RESEARCH ARTICLE

An observational prospective study on prescribing pattern of drugs among pregnant women admitted in antenatal ward of a tertiary care teaching hospital in coastal town of South India

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ABSTRACT

Background: Pharmacoepidemiological studies may provide an insight regarding the existing drug use pattern and in planning appropriate interventions to ensure rational drug therapy. Aims and Objectives: This study is aimed to evaluate the prescribing pattern of drugs among pregnant women admitted in antenatal ward of our hospital. Materials and Methods: An observational prospective study was conducted in 72 pregnant women for a period of 6 months. Each prescription was analyzed for demographic variables, various categories of drugs prescribed, individual drugs prescribed in that category, their dosage forms, the World Health Organization core prescribing indicators, and their teratogenic risk. Results: Overall 358 medications were prescribed among which vitamin and mineral supplements (57.26%) were the most commonly prescribed category followed by intravenous fluids (IVFs) (12.57%) and antiemetics (8.38%). Among vitamin and mineral supplements, folic acid (30.24%) was the most commonly prescribed drugs. Ringer lactate (46.67%) was the most commonly prescribed IVF. Ondansetron (66.67%) was the commonly prescribed antiemetics. Most commonly prescribed antimicrobial agents were metronidazole and mebendazole (27.59% each), antiulcer drug was ranitidine (87.5%), analgesic was paracetamol (58.33%), and tetanus toxoid was the only vaccine prescribed. Majority of drugs (75.69%) were prescribed by generic name. Average number of drugs per prescription was 4.97. Percentages of encounters with antibiotic prescribed were 8.10%. The percentage of injections prescribed was 22.91% and that of drugs prescribed from the National List of Essential Medicines (NLEM) was 95.53%. Tablet (43.58%) was the common drug formulation. According to teratogenic risk, category B (56.25%) was highest. Conclusion: On the whole, vitamin and mineral supplements were the most commonly prescribed drugs in our study. Prescription by generic name was high, usage of antibiotics and injections was less, and nearly all drugs were prescribed from NLEM, which indicates rational prescription. Usage of category B drugs must be reduced, and complete avoidance of category D drugs is advised.

KEY WORDS: Antenatal Ward; Generic Name; National List of Essential Medicines; Prescribing Pattern

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INTRODUCTION

Pregnancy is the most precious time period a woman goes through in her life. It constitutes special physiological changes that prevail a herculean task for the doctors in managing the disease condition and to ascertain the appropriate drug management. Drug treatment during pregnancy is always a

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special concern since every drug is potentially harmful to fetus.

In general, no medication is recommended during pregnancy unless it is indicated for any severe condition because many drugs used in maternal period can be teratogenic. The drugs taken by the pregnant mothers for therapeutic purposes may cause dangerous structural and functional adverse effects in the growing fetus.^[1] All the marketed drugs are not studied to a complete extent that they have proved to be safer in pregnancy, and hence, for this obvious ethical reason, most of the drugs are not recommended to be used during gestational period.^[2]

The drugs prescribed in pregnant women should be considered as a public health issue since there is wide lacuna in knowledge about the deleterious consequences of any drug on fetus.^[3]

In near past, the use of drugs during pregnancy has increased enormously. Few reports suggest that more than 50% of pregnant women take prescription or nonprescription drugs and social drugs at some point of time during their gestation. About 2-3% of all birth defects are results of the drugs that are taken to treat a disorder or symptom. The use of prescription drugs during pregnancy has been a serious concern since the advent of birth defects as a result of thalidomide in human pregnancy in 1960s.^[4]

