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Original Research Article

Prescription pattern during pregnancy in the tertiary care hospital of Kolar, India: A cross-sectional study

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ABSTRACT

Introduction: Pregnancy is associated with major physiological changes in the body. Recommendation to avoid all drugs during first trimester is an unrealistic situation, a benefit risk has to be analysed before prescribing, as management of various ailments during pregnancy is equally important. This study aimed to assess the pattern of drug prescription during pregnancy.

Materials and Methods: Cross sectional study was conducted at tertiary care teaching hospital by department of Pharmacology and Obstetrics and Gynecology from December 2016 to 2018 after obtaining ethical clearance from Institutional Ethics Committee. The drug prescriptions given to the antenatal women were collected after obtaining verbal consent from them and entered in a predesigned proforma.

Results: Total of 615 prescriptions were collected. The most common category of medicine was minerals/vitamins 536(46.28%). Majority of the drugs were prescribed from category A 597(51.55%) and category B 398(34.36%). Most of the prescriptions contained two drugs per prescription 301(48.9%) followed by one drug per prescription 199(32.3%). WHO prescribing indicators were compared with the finding of current studies.

Conclusion: The average number of drugs prescribed, injectables and anti microbial agents utilized were according to WHO standards. The most commonly prescribed drugs were vitamins and minerals followed by drugs used in vomiting. Category A and B drugs were prescribed to the maximum.

1. Introduction

Pregnancy is associated with profound physiological changes in the body. Drug prescription to a pregnant woman has been a concern among health care providers as it can involve risk to both mother and the offspring.[1] Recommendation to avoid all drugs during first trimester is an unrealistic situation, a benefit risk ratio has to be analysed before prescribing, as management of various ailments during pregnancy is equally important. During clinical trials there is under presentation of pregnant women hence quality information regarding the safety and effectiveness of drug during pregnancy is lacking. Most of the trials exclude pregnant women.[2] The teratogenic effects of drugs cannot be predicted based on animal studies alone and clinical trials add limited drug information at the population level to capture data from all women of child bearing age.[3] There has been constant call for extensive research into drug prescription during pregnancy and associated co morbid conditions.[4] The United States Food and Drug Administration (US FDA) has introduced a system of rating risk associated with drugs during pregnancy and categorized into A, B, C, D and X categories. The degree of precaution to be taken is indicated based on animal studies and available human data.[5] The most safe drugs

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to prescribe for pregnant women are category A and B. But many studies have shown the utilization of category D and X in women under rare circumstances.[6] Though the information on the use of drugs during pregnancy is meagre, it is surprising to know that the pregnant women consume the over the counter medication along with the prescribed medications. The studies done in countries with stringent prescription practices have raised the need to identify the rational prescription of medications to antenatal women.[7,8] This study aimed to assess the pattern of drug prescription during pregnancy in tertiary care teaching hospital.

2. Materials and Methods

This is a cross sectional study which was conducted at R L Jalappa Hospital attached to Sri Devaraj Urs Medical College, Sri Devaraj Urs Academy of Higher Education and Research, Tamaka, Kolar, Karnataka, India. The study was carried out by department of Pharmacology and Obstetrics and Gynecology from December 2016 to 2018 after obtaining ethical clearance from Institutional Ethics Committee no. DMC/KLR/IEC/96/2016-17. The drug prescriptions given to the antenatal women were collected after obtaining verbal consent from them and entered in a predesigned proforma. The proforma gathered information on age, gravidity, trimester, weight, blood group, occupation and medications prescribed, route of administration, dose and duration of treatment. Every month around 20 to 25 prescription would be collected randomly. The prescriptions given to the women on repeat visits will not be included in order to avoid duplication of data. World Health Organization (WHO) recommended specific prescribing indicators were used to analyze and compared these prescriptions.[9] Prescribing indicators average number of medicines per encounter was calculated by dividing the total number of drugs by number of encounters. Percentage of drugs prescribed by generic name, injectable medications used were calculated by dividing with total drugs prescribed multiplied by 100. The drugs prescribed were categorized based on United States Food and Drug Administration classification of drugs used in pregnancy.[10]

The data collected was entered in excel sheet and expressed as mean and standard deviation. Categorical data was expressed as actual numbers and percentage. The drugs prescribed will be presented as frequency and percentage.

