



Research Article

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**Drug utilization pattern in pregnant women in a tertiary care hospital,
Hyderabad, Telangana**

Mary Jayasheela¹, M. Purna Chandrakala², Kranti Tekulapally^{2*} and Krishnaveni T.²

¹Department of Obstetrics and Gyneacology, Malla Reddy Institute of Medical Sciences, Suraram, Hyderabad

²Department of Pharmacology, Malla Reddy Medical College for Women, Suraram, Hyderabad

ABSTRACT

Pregnancy is associated with physiological changes in the pharmacokinetics and pharmacodynamics of the drugs. Also, use of drugs in pregnancy poses great risk to the mother and fetus. It therefore requires special care to prescribe drugs to pregnant women. The main objective of this study was to explore drug utilization in pregnant women attending a private sector tertiary healthcare institution. This was a cross-sectional case study in women attending outpatient clinic, Unit I, Department of Obstetrics and Gynecology, Malla Reddy Institute of Medical Sciences. The required information obtained from their prescriptions and 174 case notes was collected in a structured data collection sheets and the results were analysed using microsoft office. There were 80 (45.9%) primigravidae, 94 (54%) multigravidae and 69 (39.6%) women were in the second trimester of pregnancy. Most women (57.4%) were between 21–25 years of age. Average number of drugs prescribed per prescription was 2.4, encounter with antibiotics and injections was 4.5% and 9.1% respectively. The second trimester accounts for most of the prescriptions (36.2%). Iron/folic acid preparations (39.71%) were the most frequently prescribed drugs. Cefixime was the most prescribed antibiotic while paracetamol was the most commonly prescribed analgesic. The results of the present study are encouraging. WHO recommended guidelines were strictly adhered to. Most of the prescribed drugs were in the FDA risk categories A-C, which are safe to be used in pregnancy.

Keywords: Drug utilisation, pregnancy, prescription analysis

INTRODUCTION

Drug utilization research was defined by WHO in 1977 as “the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences”. The principal aim of drug utilization research is to facilitate rational use of drugs in population, thereby improving the health outcome.[1]

The drug utilization pattern in pregnancy presents a special concern because it is associated with physiological changes in the pharmacokinetic and pharmacodynamic actions of the drugs and also it poses a great risk to the maternal and fetal life.

The endocrine environment appropriate for the stage of pregnancy alters the effect of drugs on reproductive tissues such as breast and uterus significantly. The effect on other tissues like heart, lungs, kidney is not significant even though certain physiologic parameters such as cardiac output and renal blood flow are altered. The changes in these parameters may require use of drugs that are not normally used in the pharmacotherapy if the patient is not pregnant such as the use of cardiac glycosides and diuretics in the treatment of heart failure precipitated by increased cardiac workload in pregnancy, insulin in the treatment of gestational diabetes mellitus.[2]

A single exposure to drugs during critical phase of fetal development can affect the fetal structure growing rapidly. The historical example of such teratogenic effect is *Thalidomide disaster* of 1960-61 in which administration of thalidomide during fourth to seventh week of gestation produced *phocomelia* or seal like limbs.

Thus pregnancy is an important period and many drugs may need to be given to modify the altered physiological functions or to treat any associated pathological disorder. It is thus imperative to evaluate the need, safety and compatibility of drugs being administered during pregnancy.

There are limited number of drug utilization studies in pregnant women from India. The present study was therefore planned to unearth the patterns of drug utilization in pregnant women – the prevalence of drug use, the average number of drugs used, the most common drug categories used, the changes in drug use throughout the pregnancy and to know the extent to which good prescribing practices in these special population are adhered to.

EXPERIMENTAL SECTION

A retrospective cross sectional study design was used. The study was carried out during the period of January 2015 to April 2015 at the Department of Obstetrics and Gynaecology, Malla Reddy Hospital, Suraram, Hyderabad. All new pregnant women attending the outpatient clinic of the unit I were included in the study. The case notes and prescriptions of the pregnant women were reviewed and the required information was collected using a structured data collection sheet prepared for the study. The data collection sheet included the patient's demographic data, obstetric history and medication profile. Data collected was entered into a spread sheet and analyzed. The WHO method of determining core prescribing indicators were employed. The average number of medicines per encounter was calculated by dividing the total number of drugs by the number of encounters. Percentage encounter with antibiotics and percentage of encounter with injections was determined by dividing the total number of occurrence by the total number of event, respectively and multiplying by 100. The Institutional ethical committee permission was taken prior to the initiation of the study. Written informed consent was taken from all the pregnant women included in the study.

RESULTS

A total of 205 case data was collected. Following the use of some exclusion criteria such as legibility of writing, prescription without signature and other parameters of a complete prescription, 174 prescriptions were selected for this study.