However, avoiding all the drugs during early pregnancy is impossible and may be dangerous to the health of the mother and indirectly the fetus too.^[5] Pregnancy should not deter the doctors from treating their patients with appropriate management of their medical problems; hence, drugs prescribed in pregnancy are an unusual risk-benefit situation.^[6,7] Sometimes, drugs are very essential for the health of pregnant woman and the fetus. Before taking any drug or any dietary supplement, a pregnant mother should consult her doctor who will recommend to take necessary vitamins and minerals, medications, and food supplements during pregnancy.^[8,9] Information on the drug used in pregnancy is scarce and rather anecdotal.^[10] In India, most of the pregnancies are unplanned and chances are pregnant women may be taking drugs before they know are pregnant and also they may be having little knowledge on the drugs consumed.^[11] Always, there is a need to educate and counsel the childbearing women regarding the advantages and disadvantages of drug use during pregnancies.^[12]

Utmost care should be taken during drug prescription in pregnancy as physical and mental growth of the fetus is at stake. Many studies conducted in developed countries where prescribing drug practice is mostly utilized and have identified the need for interventional procedures for the purpose of rational prescription during the prenatal period.^[13,14] To produce the desired effect, the drugs have

to be safe, and efficacious and rational drug use must be ensured.^[15] Rational use of drugs should follow the rule of RIGHT (right drug, right patient, right dosage, and right cost) and safety, affordability, need, and efficacy criteria.

The irrational use of drugs is an important issue in the present day medical practice and due to which few consequences such as development of resistance to antibiotics, improper treatment, adverse effects, side effects, and increased economic burden on the patients and also in pregnant women, the dangerous consequences of producing teratogenic effects. Pharmacoepidemiological studies may provide an insight regarding the existing pattern of drug use and in planning appropriate treatment to ensure rational drug therapy and especially in pregnant women, the extent of teratogenic drugs prescribed. Hence, the present study was designed to analyze the prescribing pattern of drugs among pregnant women admitted in antenatal ward (ANW) of our hospital.

MATERIALS AND METHODS

An observational prospective study was conducted in a total of 72 pregnant women who were admitted in ANW for a period of 6 months from September 2014 to March 2015 in Gynecology and Obstetrics Department of a tertiary care teaching hospital in South India. All the pregnant women with age >18 years who visited the hospital and got admitted in the ANW and who had given the consent to participate were included in the study. Pregnant women with age <18 years, incomplete data, and those not willing to participate were excluded from the study.

A written informed consent to participate in the study was obtained from all the patients who participated in the study. The study protocol confirmed to the ethical guidelines of the 1975 Declaration of Helsinki, and ethical clearance was obtained from the Institutional Ethical Committee before commencing the study.

Each prescription was analyzed for various study parameters such as patient's age, hemoglobin, height, weight, random blood sugar, gravidity, duration of gestation (trimester), common presenting complaints, various categories of drugs prescribed, and their dosage forms. The data were also analyzed using the World Health Organization (WHO) core prescribing indicators^[16] and were also classified according to the US Food and Drug Administration (FDA) pregnancy drug risk category^[17,18] that constitutes category A drugs which show no fetal risk, category B drugs are also quite compatible as there is not much evidence (both animal and human studies have failed to prove any substantial risk), category C drugs are harmless at lower doses, and category D drugs have proved teratogenic potential but has been deemed to be essential to administer only in case maternal life is threatened by some diseased state. Category X drugs are contraindicated in

women who are or may be pregnant.^[19,20] To evaluate whether the prescribing pattern of drugs conforms to our national drug policy, we have analyzed the percentage of drugs prescribed from the National List of Essential Medicines (NLEM) of India. Statistical analysis was primarily descriptive with values mainly expressed as percentages.

RESULTS

In the present study, 72 pregnant women received 358 medications during the study period, among which 43 (59.72%) were primigravida and the remaining 29 (40.28%) were multigravida. The age group of the patients was within 18-39 years, and the average age was 26 years. The majority of them were in the age group of 26-30 years (50%), followed by 21-25 years (29.71%), 18-20 years (11.11%), 31-35 years (6.94%), and the least age group was >35 years (2.78%) (Figure 1).

The average hemoglobin level was 9.93 g/dl, the average height and weight of the patients were 156 cm and 63 kgs, respectively, the average random blood sugar was 91.67 mg/dl, and the average months of amenorrhea among the antenatal patient were 6 months (Table 1).

