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Research Article

Prescribing Patterns of Drugs in Pregnant Women Among Outpatients and Inpatients in Obstetrics & Gynecology Department

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ABSRACT

A Prospective cross-sectional study was carried out in order to assess the prescription pattern in pregnant women. Attending Antenatal In & Outpatient Department of a Tertiary Care Hospital. A cross sectional study was conducted by reviewing the antenatal care In &outpatient department case papers of 230 random pregnant women. The prescription pattern was assessed and the drugs were classified based on the US FDA Risk Classification. Out of 230 prescriptions, only 177 prescriptions had drugs other than iron, folic acid and calcium lactate. In this study most of the drugs prescribed falls under category B (26.6%) , a fair number of drugs falls under category A (16.60%) and C (16.60%) and a few drugs falls under category D (6.66%). No drugs belonging to category X were prescribed. The present study reveals that the drug use during pregnancy in and around Bapatla region were minimal and the most of the drugs were prescribed by their generic names. Prescribing by generic name is known to reduce the cost of drug treatment, rationalized drug therapy and avoids confusion.

Keywords: Pregnant women, Prescribing pattern, US FDA, Drug treatment, Generic names, Confusion.

INTRODUCTION

Pregnancy[1]

Pregnancy is a special physiological state where medication intake presents a challenge and a concern due to altered drug pharmacokinetics and drug crossing the placenta possibly causing harm to the fetus. Medication treatment in pregnancy cannot be totally avoided since some pregnant women may have chronic pathological conditions that require continuous or interrupted treatment (e.g., asthma, epilepsy and hypertension). Also during pregnancy new medical conditions can develop and old one can worsen (e.g., migraine, headache, hyperacidity, nausea, vomiting) requiring drug therapy. However, before taking any drug (including over the-counter drugs) or dietary supplements (including medicinal herbs), a pregnant woman should consult her health care practitioner. A health care practitioner may recommend that a woman take certain vitamins and minerals during pregnancy. Health care practitioners also consider of the benefits to the mother and the risk to the fetus while prescribing drugs during pregnancy. It is not possible to avoid drugs during pregnancy, so women with certain chronic medical conditions such as epilepsy, diabetes, inflammatory bowel disease and asthma, the use of drugs is essential and benefits for mother and child may well outweigh the teratogenic risk of the drug. Other nonchronic diseases related or unrelated to the pregnancy may require medical treatment. The drugs prescribed to pregnant mothers for therapeutic purposes may cause serious structural and functional adverse effects in the developing child. Reducing medication errors and improving patient safety are the important areas of discussion. It is essential to consider several factors before prescription of drugs during pregnancy. Such as,

Dose and duration of drug exposure is important. The larger the dose is more likely the effects. The longer the duration of drug exposure is greater chance of susceptible periods of organogenesis and developmental problem.

Timing of exposure is very crucial. Certain organ systems may have only limited period of susceptibility for damage.

Pathogenetic mechanism, teratogen produces their adverse effect by specific mechanism.

Host susceptibility, variability in the genetic factors related to mechanism of certain drugs. All drugs can affects the health of the mother and fetus, therefore any drugs should be administer with care during pregnancy.

The FDA, in 1979 developed a classification system which groups drugs under category A, B, C, D & X, according to the degree of their potential risk of foetal teratogenicity during pregnancy[2].

US-FDA Pregnancy Risk Factor Categories

The USA Food and Drug Administration (FDA) classify the drugs for use in pregnancy using 5-letters system.

A = adequate Controlled studies in pregnant women fail to demonstrate a risk to the fetus. Very few drugs are seen in this category.

B = "Best" No risk seen in animals, but no controlled trials in pregnant women.

C = "Caution" "Adverse fetal effects in animals, no controlled trials in humans." Most drugs are category C.

D = "Danger" "Evidence of human fetal risk should be reserved for life-threatening disease."

X = strong evidence of fetal abnormality, No therapeutic indication in pregnancy.

