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Research Article

Drug pattern use during pregnancy: a prospective study at tertiary care teaching hospital

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ABSTRACT

Background: Pregnancy is a normal physiological state. It may be accompanied by some common conditions which may occur normally due to the physiological changes. For these, drug treatment may be necessary. Use of drug is of growing concern due to increased risk of teratogenicity. Hence use of safe drugs during pregnancy should be promoted. This study aims to study and evaluate the pattern of drug use in women attending the antenatal clinic.

Methods: A prospective cross sectional study was conducted in Obstetrics & Gynecology out Patients department in BRIMS Teaching Hospital for a period of 3 months. All new antenatal cases reporting to outpatient department were included. Data were then analysed for drug use pattern, WHO core drug prescribing indicators and also according to FDA drug risk category and trimester wise drug use pattern.

Results: It was observed that most common complaint was epigastric distress. Iron, calcium and Antacids were the most frequently prescribed drugs. 79% drugs were prescribed from essential drug list and 100% were given by generic name. Out of 3857 drugs prescribed 48.35% belonged to Cat A, 50.35% to Cat B and only 1.3% to Cat C and none of the drugs belonging to Cat D were prescribed.

Conclusions: Overall drug use pattern is rational with few exceptions. Majority of the drugs prescribed are as per FDA category B. This type of study can help in evaluating the existing drug use pattern and in planning appropriate interventions to ensure rational drug therapy.

Keywords: Drug use pattern, Pregnancy, WHO core drug prescribing indicators

INTRODUCTION

Drugs play an important role in improving human health and promoting well-being. The state of pregnancy requires that all medications should be prescribed with specific caution. The physiological state of pregnancy has an effect on the pharmacokinetics of drugs administered, with attendant risk on the developing foetus.[1] Therefore categorization of drugs according to their pregnancy risk should be taken into consideration before a drug is prescribed for pregnant women. However to produce the desired effect, they have to be safe, efficacious and have to be used rationally

Now there is a greater appreciation of the risks of drug use in pregnancy. It should be practiced that maternal pharmacotherapy should be avoided or minimized where possible. Approximately 2-3% of all live births are associated with a congenital anomaly. Although exogenous factors such as drugs may account for only 1-5% of these (affecting less than 0.2% of all live births),given that drug associated malformation are largely preventable, they remain an important consideration.[2]

The use of drugs in pregnancy is an issue of great concern to the patients and prescribers alike. The Thalidomide incidence of the 1960's and the teratogenic effects that was discovered related to Diethylstilboestrol in 1971 are a few instance of the dangers which prescription drugs may pose to pregnant subjects.[1] Pregnancy is associated with changes in the physiological, psychological and psychosocial aspects of a woman's life. Drug pharmacokinetic parameters are usually affected by the type of drugs administered in pregnancy, most administered drug passes the placental

barrier, and depending on the stage of pregnancy, the life of the foetus may be threatened. Therefore, special consideration needs to be given to drug prescribing in pregnancy.[3] Safe use of drugs in pregnancy is a responsibility of all members of the healthcare team, nevertheless, the bulk of this responsibility rests on the Physicians shoulder.

In 1979, the Food and Drug Administration developed a system determining the teratogenic risk of drugs by considering the quality of data from animal and human studies. It provides therapeutic guidance for the clinician. Category A is considered the safest category but some drugs from categories B, C and D are also used during pregnancy. Category X is the only rating that denotes a drug is absolutely contraindicated for use during pregnancy.[4] Categories are summarized as follows:

Category-A: Controlled studies in women fail to demonstrate a risk to the fetus in the first trimester, there is no evidence of a risk in later trimesters and the possibilities on the fetal harm appears remote.

Category-B: Either animal reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women or animal reproductive studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in first trimester and there is no evidence of risk in later trimesters.

Category-C: Either studies in animals have revealed adverse effect on the fetus (teratogenic, embryological, or other) and there are no controlled studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Category-D: There is positive evidence of human fetal risk, but the benefits from use in pregnant women may be acceptable despite the risk. (e.g., if the drug is needed in a life-threatening situation or a serious disease for which safer drugs cannot be used or are ineffective).

Category-X: Studies in animals or human beings have demonstrated fetal abnormalities or there is evidence of fetal risk based on human experience or both and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug being contraindicated in women who are or may become pregnant.[5]

METHODS

This prospective cross sectional study was carried out in obstetrics and Gynecology outpatient department of a tertiary care teaching hospital BRIMS, Bidar, India from April 2015 to June 2015. Only the new cases of antenatal patients were included. After taking verbal consent from women the data were collected in a pre-designed

proforma which included patient's demographic details, pregnancy duration, chief complaints/ provisional diagnosis and complete prescription. Data were analyzed for demographic characteristics, drug use pattern, and percentage of drugs prescribed as fixed dose combination and WHO core drug prescribing indicators.[6] Data were also analyzed according to FDA (Food and Drug Administration, USA) drug risk category and trimester wise drug use pattern.[7] Results were expressed in percentage and MeanSD$\pm$2.