Most of the women (41.67%) were in the third trimester, while 31.94% were in the first trimester, and 26.39% were in the second trimester, who visited the antenatal care department. Among the antenatal patients, 43 (59.72%) were primigravida, 20 (27.78%) were the second gravida, 8 (11.11%) were the third gravida, and a least 1 (1.39%) was the fourth gravida (Figure 2).

Most of the women presented to the hospital for routine antenatal check-ups (51.45%), and other common presenting complaints were fatigability (18.23%) due to anemia, followed by hyperemesis gravidarum (15.88%) and least complained with abdominal pain (14.44%).

A total of 358 drugs were prescribed to 72 antenatal patients. According to various categories of drugs classified, vitamins and mineral supplements were the most commonly prescribed drugs (n = 205; 57.26%) (Figure 3).

Among the vitamin and mineral supplements, oral folic acid (30.24%) was the most commonly prescribed vitamin and mineral supplement followed by oral calcium (26.34%) and then followed by oral vitamin B12 (16.59%) while the least prescribed vitamin and mineral supplements were syrup vitamin B complex (0.49%) and oral vitamin C (0.49%) (Figure 4).

The next most commonly prescribed drug group was intravenous fluids (IVF) (n = 45; 12.57%), of which ringer lactate (46.67%) was the most frequently given IVF, followed

Table 1: Demographic profile of patients in antenatal			
ward			
Parameters	Average	Mean	
Hemoglobin	9.9344 g/dl	1.8556	
Height	156.00 cm	8.948	
Weight	62.859 kg	8.6755	
Random blood sugar	91.667 g/dl	14.051	
Months of amenorrhea	6.0873 months	4.918	
Age	26.225 years	4.3299	

by the other two maintenance fluids namely dextrose normal saline (26.67%) and normal saline (26.67%) in this drug category (Figure 5).

Antiemetics (n = 30; 8.38%) was the next major drug category prescribed to antenatal patients, among which oral and parenteral ondansetron (66.67%) was the most commonly prescribed followed by oral doxylamine succinate (30%) which was the most safest antiemetic drug for treating hyperemesis gravidarum in pregnancy mentioned as category A drug by the FDA drug risk category for pregnancy, and the least given drug was oral domperidone (3.33%) (Figure 6).

The next frequently administered group was antimicrobials agents (AMA) accounting for n = 29, 8.10%, wherein the most commonly prescribed drugs were oral metronidazole and mebendazole (27.59% each) followed by parenteral cefixime (24.14%), and the most least prescribed AMA was oral doxycycline (3.45%) which was mentioned in the FDA drug risk category as a category D drug (Figure 7).

The next most commonly prescribed drug category was antiulcer drugs (n = 16; 4.47%). Among them, oral and parenteral ranitidine (87.5%) was the most frequently prescribed drug followed by parenteral pantoprazole (12.5%).

Among the analgesics (n = 12; 3.52%), the most frequently prescribed drug was oral paracetamol (58.33%) for the management of intermittent abdominal pain during gestation period and followed by parenteral diclofenac (41.67%).

Miscellaneous drugs include vaccines such as tetanus toxoid (n = 07; 1.96%), nutritional supplements such as arginine (n = 05; 1.40%), Antihistaminics such as cetirizine and pheniramine maleate (n = 04; 1.12%), local anesthetic such as lignocaine (n = 03; 0.84%), and corticosteroids such as dexamethasone (n = 02; 0.56%) were prescribed (Table 2).

Majority of the drugs (75.69%) in our study were prescribed by their generic names which were almost the same across all trimesters. Average numbers of drugs per prescription were 4.97. Percentages of encounters with antibiotics prescribed were 10.06%. The percentage of prescriptions with injection



Figure 1: Age wise distribution of patients in antenatal ward



Figure 2: Distribution of patients in antenatal ward according to trimester and gravidity



Figure 3: Category wise drug prescription among patients in antenatal ward

prescribed was 22.91%, and the percentage of drugs prescribed from NLEM was 95.53% (Table 3).

