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To Analyse the Drugs for who Prescribing Indicators in a Tertiary Care Hospital Prescribed For Pregnant Women

[1]Dr. Kuruvila P Chacko, [2]Ms. Hanna Maria Baiju, [3]Ms. Romy Susan Thomas, [4]Ms. Ashley Varghese, [5]Dr. Philip Jacob, [6]Dr. Abel Abraham Thomas

[1]Department of Obstetrics and Gynaecology, Professor, Believers Church Medical College Hospital, Thiruvalla, Kerala, India

[2, 3, 4] Pharm D Interns, Nazareth College of Pharmacy Thiruvalla, Kerala, India

[5]Assistant Professor, Department of Pharmacy Practice, Nazareth College of Pharmacy, Thiruvalla, Kerala, India

[6]Associate Professor, Department of Pharmacy Practice, Nazareth College of Pharmacy, Thiruvalla, Kerala, India

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Corresponding Author: Miss Hanna Maria Baiju, Pharm D Interns, Nazareth College of Pharmacy Thiruvalla, Kerala, India

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Abstract

Background

Pregnancy is a physiological state appropriate use of drugs during pregnancy is beneficial as it affects not only the health of the pregnant woman but also the developing foetus.

Aim

This study was carried out to evaluate the drug use pattern and to analyse drugs prescribed using WHO prescribing indicators. *Method:* A Cross Sectional Descriptive Study was carried out among 150 pregnant women for six months. Data was obtained by direct interview with the subjects and from treatment chart of subjects which were recorded in data collection form. WHO prescribing indicators and the FDA risk pregnancy category was used to analyse the drugs.

Results

Majority of the subjects were under the age group of 18-28 years (50%) and were at the third trimester (57%) of their pregnancy. About 635 drugs were prescribed and the average drugs per prescription

were 4.3 drugs. About 6.1% of subjects received at least one antibiotic and 8.5% of subjects received at least one injection. The total percentage of drugs prescribed by generic name and percentage of drugs prescribed from Hospital Formulary was 100%. The drug was classified according to the FDA risk category as A, B, C, D, X & NA. Most of the drugs prescribed belonged to category B.

Conclusion

The drug use pattern in a tertiary care hospital was analysed carefully and found that the drugs were given according to FDA risk category and WHO prescribing indicators.

Keywords

Drug use pattern during Pregnancy, FDA category, WHO prescribing indicators.

Impact on Practice

- Pregnancy is a period that demands special care from health care providers as it can affect both mother and foetus simultaneously.
- Total avoidance of pharmacological treatment may be dangerous because some become pregnant with medical conditions that require on-going and episodic treatment.
- Hence drugs used by the pregnant women should be monitored and access according to FDA category along with WHO prescribing indicators

Introduction

Pregnancy is defined as the carrying of one or more offspring known as a foetus or embryo inside the uterus of a female. [1] The use of drugs during pregnancy needs special attention as it can affect the mother, as well as the developing child. [2] Pregnancy period consists of 40 weeks. Medical scientist has divided this period into three trimesters. [5] Proper use of medications during pregnancy is an essential part of prenatal care. [7]

Pregnancy presents a responsibility in pharmaceutical treatment of chronic and acute disorders and for symptom management of many complaints associated with pregnancy. [8] There are some unparalleled events, e.g., abortions, premature births and embryopathies which could be avoided by managing diabetes, infections etc. with proper treatment. [9] Timely treatment of such conditions can reduce the perinatal morbidity and mortality to an extent. [10] Thus pregnancy is special physiological condition where drug treatment presents a special concern. [11]

Total avoidance of pharmacological remedy in pregnancy is not possible. It may be dangerous because some women become pregnant with medical conditions that require on-going and episodic treatment. Appropriate dispensing is one of the critical steps for rational drug use, including minimizing the use of teratogenicity drugs during pregnancy. [22]

The rational use of drugs means that patients receive medicines appropriate for their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community. [23] Rational drug use in pregnancy thus requires the balancing of benefits and potential risks associated with the use of the drug. The benefits of rational drug use during pregnancy are not only restricted to the recovery of maternal health, but are also helpful in the development of the foetus. [24] Thalidomide crisis in the 1960's and the teratogenic effects of use of diethylstilboestrol in 1971 led the US Food and Drug Administration [US FDA] to demonstrate safety and efficacy of any drug before it is marketed. [25] To safe guide drug use during

pregnancy, the United States (US) Food and Drug Administration (FDA) 1979 classified drugs into five categories: A, B, C, D, and X with category D and X indicating evidence of risk in pregnancy. [26]

Prescribing pattern were analysed using a tool specifically the WHO indicator.