RESULTS

A total 1000 women received 3857 prescriptions. The age of patients ranged from 18-40 years. Majority of the patients in the study were in the age group 25-35 years (78.2%), followed by <25 years (20.6%) and >35 years (1.2%) (Table 1). Majority of patients in the study were in second trimester of gestation (52.5%) followed by third trimester (28%) and least in first trimester (19.5%).

Table 1: Age wise distribution of antenatal women (N=1000).

| Age groups (years)	No. of patients	Percentage
<25	206	20.6%
25-35	782	78.2%
>35	12	1.2%

Most common complaints of women coming to antenatal OPD were epigastric distress (22.4%), abdominal pain (14.8%) and vomiting (13.8%) followed by fever (6.5%), cough (1.4%), urinary tract infection (2.7%) and discharge per vagina (2.6%). Majority of women were coming for routine antenatal check-ups. Number of drugs prescribed was observed to vary with each trimester. Majority of the drugs were given to the patients in 2nd trimester, followed by 3rd trimester, and minimum drugs were given to 1st trimester patients (Table 2).

Table 2: No. of drugs prescribed.

Drugs	No. of drugs given	% of drugs given
1st trimester	502	13.02%
2nd trimester	2058	53.36%
3rd trimester	1297	33.62%
Total	3857	100%

Calcium gluconate (80.5%), Iron salts (67%), Ranitidine (56%) were most frequently prescribed drug groups followed by paracetamol (48%), antispasmodic drug (36.2%), antimicrobial agents (26%), folic acid (19.5%), antiemetic drugs (19.5%) and others.

Out of 3857 drugs prescribed, 48.35% were FDA drug risk category A which is the safest category described by FDA followed by 50.35% belonged to Category B, 1.3% to Category C and none of the drugs belonging to category D were prescribed (Table 4).
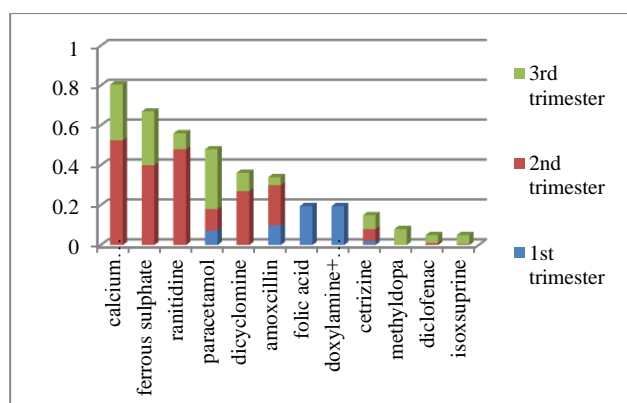
Figure 1: Prescribing frequency of different drugs (n= 1000).

Table 3: WHO core drug prescribing indicators.

Indicator	Value
Average number of drugs per prescription	3.85
Percentage of drugs prescribed by generic name	100%
Percentage of encounters with antibiotic prescribed	26%
Percentage of encounters with an injection prescribed	1.29%
Percentage of drugs prescribed from essential drug list	79.08%
Percentage of Fixed dose combinations prescribed	5.05%

Table 4: FDA drug risk category wise prescription pattern.

Category	Percentage
Category A	48.35
Category B	50.35
Category C	1.3
Category D	0

DISCUSSION

Out of 1000 pregnant women, about 78.2% were between 25 to 35 years which represents the normal reproductive age group. About half of the patients visited antenatal OPD in second trimester. More than 50% of women in this study came for routine antenatal check-up, with no complaints. Calcium Iron and Antacids were the most frequently used drugs in pregnancy, accounting for 67%, 80% and 56% respectively. Doxylamine and pyridoxine combination was used most commonly in first trimester followed by Paracetamol and Cetrizine acetate. Study from West Indies, multivitamins, iron/folic acid and calcium were the most frequently prescribed drugs during the first, second and third trimesters followed by dimenhydrinate, insulin, metformin and paracetamol.[8]

During second trimester Antacids followed by dicyclomine, paracetamol and in third trimester drug groups like uterine relaxants, analgesics, antimicrobial agents and antihypertensives were prescribed. In our study majority of drugs were from category B (50.35%) followed by category A (48.35%), category C (1.3%) and category D (0.00%). No drugs were prescribed from category X. In a retrospective study in Finland, it was found that 20.4% of women purchased at least one drug classified as potentially harmful during pregnancy and 3.4% purchased at least one drug classified as clearly harmful.[9] In a study by Bratislava and Nitra, it was reported that a vast majority of prescribed drugs during pregnancy, belonged to category C.[10] So from the above data we can say that the prescription habit in our set up was quite safe. Percentage of drugs prescribed by generic name was 100%. Percentage of encounters with antibiotic prescribed was 26%. Percentage of encounters with an injection prescribed was 5%, which is also low. Percentage of drugs prescribed from essential drugs list was 79.08%.

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