Regarding the drugs prescribed to the pregnant women by dosage forms, nearly half (43.58%) were tablets which were the most commonly prescribed dosage form across all trimesters. Injections (22.91%) and capsules (19.27%) were



Figure 4: Prescription of vitamins and mineral supplements among patients in antenatal ward



Figure 5: Prescription of intravenous fluids among patients in antenatal ward



Figure 6: Prescription of antiemetics among patients in antenatal ward



Figure 7: Prescription of antimicrobial agents among patients in antenatal ward

the next frequently prescribed dosage forms, and the least was syrup (0.28%) (Table 4).

Table 5 represents FDA drug risk category wise prescription pattern among patients in ANW based on their teratogenic potential. Among them, category B drugs which constituted 56.25% (18) were the most commonly prescribed drugs followed by category C, A, and D which account for 25%, 15.63%, and 3.13%, respectively. However, category X was never prescribed during any trimester.

DISCUSSION

Although there were many similar studies that had been conducted in North India and other parts of the world, this is the first study to the best of our knowledge that had been conducted in coastal town of South India which had analyzed the prescribing pattern of antenatal care providers in tertiary care teaching hospitals. In spite of less safety details regarding the drugs used in pregnancy, many studies consistently find the use of drugs in pregnant women with established risks without knowing the adverse effect to both mother and fetus. A constant monitoring of the drug prescription is required to prevent the adverse effects, and hence, many studies have been carried out all over the world. This study was undertaken

Table 2: Category wise drug prescription amongpatients in antenatal ward		
Drugs	Total number (%)	
Vitamins and mineral supplements	205 (57.26)	
Intravenous fluids	45 (12.57)	
Antiemetics	30 (8.38)	
Antimicrobial agents	29 (8.10)	
Antiulcer drugs	16 (4.47)	
Analgesics	12 (3.52)	
Miscellaneous		
Vaccines	07 (1.96)	
Nutritional supplements	05 (1.40)	
Antihistaminic	04 (1.12)	
Local anesthetic	03 (0.84)	
Corticosteroids	02 (0.56)	
Total	358 (100)	

Table 3: WHO core drug prescribing indicators amongpatients in antenatal ward		
Indicator	Value (%)	
Average number of drugs per prescription	4.97	
Percentage of drugs prescribed by generic name	75.69	
Percentage of encounters with antibiotic prescribed	8.10	
Percentage of encounters with an injection prescribed	22.1	
Percentage of drugs prescribed from essential drug list	95.53	
WHO: World Health Organization		

at a tertiary care teaching hospital to analyze the prescription pattern in pregnancies, WHO core drug prescribing indicators and simultaneously the drug risk categorization of these prescribed drugs as per the FDA guidelines.^[19]

In our study, the mean age of the patient was 26.23 ± 4.33 years, and the most common age group was between 26 and 30 years which is in accordance with the other prospective studies^[15,21] that represent the normal reproductive age group. Almost half of the patients (41.67%) of antenatal inpatient department were in their third trimester during the study period which is contrast to the observation made in some studies in which the first trimester mothers were more in number.^[22,23] Most of the pregnant women came only for routine antenatal check-up with no complaints but were admitted as they were severely anemic. Majority of antenatal mothers were primigravida (59.72%) in this present study which is consistent with another study report.^[24]

Vitamins and mineral supplements were the most frequently used drug for pregnancy in our study which is in accordance with earlier prospective studies.^[12,15,25] Folic acid, calcium, and iron supplements were prescribed to majority of patients which may be because of high prevalence of anemia in pregnancy due to the poor nutritional status of the pregnant women. Vitamins and mineral supplements play a pivotal role in the prevention of maternal and child mortality and morbidity.^[26]

The second most prescribed category was IVF among which ringer lactate was most frequently prescribed in our study which is in line with a study.^[27] As most of pregnant