WHO drug prescribing indicators data were analysed for: [28]

- Average number of drugs per encounter.
- Percentage of drugs prescribed by generic name.
- Percentage of encounters with an antibiotic prescribed.
- Percentage of encounters with an injection prescribed.
- Percentage of drugs prescribed from essential drug list and formulary.

Thus it helps in evaluating the drug use among the pregnant women and the possible awareness among the pregnant women and medical personnel. The study also helps in understanding– the average number of drugs used, the most common drugs used, FDA risk categories of the used drugs, WHO core indicators and the prevalent practices of self-medication.

Objectives

- To analyse the drugs for WHO prescribing indicators.

Ethical Approval

This study was performed in line with principles of Declaration of Helsinki. Approval was granted by Ethics Committee of Believers Church Medical College Hospital, Thiruvalla (Date: 11/06/2021; IEC study No: IEC/2021/08/223).

Methodology

This Cross sectional descriptive study was conducted between March 2021 and August 2021 among IP and OP admissions of pregnant women in the Department of Obstetrics and Gynaecology at Believers Church Medical College Hospital (BCMCH), Thiruvalla. The number of study subjects was 150. The study was initiated after the Institutional Ethical Committee give approval for the study. The patients who met inclusion and exclusion criteria were included in the study.

Inclusion Criteria

1. Pregnant women who visited IP and OP department of OBG.

Exclusion Criteria

2. Pregnant women who informed their unwillingness to participate in the study.

Source of Data

1. Patient Records: Current case sheet and treatment chart.
2. Interviewing the inpatients as well as the outpatients.

Study Procedure

- Patients were enrolled into the study, after taking their prior consent (in local language) and considering inclusion and exclusion criteria. All the necessary and relevant baseline information was collected on a patient data collection form (in local language) which includes the following:

a) Basic socio-demographic details such as age, education, occupation, place of residence,child bearing trimester, parity, timing of first prenatal visit, abortion history, habits, maternal chronic diseases, medications taken, and medical condition before pregnancy were collected using questionnaire.

b) Information about drug use including the generic and brand name of the drug, dose, dosage frequency and route of administration were also collected.

c) The drugs prescribed were grouped under their pharmacological classes and under the Food and Drug Administration (FDA) pregnancy risk classification groups A, B, C, D, and X.

d) WHO drug prescribing indicators data were analysed for:

- Total number of drugs prescribed.
- Average number of drugs per encounter.
- Percentage of drugs prescribed by generic name.
- Percentage of encounters with an antibiotic prescribed
- Percentage of encounters with an injection prescribed.
- Percentage of drugs prescribed from essential drug list and formulary.

Statistical Analysis

The results were Statistical Analysed using MS Excel.

Result

The study was conducted among 150 pregnant women who undergo inclusion and exclusion criteria

Table 1 shows the **age group** distribution in which majority of them belong to the age group of 18-28 years (50%), followed by 29-38 (49%) and remaining 1% belong to 39-48 group.

Figure 1 assessed the number of pregnancy (**Gravida**) in which majority of the pregnant women were primigravida (45%), 38% were secundigravida and the remaining 17% of pregnant subjects were multigravida.

Figure 2 evaluate the stage of pregnancy (**Trimester**) and found that among 150 pregnant women the most subjects were in their third trimester (57%), 23% of pregnant subjects were in their first trimester and 20% were in their second trimester.

On account of **Medical history**, 33.33% of the subjects had no medical history, 16% had Thyroid disorder followed by 12% with history of Diabetes Mellitus, 5.8% with Gestational diabetes, 5% with PCOD, 3.7% with Hypertension, UTI, Migraine, 3.1% with Anaemia, 2.1% with Pregnancy Thyroid and Asthma, 1.5% with Skin Disorders, 1% with Allergy, DLP and Hypothyroidism and the remaining 0.5% pregnant subjects had history of Nephrotic Syndrome, Scoliosis, Sinusitis, Gestational Thrombocytopenia, Behcet's Disease, Allergic Bronchitis, Pre-Eclampsia, Trigeminal Neuralgia, TDS and Hypotension.