3. Results

Total of 615 prescriptions were collected and entered in predesigned proforma. The demographic details are represented in Table 1. The average age of women was 24.94 years, range was 16-39years with majority being housewife 492 (80%), primigravida 324(52.6%). The commonest blood group was B+ followed by O+, AB+ and A+.

Table 1: Demographic details

Parameters	**Range (mean±SD)/ n**
Age (range) (mean±SD)	16-39 (24.94±5.06)
Parity (n)	
0	324
≥1	291
Weight (Kgs)	35-90 (58.91±12.85)
Blood group (n)	
A+	73
B+	183
O+	145
AB+	115
A-	07
B-	07
O-	34
AB -	Nil
Not mentioned	51
Occupation (n)	
Housewife	492
Doctor	07
Teacher	44
Nurse	14
Technician	14
Clerk	23
Tailor	09
Attender	07
Student	05
Trimester (n)	
First	153
Second	174
Third	288

Table 2: Number of drugs prescribed per patient per prescription (n=615)

Number of drugs	**Number of prescription (%)**
One	199 (32.3%)
Two	301 (48.9%)
Three	103 (16.7%)
Four	012 (1.9%)

Table 3: Drug prescription with period of pregnancy

Trimester	**Number of drugs prescribed n(%)**
First	207(17.8%)
Second	611(52.7%)
Third	340 (29.36%)

The number of drugs prescribed per prescription is represented in Table 2. Most of the prescriptions contained two drugs per prescription 301(48.9%) followed by one drug per prescription 199(32.3%). The maximum number of drugs per prescription was four. Drug prescribed during various period of pregnancy is depicted in Table 3.

The distribution of medicines belonging to different categories is depicted in Figure 1. The most common category of medicine was minerals/vitamins 536 (46.28%).

The classification of drug according US FDA based on the risk to the fetus is shown in Table 3. Majority of the drugs were prescribed from category A 597(51.55%) and category B 398(34.36%). The WHO prescribing indicators are shown in Table 5.

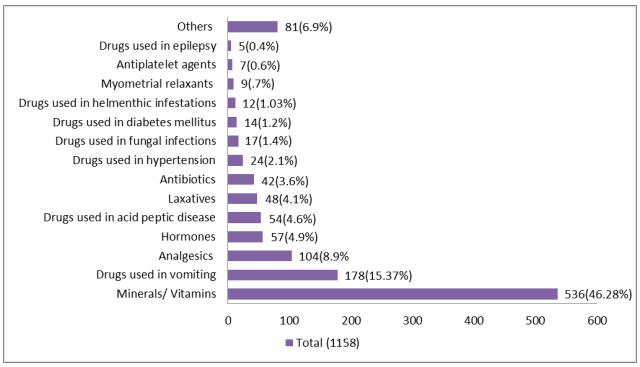

Fig. 1: Distribution of medicines belonging to different categories

4. Discussion

The prescription received by women attending antenatal clinic were included in the study. These prescriptions were collected at regular intervals over a period of 2 years. The average maternal age observed was 24.94, which was similar to that obtained in a study done in Nepal and Nigeria.[5,7] The majority of the women in our study were primigravida and homemakers by profession. Women in third trimester were more compared to first and second trimester. This could be because the checkups at third trimester are more frequent and stringent.

The number of drugs prescribed over the three trimester showed an increase pattern in second trimester compared to first and third trimester. This finding is in contrast to the previous studies conducted in West Indies and Oman, which showed increasing trend in the use of drugs with progress in trimester.[11,12] The use of drugs in first trimester were less in both the studies. The average number of drugs prescribed per encounter in the antenatal clinics was different compared to WHO standards. Similar deviations were observed in the studies done in Oman, Nepal and Africa.[12–14] The maximum number of drugs prescribed were four which is less compared to other studies.[12,13] It is close to the reference value according to WHO prescribing indicators. This could reduce the chances of adverse drug interactions. Very few prescriptions had drugs by generic name. This was less compared to a study conducted in Oman and Nepal. The increased use of brand names would have costed additional to these women. Pharmaceutical company representatives, drug promotional literature and additional incentives to the prescribers could have been certain factors to prescribe by brand name. Another aspect which can be considered is lack of faith in generic drugs by the prescribers. The low percentage of generic drug prescription is one of the factors in irrational prescription. The use of injectables was low, which is an encouraging observation because injectables are harmful due to high concentration introduced in the body leading to toxicity. The percentage of antibiotics was lower, which was in the range of WHO prescribing indicators. Another study was found with similar observations.[12]