Teratogenic Drugs: "Most Teratogenic FDA-approved

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Table 1:

Patients details	No of patients	Percentage (%)
In patients	52	22.60
Out patients	178	77.39
Total	230	100

Table 2:

Age in years	Number of pregnant women	Percentage (%)
18	12	5.23
19	14	6.02
20	20	8.61
21	14	6.08
22	15	6.52
23	28	12.17
24	12	5.21
25	16	6.95
26	13	5.65
27	6	2.60
28	7	3.04
29	9	3.91
30	8	3.47
31	5	2.17
32	6	2.60
33	8	3.47
34	7	3.04
35	5	2.17
36	10	4.34
36	6	2.60
38	5	2.17
39	4	1.73
TOTAL	230	100

Table 3:

Months	No. of pregnant women	Percentage (%)
1	10	4.34
1.5	9	3.91
2	15	6.52
3	14	6.02
4	30	13.0
5	22	9.56
6	28	12.17
7	23	10.0
7.5	4	1.72
8	35	15.21
8.5	32	13.91
9	8	3.47
Total	230	100

Table 4:

Trimester	No. of pregnant women	Percentage (%)
1st	48	20.8
2nd	107	46.52
3rd	75	32.60
Total	230	100

medications are in categories D or X, some drugs in C".

Prescribers should look the US-FDA risk categories when prescribing to pregnancy.

Prescribing patterens[3]

A Prescription is an instruction from a prescriber to a dispenser. Prescription by a doctor may be taken as a reflection of physician's attitude to the disease and the role of drug in its treatment. Prescription writing is a science and an art, as it conveys message from prescriber to the patient. The prescriber is not always a doctor but also can be a paramedical worker. Prescribing is expected to be judicious, appropriate, safe, effective and economical. The dispenser is not always a pharmacist, but can be a pharmacy technician, an assistant or a nurse. Prescribing patterns are one of the currently powerful exploratory tools to ascertain the role of drugs in the society. Prescribing practices are a health professional's abilities to determinate among the various choices of drugs and determine the ones that will most benefits the patient. Prescribing patterns need to be evaluated periodically to increase the therapeutic efficacy, decrease adverse effects and provide feedback to prescriber. The study of prescribing pattern is a part of a medical audit and seeks to monitor, evaluate and if necessary, suggest modification in prescribing practices to make medical care rational and cost effective. The medicines are prescribed by means of Essential Drug List[EDL].Essential medicines are those that satisfy the priority health care needs of the population. Revolving Drug Fund List 2015 was used as Essential Drug List. An essential tool for such work is an objective to measure drug use in health facilities that will describe drug use patterns and prescribing behavior "drug *use indicator. The WHO* in collaboration with International Network for the Rational Use of Drugs (INRUD**)** has formulated these set of core drug use indicators. The core prescribing indicators measure the performance of prescribers, the patient care indicators measure what patients experience at health facilities, and the facility indicators measure whether the health personnel can function effectively.

Types of indicators were used include

Average number of drugs per encounter.

Percentage of drugs prescribed by generic name.

Percentage of encounters with an antibiotic prescribed.

Percentage of encounters with iron preparations prescribed.

Percentage of drugs prescribed from an essential drugs list or formulary.

The indicators of prescribing practices measure the performance of health care providers in several key dimensions related to appropriate use of drugs. The present study was undertaken to evaluate the drug prescription patterns in pregnant women patients attending the outpatient and inpatient department and to generate data on the extent of rational/irrational prescribing in this institute.

MATERIALS AND METHODS

Study Location

A study was carried out in

Area hospital (APVP), BAPATLA.

Adilakshmi nursing home, PONNUR.