The **medication history** among the 150 pregnant subjects enrolled in the study, majority of the pregnant subjects had taken Thyroxine (40.2%), followed by 22% had Metformin, 9.1% had insulin, 5% had aspirin and iron supplements, 2.2% had Progesterone, Antibiotics, Nifedipine and Furosemide, 1.1% had Atenolol, Carbimazole, Nasal Inhaler, Nasal Spray, Nitrofurantoin, Labetalol, Salmeterol+ Fluticasone Propionate, Prednisolone and Flunarizine.

The **drug treatment chart** among the 150 pregnant womenshowed 7.5% had Folic Acid, followed by 7.2% had Progesterone, 6.9% had Pantoprazole, 5.3% had Paracetamol and Metformin, 5% had Serratiopeptidase, 3.5% had Cefuroxime, 2.9% had Thyroxine and Fluconazole, 2.3% had Hydrogestrone, Nitrofurantoin and Metronidazole, 1.9% had Bisacodyl and Iron, 1.5% had Hydroprogestrone, Lignocaine, Misoprostol, Promethazine, Aspirin, Albendazole, Nifedipine and Insulin, 1.3% had Clotrimazole, Oxytocin, Tramadol, Amoxicillin and Ondansetrone, 0.9% had Betamethasone, Mupirocin, Vitamin K, Betadine, Ranitidine and Cetirizine, 0.6% had Levocarnitidine, Norethisteroneand Miconazole and the remaining 0.3% had CMC Eye Drop, Rabeprazole, Prednisolone, Montelukast, Oseltamivir, Enoxaparin, Vitamin D,

Fusidic, Alprazolam, Gabapentin, Dicyclomine, Hydrochloroquine, Selfarazine, Human Menopausal Gonadotrophin, Human Chorionic Gonadotrophin, Medroxyprogestrone, Letrazole, Metoclopramide, Azithromycin, Sucralfate, Vitamin C and Nidafloxacin.

In**distribution of combination drugs** among 150 subjects, majority of them had Ferrous fumarate+ folic acid+ zinc (28.5%) , followed by 23.5% had Cholecalciferol+ elemental calcium, 6% with Calcium citrate+ cholecalciferol+ folic acid, 5.1% had Clindamycin+ clotrimazole+ tinidazole, 3.9% had Vitamin B complex+ vitamin C, 3.2% had Folic acid+ mecobalamine+ pyridoxine, Doxylamine+ pyridoxine with 2.8% ,2.6% had Cyanocobalamin+ ferrous fumarate+ folic acid, Diclofenac+ capsaicin+ menthol and Maltodextrin+ sodium & calcium caseinates, 2.2% had Magaldrate+ dimethicone, 1.6% had Milk of magnesia+ liquid paraffin, 1.3% had Calcium+ cholecalciferol, Cyanocobalamin+ ferric ammonium citrate+ folic acid, 0.9% with Docosahexaenoic acid+ folic acid+ methylcobalamin+ pyridoxine and Vitamin A+ vitamin B complex+ magnesium+ iodine, 0.6% had Activated Poly Dimethyl Siloxane + Dried Aluminium Hydroxide+ Magnesium Aluminium Silicate+ Magnesium Hydroxide, Aloe vera+ glycerine+ tocopheryl acetate, Calcium+ vitamin D3+ Magnesium+ zinc, Disodium hydrogen citrate and LArginine + zinc sulphate and the remaining 0.3% had Aluminium hydroxide + Magnesium hydroxide + Simethicone, Amoxicillin + clavulanate, Anti Rh D immunoglobulin, Ascorbic acid + bioflavonoids, Bromhexine + Guaifenesin + Terbutaline + Menthol, Calcium carbonate+ vitamin D3 + Iron fumarate, Citric acid + sodium citrate, Clotrimazole + Betamethasone, Dextromethorphan + chlorpheniramine + phenylephrine, Doxycycline+ lactobacillus, Fluticasone + mupirocin, Heme iron polypeptide, Ipratropium bromide +Levosalbutamol, L-arginine + proanthocyanidine, Liquid Paraffin + Magnesium Hydroxide + Sodium Picosulphate, Paracetamol+ chlorzoxazone and Phenylephrine+ Beclometasone + Lidocaine.

The **FDA categorization** of drugs given for the 150 subjects was done and represents in Table 2. It was found that majority of drugs belongs to category B (52.2%), followed by 24.4% were category C, 12.8% category A, 6.8% were category X drugs and least prescribed (1.9%) were category D and NA drugs.