Table 1. Patient's demographic and obstetric history

N= 174	n (%)
Age in years	
18 - 20	43(24.7)
21 - 25	100(57.4)
26 - 30	30 (17.2)
31 - 40	1(0.5)
Un known	Nil
Gravidity	
Primigravida	80 (45.9)
Multigravida	94(54)
Missing	Nil
Trimester	
1 st (0 to 12 weeks)	44 (25.2)
2 nd (13 to 24 weeks)	69 (39.6)
3 rd (25 to 40 weeks)	60 (34.4)
Missing	1

Table 2. Drug count

N= 174	n (%)
Antimicrobials	8 (1.86)
Antiemetics	37(8.6)
Iron containing preparations	170 (39.71)
B- complex+ Multivitamins	30 (7.05)
Anti- APD	4 (0.9)
Analgesics	26(6.0)
Calcium supplements	129(30.14)
Hormonal preparations	15(3.5)
Others	9 (2.1)
Total drug count	428(100)

Table 3. Drug use based on trimester of pregnancy

	1 st trimester n (%)	2 nd trimester N (%)	3 rd trimester n (%)	FDA class
Antimicrobials				
Cefixime	-	3(75)	1(25)	B
Cotrimoxazole	-	1(25)	-	B
Amoxicilin	-	-	2(50)	B
Nitrofurantoin	-	-	1(25)	B
Total	-	4(100)	4(100)	B
Analgesics				
Paracetamol + Pseudoephedrine hydrochloride	1(16.6)	-	2 (20)	B
Paracetamol	5 (83.3)	10 (100)	8(80)	B
Total	6 (100)	10(100)	10(100)	
Antiemetics				
Doxylamine + Pyridoxine	27(90)	4(80)	1(50)	A
Hyoscine	-	1(20)	1(50)	C
Ondansetron	3 (10)	-	-	N
Total	30(100)	5(100)	2(100)	
Anti -APD				
Pantoprazole antacid	-	2(100)	1(50)	B
Total	-	2(100)	2(100)	A
Iron containing preparations				
Folic acid:				
L-Methylfolate	19(36.5)	3(5.08)	1(1.69)	
Folic acid + Iron + Vit C	2(3.8)	5(8.47)	3(5.08)	A
Folic acid + iron + zinc	6(11.5)	22(37.2)	16(27.1)	A
Elemental Iron + Folic acid	24(46.1)	29(29.1)	39(66.1)	A
Ferrusbiglycinate + elemental iron + F.A + Zn bisglycate + Methylcobalamin	1(1.92)	-	-	A
Total	52(100)	59(100)	59(100)	
B-Complex, Multivitamin, protein & mineral preparations				
Protein powder	-	-	-	
Multivitamin syrups	1(20)	5(31)	2(25)	A
Arginine preparations	1(20)	10(62.5)	1	A
Total	3(60)	1(6.2)	6	A
Calcium supplements				
calcium carbonate + calcitriol	27(90)	33 (68.7)	39(76.4)	A
calcium citrate + Calcitriol + Zinc +Magnesium	3 (10)	4 (8.3)	-	A
calcium citrate +calcitriol	-	5 (10.4)	6(11.7)	A
Total	30(100)	48(100)	51(100)	
Hormonal preparations				
Progesterone	3(100)	3(42.8)	-	
Human actified Insulin	-	1(14.2)	-	B
Thyroxine	-	3(42.8)	5(100)	C
Total	3(100)	7(100)	5(100)	A
Miscellaneous				
lactulose	1(50)	3(75)	-	B
IV Fluids- NS	1(50)	-	2(66.6)	N
ORS	-	1(25)	-	N
Disodium hydrogen citrate	-	-	1(33.3)	N
Total	2(100)	4(100)	3(100)	

Table 4. Trimester - wise comparison of FDA risk category of drugs used during pregnancy

Category of drugs	First TM n (%)	Second TM n(%)	Third TM n (%)
A	114(26.6)	125(29.2)	119(27.8)
B	10(2.3)	22(5.1)	15(3.5)
C	-	2(0.4)	1(0.2)
D	-	-	-
X	-	-	-
N	4(0.9)	1(0.2)	3(0.7)

At the end of the study, data of 174 patients was analyzed. The data showed that the mean age of the population was 34.5, majority of the subjects were in the age group of 21-25 yrs (57.4%). Patient's obstetric history showed that 80

(45.9%) were primigravidae while 94(54%) were multigravidae. Out of total women in the study, 44(25.2%) were in their first trimester, 69(39.6%) were in their second trimester and 60(34.4%) were in the third trimester.