Duration of study

Table 5:

Gravida	No. of pregnant women	Percentage (%)
Primi	104	45.21
Multi	126	54.78
Total	230	100

Table 6:

No. of drugs per prescription	No. of prescriptions	Percentage (%)
1	10	4.34
2	70	30.4
3	43	18.61
4	33	14.13
5	38	16.52
6	29	12.65
7	15	5.41
8	5	2.17
Total	230	100

Table 7:

Generic drugs	No. of times Generic drugs prescribed	Percentage (%)
Cefotaxime	26	11.30
Amikacin	50	21.74
Metronidazole	18	7.83
Ranitidine	43	18.70
Diazepam	18	7.83
Diclofenac	19	8.26
Monocef	23	10
Folic acid	196	85.2
Calcium supplements(calcium carbonate)	228	99.13
Xylocaine	22	9.57
Amoxicillin	35	15.22
Orofer	12	5.22

Table 8:

Category	% of prescription of drugs in each category
A	64.20
B	27.30
C	6.82
D	9.85
X	-

3 Months (January,2018 - March,2018)

Patient's selection

Pregnant out-patient and in-patient attending Obstrectics& Gynecology department of the hospital.

Study criteria

Inclusion criteria

All the pregnant women attending obstetrics &gynecology department above 18 years

Patients prescribed with at least one medication.

Pregnant women who are willing to participate in the study.

Pregnant women with co-morbidity conditions.

Table 9:

Category	No. of drugs	Percentage (%)
A	5	16.6
B	8	26.6
C	5	16.6
D	2	6.66
X	-	-

Exclusion criteria

Lactating mothers

Patients with incomplete information

Pregnant women who are not willing to participate in the study.

Patients suffering with diseases like AIDS, Liver problems and kidney problems

RESULTS

Profile of The Patients

A total of 230 pregnant out-patients and in-patients were recruited in the study.

No of the patients attending the hospital

Among 230 patients attending hospital 52 among them are inpatients and 178 among them are out patients. Table 1

Age Distribution of Patients

Out of 230 patients induced in the study, majority of patients (12.17%) belonged to the age group of 23 years. The age distribution is shown in the table 2.

Trimester distribution of patients:

Out of 230 patients involved in the study majority of patients (15.21%) belonged to 3 trimester (8 months of gestation). Trimester distribution is shown in the table 3. Out of 230 patients involved in the study majority of patients (46.52%) belong to second trimester. Trimester distribution is shown in table 4.

Gravida Conditions of Patients

Out of 230 patients included in the study, majority of the patients (54.78%) belong to multi gravid. The gravid condition is shown in the table 5.

Prescribing indicators

The prescribing indicators were calculated for all the patients to determine the differences in the prescription. Average number of medication per prescription Table 6 enlists the total number of medicines were prescribed to 230 patients.

Percentage of Medicines Prescribed By Generic Name

Table 7 showed that only of medicines were prescribed by generic name

Drugs Prescribed According To Us-Fda Category

the total drugs prescribed around 64.20% drugs belongs to category A Around 27.30% drugs comes under category B and approximately 6.82% drugs falls under category C and around 9.85% drugs are under category D .table 8

Drugs prescribed in & out patients department:

Out of 230 patients included in the study, total numbers of drugs prescribed are among them 5 drugs are in A-category, 8 drugs in B- category, 5 drugs in C- category and 2 drugs in D and no drugs in X category. Drugs prescribed in out- patients in pregnant women are shown in table below.

US-FDA category drugs are shown in the table 9

Table 10:

Category A	Category B	Category C	Category D	Category X
B complex	Amoxicillin	Diclofenac	Amikacin	-
Doxylamin	Metronidazole	Nifedipine	Diazepam	-
Monocef	Cefixime	Paracetamol	-	-
Augmentin	Rantidine	Labetalol	-	-
Folic acid	Metro gel	Zentamicin	-	-
-	Ondansetron	-	-	-
-	Ibuprofen	-	-	-
-	Xylocaine	-	-	-
-	Ambroxol	-	-	-

Table 11:

Drugs	No .of pregnant women	Percentage (%)
Iron&folic acid capsules	85	36.96
Calcium tablets	92	40.0
I.v fluids	53	23.04

Commonly Prescribed Drugs in The Study

Commonly prescribed drugs in the study were mostly folic acid followed by iron capsule, calcium tablet, I.v fluids. Commonly prescribed drugs in the study are shown in the table 11.