Most common mode of drug administration was by oral route (84.3%). Minerals and vitamins (46.28%) were the most commonly prescribed drugs followed by drugs used in vomiting (15.37%), analgesics (8.9%) and hormones (4.9%). Similar pattern with slight difference was seen in a study done in Pakistan where vitamins and minerals (79.4%) were the most frequently prescribed group of drugs followed by analgesics (6.2%) and antibacterial agents (2.2%).[8] Few studies conducted at various parts of the world showed a similar pattern which had vitamins and minerals as most commonly prescribed drugs followed by analgesics, antidiabetic agents and others.[12,15,16] The main reason for this pattern is due to excessive demand for nutrients such as minerals and vitamins during pregnancy. Folic acid is prescribed from preconception period and continued till third trimester in some pregnant women in order to prevent neurological complications in new born. However certain studies conducted in developed countries such as Germany and France showed increased prescription of antimicrobial agents followed by other drugs.[4]

Majority of the drugs that were prescribed in this study were from category A and B and least from category X. Sodium valproate was the only drug from category X that was prescribed to a women for controlling epilepsy. By considering benefit risk ratio the use of sodium valproate was justified. These findings were similar to a study done in Nigeria where the majority of prescribed drugs were from category A and B.[6] In contrast to this finding another study from United States of America and Oman reported that the commonly used drugs were from category B and C.[12,17] In a study from Ethiopia and Taiwan the prescription of category D and X were 4% and 1.1% respectively. Compared to these two studies in our study there was negligible use of category D (4.1%) and X (0.08). These two categories of drug are avoided due to the evidence of teratogenicity in humans. There are certain drugs which are not categorized into any of these groups and hence avoided during pregnancy. There is a need of strong evidence for each drug used in order to avoid unwanted ill effects to the fetus. In this study the prescriptions were collected randomly and regularly every month. Still, the sample size was small compared to few studies done in other countries. If all the prescription could be collected and analyzed, it would have given us a better picture on the prescription pattern among antenatal women. This study was conducted in tertiary care teaching hospital in Kolar, hence the results cannot be generalized.

Table 4: Risk classification of medicines frequency of their occurrence

Category	Details	Drugs	n (percentage)
A	Adequate clinical studies have shown no risk to fetus in any trimester:	Folic acid Iron preparations Vitamin C Calcium Vitamin B complex Thyroxin Bisacodyl Doxylamine	597 (51.55)
B	Animal studies have not shown adverse effect on the fetus and there are inadequate clinical studies	Paracetamol Amoxycillin Ampicillin/Cloxacillin Ceftriaxone Clindamycin Nitrofunrantoin Azithromycin Metronidazole Clotrimazole Metoclopramide Domperidon Ondensetron Dicyclomine Ranitidine Insulin Progesterone	398 (34.36)
C	Animal studies have shown adverse effects, no adequate clinical studies. May be useful in pregnancy despite potential risks	Codeine Salbutamol Levocarnitine Spiranolactone	114(9.84)
D	There is evidence of risk to human fetus, but potential benefits may be acceptable despite potential risks:	Aspirin Labetolol Frusemide Carbamazepine Carbimazole Betamethasone Buspirone Imipramine	48 (4.14)
X	Animal/human studies show foetal abnormalities. Risks involved clearly outweigh benefits:	Sodium valproate	1 (0.08)

Table 5: World Health Organization prescribing indicators

Prescribing indicators	Value observed	Reference value
Average number of medicines per encounter	2 (range 1 – 4)	1.6 – 1.8
Percentage of medicines prescribed by generic name	10	100
Percentage of drugs prescribed from essential drugs list or formulary	100	100
Percentage encounter with injectables	15.7	13.4 – 24.1
Percentage encounter with antibiotics	11.2	8.8 20 – 26.8

5. Conclusion

The average number of drugs prescribed, percentage of injectables and anti microbial agents utilized were according to WHO standards. Prescription of drugs by generic name was less. The most commonly prescribed drugs were vitamins and minerals followed by drugs used in vomiting. Category A and B drugs were prescribed to the maximum.

6. Source of Funding

None.

7. Conflict of Interest

None.

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