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DRUG USE PATTERN IN INPATIENTS OF OBSTRETICS WARD IN A TERTIARY CARE HOSPITAL.

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ABSTRACT

Background- Pregnancy is a special physiological condition, where drug treatment presents a special concern. In pregnancy, drug treatment presents a special concern due to the threat of potential teratogenic effects of the drug and physiologic adjustments in the mother, in response to pregnancy. Most studies recently have reported increase in drug use in pregnancy. **Objective-** To study and evaluate the pattern of drug use in women admitted in low risk and high risk ward of obstretics and gynecology department at a tertiary care hospital. **Results:** Out of 120 women, 65.8% were 20-35 years of age. Common conditions admitted were Anemia, Polyhydramnios, Oligohydramnios, Hypothyroidism, Pregnancy induced hypertension, Premature rupture of membranes, Gastroenteritis, type 2 Diabetes mellitus and others. Iron/folic acid preparations were the most frequently prescribed drugs. Cefotaxime was the most prescribed antibiotic while paracetamol was the most commonly prescribed analgesic. Ondansetron was the most commonly used antiemetics. Pantaprazole was the most commonly used antiulcer agent. Insulin (Actrapid or mixtard) was used in all cases of gestational diabetes mellitus. Thyroxine was the drug of choice for hypothyroidism in pregnancy. Most of the prescribed drugs were in the FDA risk categories A-C, which are safe to be used in pregnancy.

KEYWORDS: Anemia, Polyhydramnios, Oligohydramnios, Hypothyroidism etc.

INTRODUCTION

Pregnancy is a special physiological condition, where drug treatment presents a special concern. In pregnancy, drug treatment presents a special concern due to the threat of potential teratogenic effects of the drug and physiologic adjustments in the mother, in response to pregnancy. Reproductive studies with drugs in animals can provide an indication of possible teratogenicity, but they do not reliably predict (or exclude) risks when these same drugs are given in human pregnancy. Pregnant women consume drugs including prescription and non-prescription (OTC) medications as well as herbal products and dietary supplements. About 8% of pregnant women need permanent drug treatment due to various chronic diseases and pregnancy induced complications.[1] The prescription of medications during pregnancy presents a great challenge to the physicians who must consider the risk-benefit relation for both the mother and the fetus[2], that's why DU by pregnant women should be viewed as a public health problem.[3] Medication use during pregnancy has been an issue of concern since the discovery of birth defects resulting from Thalidomide use in early pregnancy during the 1960s.[4,5] Pharmacological treatment should be avoided in pregnancy, unless absolutely necessary.[6-8]

Pregnant women are generally excluded, for ethical reasons, from randomized clinical trials in drug development. This has left questions about the safety of new medications on the developing fetus unanswered, upon drug approval and marketing.[9,10] However, to guide safe drug use during pregnancy, the U.S.A. Food and Drug Administration (FDA) classified drugs into the following major categories; A, B, C, D and X with categories D and X indicating evidence of risk in pregnancy.[11-13]

Category A

Controlled studies in women fail to demonstrate a risk to the foetus in any trimester and the possibility of foetal harm remains remote.

Category B

Either animal-reproduction studies have not demonstrated a foetal risk but there are no controlled studies in pregnant women or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the 1st trimester (and there is no evidence of a risk in later trimesters.

Category C
Either studies in animals have revealed adverse effects on the foetus (teratogenic or embryocidal or other) and there are no controlled studies in women and animals are not available. Drugs should be given only if the potential benefits justify the potential risk to the foetus.

Category D
There is positive evidence of human foetal 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 for a serious disease for which safer drugs cannot be used or are ineffective).

Category X
Studies in animals or human beings have demonstrated foetal abnormalities or there is evidence of foetal risk based on human experience or both and the risk of the use drug in pregnant women clearly outweighs any possible benefits. The drug is contraindicated in women who are, or may become pregnant.[14]

The aim of this study was to evaluate the utilization pattern and the teratogenicity risk of the drugs prescribed to pregnant women admitted to ANC and high risk ward in a tertiary care hospital.

METHODOLOGY

A retrospective cross sectional study design was used. The study was carried out for a period of 2 months at the Department of Obstretics and Gynaecology. All new pregnant women admitted to the inpatient wards 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 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.

The study was planned and executed by the Department of Pharmacy practice in collaboration with Department of Obstetrics and Gynecology. The study population consisted of the pregnant women admitted to the inpatient high and low risk wards.

For the purpose of this study, first trimester was considered for first 12 weeks, second trimester for 13 to 24 weeks and third trimester for 24 weeks onwards. Drug use during pregnancy was classified according to US Food and Drug Administration (FDA) category.

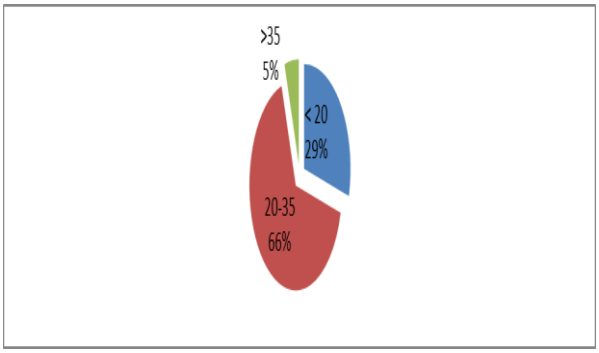
Statistical Analysis: Statistical analysis was done by simple sampling method. Descriptive statistics were used to analyze data.