Table 3 represents the **WHO indicators**. Total number of drug prescribed in the study was 635 drugs. Thus the drugs were classified accordingly. From this the average number of drugs per prescription was found to be 4.3. Percentage of drugs prescribed by generic name was found to be 100%. Percentage of encounters with antibiotic prescribed was found to be 6.1%. Percentage of encounters with an injection prescribed was found to be 8.5%. Percentage of drugs prescribed from essential drug list and formulary were found to be 100%.

Discussion

The care during pregnancy is one of the great challenges in health care systems. Irrational use of drugs is a huge concern where it can lead to many serious adverse events thus appropriate monitoring of the drug intake by the pregnant subjects should be examined. In this study it is to determine drug use pattern among the pregnant population. The WHO prescribing indicators and FDA risk category were also carried out. The study population consist of 150 pregnant women from IP and OP admissions of OBG

department. The study was cross sectional descriptive study. The data was collected using questionnaire and prior consent from the subjects.

The assessment on age group is similar to the study done by **Fasalu Rahiman OM** which also states that the increase in number of pregnancies between the age ranges 21-25 years were 32.5%. Decrease in the number of pregnant subjects as the age increases gives us an insight that there will be more complications during pregnancy and sometimes the health of the child may be at stake. In this study majority of the pregnant subjects were within the reproductive age.

The evaluation of gravidagives a similar status in a study done by **Kumarjit S** among the 150 subjects of pregnant women in which 42.67% were primigravidae while the remaining 57.33% were multigravidae. In the present study 45% of the pregnant subjects were primigravidae, 38% of the pregnant subjects were secundigravidae and 17% were multigravida. Here mainly the number of subjects who were pregnant more than one time is seen, there may be a possibility that abortions may have resulted in multiple pregnancies or the want of more than one child could have resulted it.

Maximum number of women (57%) were in third trimester, followed by 20% in the second trimester and 23% were in the first trimester in the present study. A similar status can be seen in a study done by **Kinnari B Thacker** where number of pregnant subjects was more (61.2%) in third trimester and 28.8% in the second trimester. And 10% of the subjects visited during the first trimester. Mainly during the third trimester more visits are done as it is near to the time of delivery. Most complications can also occur during this time and the drugs taken during this time should also be monitored.

In the present study 33.33% of the pregnant subjects had no medical history. Medical history of thyroid disorder was the most (16%) followed by subjects with diabetes mellitus which was 12% and 5.8% of the subjects with gestational diabetes.

Then the medication history was assessed. In the present study medication were given the most for thyroid disorder which is thyroxine (40.2%), followed by medication for diabetes which is Metformin (22%) and 9.1% had insulin. 5% of aspirin and iron supplements were given which comes the next.

Drugs prescribed by the healthcare providers were evaluated. In the present study folic acid (7.34 %) is the most seen drug in treatment chart followed by progesterone (7.03%) and pantoprazole (6.72%).
The most seen combination drug was Ferrous fumarate+ folic acid+ zinc (28.4%) followed by Cholecalciferol+ elemental calcium (23.3%) and Calcium citrate+ cholecalciferol+ folic acid (6%) in the present study.

The drugs were also categorized according to the FDA risk category. In case of the single drugs given, 12.8% were category A, 52.2% were category B, 24.4% were category C, 1.9% were category D& NA and 6.8% were category X. According to a study done by **Adefolarin A Amu,**most prescribed drugs fell under category A (64.9%) and the following category B (27.3%).

By using WHO indicators, the pattern of prescription was analysed. From this, the total number of drugs prescribed among 150 pregnant women is 635. The average number of drugs per prescription is 4.3, that is majority of prescription contains at least 4 drugs each. 6.1% of pregnant subject received at least

one antibiotic in their prescription. 8.5% received at least one injection. Percentage of drugs prescribed by generic name and that of drugs prescribed from essential drug list and hospital formulary was found to be 100%. The results obtained were contradictory to results obtained, in the study conducted by **Satish Kumar B. P**, were the total number of drugs was 574 drugs. And each prescription contained 3.82 drugs on an average. 16.2% of the total patients received at least one antibiotic in their prescription and only 18.8% of patients received at least one injection in their prescription. The total percentage of drugs prescribed in generic name was found to be 6.2% and percentage of drug prescribed from hospital formulary was 92.1%. This states that good and well versed prescribing patterns was followed here and have avoided all the possible maximum error.