Table 5. Reasons for drug use among pregnant women in MRIMS

Reason For Medicine Usage	Frequency N(%)
To prevent anemia and Vitamin deficiency in pregnancy	170 (62.5)
As pain Killer	24 (8.8)
To treat Respiratory infections	6 (2.2)
To manager Gastro intestinal infections	13(4.7)
To treat Genitourinary infections	4(1.4)
To suppress nausea/ Vomiting	36 (13.2)
Others	19 (6.9)
Total	272 (100)

Table 6. WHO core prescribing indicators

PRESCRIBING INDICATORS	n(%)
% Encounter with injectables prescribed	16(9.1)
% Encounter with antibiotics prescribed	8(4.5)
Total injectables prescribed	19(4.4)
Total antibiotics prescribed	8(1.86)
Total drug count	428
Average drugs per prescription	2.4

Based on WHO/ INURD core prescribing indicators, out of the total number of drugs prescribed, the average number of drugs per prescription was 2.4. Percentage encounter with antibiotics and injectables were 4.5% and 9.1% respectively. Patient's medication history showed that folic acid containing preparations were most commonly prescribed (39.71%) followed by calcium supplements (30.14%). The least prescribed drugs were antacids (0.9%) and antimicrobials (1.8%). The drug use based on the stage of pregnancy in this study indicated that 29.9% of the total drugs were prescribed during the first trimester while that during second and third trimesters were 36.21% and 33.8% respectively. Drug use according to the class of drugs showed that cefixime (50%) was the most commonly used antimicrobial agent, Paracetamol use was 88%. Doxylamine and pyridoxine combination was most commonly used antiemetic(86.4%).

DISCUSSION

The research was able to establish that women in their second trimester attended the antenatal clinic more than those in the first and third trimester of pregnancy. This finding is in accordance to the study of Harsh et al [3] where majority of the pregnant women were in second trimester. In contrast, the study of Inamdar et al [4] showed that majority of women were in their first trimester while in the study of Gawde et al [5] majority were in their third trimester. Most of the women were multigravida. This can be due to increase in the awareness among the women of the need of routine antenatal checkups to reduce maternal mortality and for safe motherhood. The prescription of injectables was 9.1% which is within the acceptable range of 10% or less. Similar studies in India reported the percentage encounter with injectables to be 2.17 [3] and 10.97%[6]. Percentage encounter with antibiotics was 4.5%, much less than WHO recommended less than 20%. The previous studies reported the percentage encounter with antibiotics to be 11.7[3]and 9.6[6]. The average number of drugs per prescription was 2.4, slightly more than recommended 2 or less. Similar results were reported in previous studies[5,6]. With comorbid conditions associated with pregnancy, polypharmacy has become a necessity today. Moreover, most pregnant women take haematinics and vitamins such as Iron preparations, folic acid, ascorbic acid and vitamin B complex tablets. As such iron, folic acid and multivitamin containing drugs are most commonly prescribed drugs in this study (39.7%). Balanced nutritional supplementation may be beneficial in women with marginal diet. The benefit of Folic acid supplementation in decreasing the risk of neural tube defects is well known [3].

Majority of the patients were prescribed two drugs (40.8%), followed by three drugs (33%) and four drugs (17.2%). Only four patients had been prescribed five drugs (2.2%).

Cefixime is the most commonly prescribed antibiotic. It is an oral third generation cephalosporin which has good activity against gram positive and gram negative bacteria. It can cross the placental barrier. Reproduction studies performed in mice and rats up to 40 times the human dose have revealed no evidence of harm to fetus but there are no adequate studies in pregnant women. It thus comes under FDA risk category of B and should be used only of clearly needed during pregnancy. cefixime was prescribed to cases with urinary tract infections. Ampicillin,

nitrofurantoin and cephalexin are the drugs that are recommended in the treatment of urinary tract infections associated with pregnancy [7].

Paracetamol was the most prescribed analgesic during pregnancy. This may be due to its low cost, good safety profile and better tolerability.

Antiemetics were most commonly prescribed during the first trimester to treat hyperemesis gravidarum or morning sickness. Among the antiemetics, Doxylamine, a H₁ antagonist was the most commonly prescribed. Doxylamine is under FDA category B. In combination with pyridoxine, it is promoted in India and USA. It is not available in UK following the unproven reports of fetal malformations in 1981.

The US FDA classification was used to evaluate risk categorization of drugs prescribed in the study. Almost all the prescribed drugs were in FDA categories A-C which are safe to be used during pregnancy. No woman was prescribed category X drug. Thus, prescribing pattern described in our study is a fine example of good prescribing practices.

CONCLUSION

Iron, folic acid and calcium were the most frequently prescribed drugs to the pregnant women. Overall drug use pattern is rational. All the prescribed were safe to be used in pregnancy as per the FDA risk categorization.

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