RESULTS

Out of 120 women, 65.8% were 20-35 years of age. Common conditions admitted were Anemia, Polyhydramnios, Oligohydramnios, Hypothyroidism, PIH, Premature rupture of membranes, Gastroenteritis, type 2 Diabetes mellitus and others. Anemia was the maximum observed diagnosis for admission followed by PIH. The required information obtained from their treatment charts was collected in a structured data collection sheets and the results were analysed using microsoft office. There were 46 (38.33%) primigravidae and 74 (61.66%) multigravidae cases. 5 (4.16%) women were in the first trimester of pregnancy, 12 (10%) and 103(85.83%) were in the second and third trimester of pregnancy. The Third trimester accounts for most of the admissions (85.83%). Iron/folic acid preparations were the most frequently prescribed drugs. Cefotaxime was the most prescribed antibiotic while paracetamol was the most commonly prescribed analgesic. Ondansetron was the most commonly used antiemetics. Pantaprazole was the most commonly used antiulcer agent. Insulin (Actrapid or mixtard) was used in all cases of gestational diabetes mellitus. Thyroxine was the drug of choice for hypothyroidism in pregnancy. Most of the prescribed drugs were in the FDA risk categories A-C, which are safe to be used in pregnancy.

Demographic distribution of patients

AGE GROUPS	NO. OF PATIENTS	PERCENTAGE
< 20	35	29.16
20-35	79	65.83
>35	06	5.0



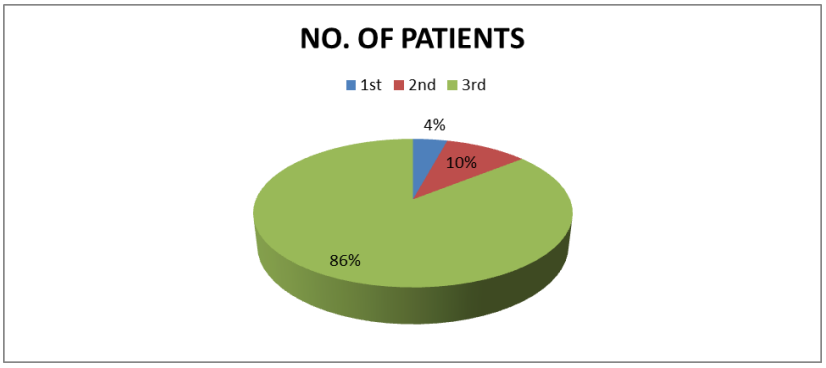
Gravidity wise distribution of patients

GRAVIDA	NO.OF PATIENTS	PERCENTAGE
primi	46	38.33
multi	74	61.66

Diagnosis	NO.OF PATIENTS	PERCENTAGE
Gastroenteritis	4	3.33
Placental abruption	10	8.33
Oligohydramnios	10	8.33
polyhydramnios	15	12.5
Anemia	44	36.66
Gestational diabetes mellitus	5	4.16
LRTI	2	1.66
RHD	2	1.66
Hypothyroidism	10	8.33
PIH	16	13.33
Convulsions	3	2.5
Nausea and vomiting	2	1.66
UTI	1	0.83
PPH	1	0.83
Bronchial Asthma	1	0.83
URTI	3	2.5
Typhoid fever	2	1.66
Hypotension	1	0.83
Others	14	11.66

PARITY	NO.OF PATIENTS	PERCENTAGE
Primigravida	46	38.33
Multiparity	23	19.16
Primiparity	51	42.5

Trimester	No. OF PATIENTS	Percentage
1st	5	4.16
2nd	12	10
3rd	103	85.83



DRUGS PRESCRIBED	1st Trimester	2nd Trimester	3rd Trimester	FDA CLASS
ANTIMICROBIALS				
Cefotaxime	3	12	103	B
Ceftriaxone	2	-	-	B
Ofloxacin-Ornidazole	-	-	19	C
Nitrofurantoin	-	4	-	B
Azithromycin	-	-	2	B
Metronidazole	1	-	3	B
ANALGESICS				
Tramadol	-	1	4	C
Paracetamol	3	2	10	N
ANTIEMETICS				
Ondansetron	1	-	3	N

Doxylamine	2	-	-	A
ANTI-ULCER				
Pantoprazole	2	4	98	B
Ranitidine	1	2	6	A
IRON				
Ferrous-Sulphate	5	12	103	A
Folic-Acid	5	3	-	A
Iron-Sucrose	-	1	23	A
B-COMPLEX, MULTI-VITAMIN, PROTEINS & MINERALS PREPARATION				
Protein Powder	5	12	103	A
Multi-Vitamin Syrup	-	6	96	A
Arginine (Hermin)	-	4	33	A
B-Complex	3	1	13	A
CALCIUM SUPPLEMENTS				
Calcium carbonate	5	12	103	A
Calcium Gluconate	1	6	4	A
HORMONAL PREPARATIONS				
Hyrocortisone	-	6	30	C
Beclomethasone	-	9	27	C
Thyroxine	4	2	4	A
Human Actrapid	-	2	2	B
Human Mixtard	1	-	1	B
MISCELLANEOUS				
Sporolac	1	-	3	B
Salbutamol & Ipatropium	1	-	1	C
Bromide	-	-	2	C
Magnesium Sulphate		2	2	A
Ecospirin	-	-	1	C

DISCUSSION

The research was able to establish that women in their third trimester were admitted due to co morbidities more than those in the first and second trimester of pregnancy. Most of the women were multigravida. With co morbid 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. 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]

Cefotaxime 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.

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, Ondansetron, a 5-HT $_3$receptor antagonist was commonly prescribed. Doxylamine, a H1 antagonist was also 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.

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