by WHO, a bit unrealistic though in the context of climate and environment of Bangladesh and the data do represent the divergence with some studies done in other countries.[11,13] Since the time, place and individuals of the studies were different, the data do not necessarily have to be in accordance with each other. Now if that was the case, the study reveals that undoubtedly there has been an outstanding improvement of awareness of being careful to avoid infection possibility during the pregnancy and lactation period of the women, majority of whom were housewives, of that mentioned regions of Bangladesh.

After we focus on the perception of the safety and adverse effects of the medicines in Table 6, it comprehends that the majority of the participants having better education, secondary to university constitutes 92.0% (Table 1), responded that poly-pharmacy practice was prominent. Since the number of drugs was clearly visible in the prescription, they noticed the matter, but they have a perception that taking more medicine may help and have meagre knowledge of the harmful effect of medicine. This can possibly result from the lack of access to the awareness program. On the contrary, when there was a concern about the harmful effects of the fetus or inborn babies and concerning the inhibition of lactation majority of the patients agreed to avoid the medicines.

A showcase of substantial number of unsafe drugs in the prescription for the pregnant and lactating mothers prove the communication gap between the patients and the doctors or the lack of proper assessment of the patients that can be due to the lack of time. On the contrary, more than 60% of the individuals agreed that even though the doctors had more time with the patients, they would have prescribed fewer medicines (Table 5). Now, here comes the opportunity for the hospital or clinical pharmacists to play a major role regarding the assessment, counseling and follow up of the patients to assure the understanding of the safety and adverse effects of the medicines. Moreover, the study suggests an absolute necessity of the control and monitoring of the prescription errors to avoid the unintentional detrimental effect of the medicines to the pregnant and lactating women. Without increasing access to essential drugs and their rational use, it will never be possible to improve health status and secure development gains. The hospitals should keep in mind that they have a special responsibility to society to promote rational use of the drugs by their staff and, through them, the future generations of doctors [24]. Therefore, it is recommended that the setting of target quality values for the practitioners should be geared to improving the therapeutic performance, thus the quality of care.

Limitations

This study intended to address the overall drug utilization pattern during pregnancy. The study had some limitations as we faced some complications during the survey. Firstly, the study was covered in only one hospital and so this data obtained from a tertiary care hospital cannot be accounted as a representative data from several maternal care hospitals in Bangladesh. The drugs whether injectable or not were not taken into consideration (which is an integral part of WHO/INTRUD prescribing indicator). Moreover, the study only analyzed the drugs prescribed but not the outcomes of the therapy. So, the success of the therapy cannot be measured from this study. Finally, social desirability bias may have impacted the responses since the interviews were done in person.

CONCLUSION

We should conclude that poly-pharmacy, very short assessment, consultation times, and lack of patients' knowledge about prescribed medicines were the major issues that need the attention of the healthcare authorities. This study shows that although prescribing of drugs during pregnancy and lactation is very common and, the levels of prescribing of drugs that are almost only when necessary. From data, almost every participant took at least one nutritional supplements. There was insufficient drug information on patients' medical records and some patient's medical records didn't have diagnosis for the prescribed drugs at all. Therefore, health-care professionals should be aware of women's attitudes when advising them to take medication during pregnancy and lactation. Moreover, this study necessitates the requirement to implement the relevant WHO recommended core interventions to promote rational use of medicines in the hospital.

Recommendations

Medication safety can often be a great source of concern for women and healthcare professionals alike, leading to decisions that can negatively impact on outcomes. Although appropriate drug utilization is one of the key ways to prevent the irrational use of medicine and thereby to reduce the fatality and teratogenic risk during pregnancy and lactation. This study findings suggest that regulations and monitoring on drug dispensing should be strengthened by the legislative authorities. Therefore, based on the findings of this current study, we recommend the following: use medication only if absolutely indicated. Avoid initiating therapy during the first trimester. Select a medication with a proven track record in human pregnancy. Use a single-agent with the lowest effective dose. Discourage the use of over-the counter drugs that might interact with prescription medications. Appoint clinical pharmacist and consult with them in monitoring, assessing and contributing to changes in existing and evolving trends related to medication use during pregnancy and lactation in order to improve quality use of medicines.

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