DISCUSSION

Correct diagnosis of a disease and its management with medicines constitute important aspects of patient care, which is more important in case of pregnant women. The results of present study are based on data obtained from 230 patients.

In this study average percentage of drugs prescribed per prescription was 4.5% among 230 prescriptions. The rational use of drug demands use of minimum number of drugs not only to reduce cost but also to minimize drug-drug interations and adverse drug reactions.

In this study 48% of medications were prescribed by generic names. A fair number of drugs (about 80%) were prescribed from essential drug list for pregnant women. The prescribing from essential drug list should be promoted for optimal use of financial resources and to satisfy the health care needs of the majority of population safety.

In this study parenterals were prescribed for inpatients during and after C-section and the parenterals were not prescribed for outpatients.

Prescribing percentage of Antibiotics was 22.06 %. Antibiotics are prescribed in pregnancy resulting in considerable pharmaco epidemologic evidence regarding the association of prenatal antibiotic exposure and birth defects and therefore a precaution has to be taken while prescribing antibiotics during pregnancy.

US FDA has categorized drugs used in pregnancy as follows based on their effects on fetus

Category A- Controlled human studies shows no risks

Category B- No evidence of risk in humans

Category C- Risk can't be ruled out

Category D- Positive evidence of risk

Category X- Contraindicated in pregnancy

In this study most of the drugs prescribed falls under category B (26.6%), a fair number of drugs falls under category A (16.60%) and C (16.60%) and a few drugs falls under category D (6.66%). No drugs belonging to category X were prescribed.

Generally the interactions are encountered more in patients who receive polypharmacy. In this study, as the average percentage of drugs in each prescription were found to be only 4.5 and most of them are supplements so the possibility for major drug – drug interactions is insignificant.

CONCLUSION

A prescription based survey is considered to be one of the most effective methods to assess drug utilization of the medication. It is also important to consider the recommendations of FDA drugs on pregnancy that helps to improve prescribing patterns of the prescriber and ultimately the clinical standards. A continuous supervision is required through such kind of systematic audit that provides feedback from the physicians and helps to promote rational use of drugs and antenatal care.

The present study reveals that the drug use during pregnancy in and around Bapatla region were minimal and themost of the drugs were prescribed by their generic names. Prescribing by generic name is known to reduce the cost of drug treatment, rationalized drug therapy and avoids confusion.

Our study revealed that prescribing patterns of the physicians in and around Bapatla region was carefulfor pregnant women in antenatal care. We conclude by strongly recommending that the habit of prescribing drugs by generic names should be inculcated among more physicians. Awareness of low cost prescribing practices should be initiated among prescribers because a large number of patients visiting the hospitals are from poor socio economic backgrounds. A further cost analysis study should be undertaken to determine if the cost per day is affordable to the patients.

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CONFLICT OF INTEREST

The authors have no conflict of interest to disclose.

ABBREVIATION

a.c. :Before meal ;a.m : Before noon; alt.hor. : Every two hours ; b.i.d, b.d. : Twice a day ; Caps : A capsule ; i.c. : between meals ; i.m. : Intramuscular ; Inj : An injection ; i.v. : Intravenous ; Matu t : of the morning ; o.h. : Every hour ; o.q.h : Every fourth hour ; p.c. : After meals ; p.m : Afternoon ; pomerid : of the afternoon : q.i.d, q.d. : Four timesa day ; quart. Hor : Every four hours ; sem in die : Once a day ; sex.i.d : Six times a days ; ext. Hor : Every six hours ; sing. Hora : Every hour tab : A Tablet ; tert. Hor: Every three hours; t.i.d, t.d.: Three times a day.

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