Table 4: Prescription of drugs according to the dosageforms among patients in antenatal ward		
Drug formulations	Numbers (%)	
Tablets	156 (43.58)	
Injections	82 (22.91)	
Capsules	69 (19.27)	
Infusions	45 (12.57)	
Powders/granules	05 (1.39)	
Syrups	01 (0.28)	
Total	358 (100)	

Table 5: Prescription pattern according to FDA drug risk-category wise		
Category	Numbers (%)	
Category A	5 (15.63)	
Category B	18 (56.25)	
Category C	8 (25)	
Category D	1 (3.13)	
Category X	0.00	

FDA: Food and Drug Administration

women suffer with hyperemesis gravidarum, it is necessary to manage the electrolyte imbalances for which ringer lactate is the preferred IVF.

Among the antiemetics, ondansetron was the most prescribed drug in our study. Even though doxylamine succinate is the only FDA-approved drug for treating nausea and vomiting in pregnancy,^[28] it was prescribed less than ondansetron in our study.

The next common categories of drugs were AMA (8.10%) which are in contrast to two previous studies that reported comparatively more usage of AMAs.^[29,30] Among the AMAs, metronidazole and mebendazole were the frequently prescribed drugs which are similar to a previous study done in North India.^[10] Even though doxycycline belongs to category D and has substantial teratogenic risk, it was prescribed for one patient in our study, which must be avoided.

Percentage of drugs prescribed by generic name was 75.69% which reveals a greater tendency to prescribe by generic name rather than by brand name in our hospital which is a good sign as it reduces the economic burden on the patients. In other previous studies, it was less.^[21,31] Percentage of antibiotics prescribed was 8.10% which is similar to other studies.^[6,32] Unnecessary usage of antimicrobials will result in both excess cost to the patient and also development of widespread resistance. Percentage of encounters with an injection prescribed was 22.91%, which is relatively high. Percentage of drugs prescribed from NLEM was high (95.53%) which indicates that prescribing in our hospital is complying with the national drug policy.

Majority of patients used oral dosage form across all trimesters (43.58%), the simplest route for any patient to take medication.^[33] Injections were also frequently used in all trimesters of gestations. This may be because many pregnant women were admitted for hyperemesis gravidarum whom they took different parenteral drugs such as antiemetics, analgesics, IVF, and antibiotics.^[34]

As far as the FDA drug risk category is concerned, the majority of the drugs used during pregnancy in our study belonged to FDA category B followed by category C and category A which is similar to results obtained in previous studies done in USA and Nigeria,^[8,35] but they are in contrast to other studies^[21,36,37] which reported more use of category A, followed by category B and category C. No drugs were prescribed from category X. Similar pattern of category distribution was reported from a study at Netherland.^[38]

In another study, it was reported that a wide majority of prescribed drugs during pregnancy, belonged to category C.^[39] When compared to this study, the prescription pattern followed in our hospital is relatively safe. In a retrospective Finnish

study, 20.4% of women purchased at least one drug classified as potentially harmful drug during pregnancy^[40] and 3.4% purchased at least one drug classified as clearly harmful.^[41] According to a study done in France,^[13] 4.6% of women were exposed to drugs (mainly NSAIDs), involved in risk during pregnancy. Concern on safest category pattern during pregnancy must be ensured.

These findings highlight the importance for studies of drug exposure during pregnancy. To prevent such exposures, it is recommended to avoid all drugs having potential teratogenic effect in women of childbearing age who plan to become pregnant. Therefore, a more cautious prescribing of drugs to healthy women in the fertile age group is necessary.

CONCLUSION

We conclude that vitamins and mineral supplements were the most frequently prescribed drugs in our study. Majority of antenatal women were primigravida and in the third trimester. Prescription by generic name was high, usage of antibiotics and injections was less, and nearly all drugs were prescribed from NLEM, which indicates rational prescription. Usage of category B drugs must be reduced, and complete avoidance of category D drugs is advised.

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