Conclusion

The drug use pattern among the pregnant women varies. Prescribing of drugs among pregnant population is a concern. A total of 150 pregnant women were reviewed. Majority of the subjects were in 18-28 age group (50%). About 57% of subjects were in third trimester of pregnancy. Major Comorbid condition was thyroid disorder (16%), followed by diabetes but 33.3% pregnant subjects from the 150 subjects had no co-morbidity. Hence majority of medication history included thyroxin (40%) followed by anti-diabetic medicines (31.1%). The drugs prescribed to the pregnant women was analysed and in the present study folic acid (7.34 %) is the most seen drug in treatment chart followed by progesterone (7.03%) and pantoprazole (6.72%). The most seen combination drug was Ferrous fumarate+ folic acid+ zinc (28.4%) followed by Cholecalciferol+ elemental calcium (23.3%) and Calcium citrate+ cholecalciferol+ folic acid (6%) in the present study. It is also essential to find the FDA risk category of drugs that can helps in improving the prescription pattern. For which most of the prescribed drugs were category B. The WHO prescribing indicators were assessed and showed that an average of 4.3 drugs per prescription. All the drugs were prescribed from essential drug list and hospital formulary. Hence occurrence of poly-pharmacy is avoided.

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Tables and Graphs

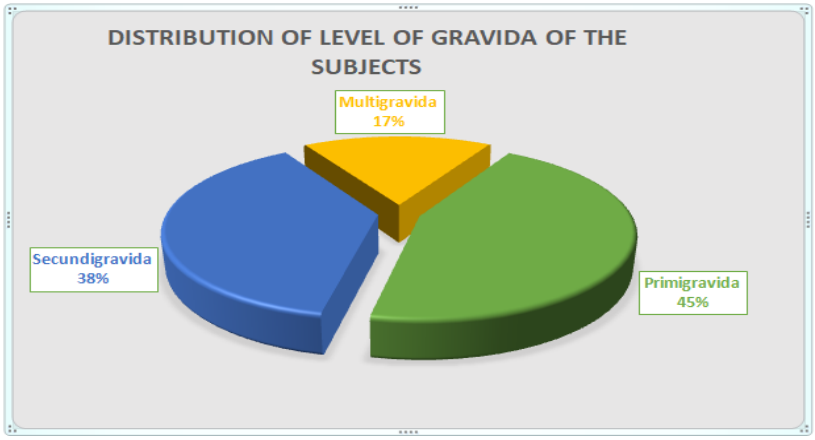

Figure No.1: Distribution of level of Gravida of the subjects

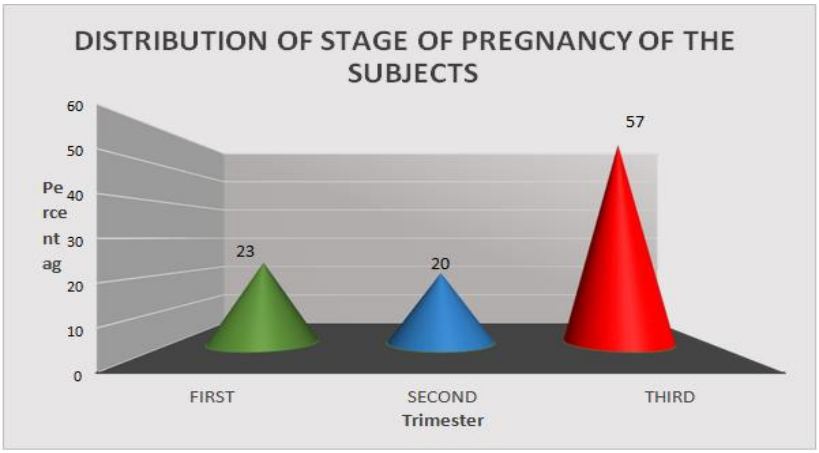

Figure No.2: Distribution of Stage of the pregnancy of the subject

Table No.1: Age group of the subjects

S. No.	Age Group	Frequency	Percentage (%)
1	18-28	75	50
2	29-38	73	49
3	39-48	2	1
	Total	150	100

Table 2: FDA classification of drug

S. No.	FDA Category	Frequency	Percentage(%)
1	A	41	12.8
2	B	167	52.2
3	C	78	24.4
4	D	6	1.9
5	X	22	6.8
6	NA	6	1.9
	Total	320	100

Table No.3: WHO prescribing indicator

Sl. No	Indicator	Value
1	Total number of drug prescribed	635
2	Average number of drugs per prescription	4.3
3	Percentage of drugs prescribed by generic name	100%
4	Percentage of encounters with antibiotic prescribed	6.1%
5	Percentage of encounters with an injection prescribed	8.5%
6	Percentage of drugs prescribed from essential drug list and formulary	100%