



Utilization Pattern of Drugs in Expecting Mothers Visiting Department of Obstetrics and Gynaecology in Rural Tertiary Care Center

Chanderpriya Agarwal*, PG Final Year, Department of Pharmacology, MMIMSR, Mullana, Ambala, Haryana

Dr. Anshu Gupta, Professor, Department of Pharmacology, MMIMSR, Mullana, Ambala, Haryana

Dr. Rani Walia, HOD and Professor, Department of Pharmacology, MMIMSR, Mullana, Ambala, Haryana

Dr. Naina Kumar, Associate Professor, Department of Obstetrics and Gynaecology, MMIMSR, Mullana, Ambala, Haryana

Corresponding Author: Chanderpriya Agarwal, PG Final Year, Department of Pharmacology, MMIMSR, Mullana, Ambala, Haryana

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Abstract:

Objectives: To assess and evaluate the rationale prescribing skills of Obstetricians in expecting mothers as per WHO standards and standards of developed countries.

Methodology: This prospective observational study was conducted at MMIMSR, Mullana on 200 pregnant patients in the Department of Obstetrics and Gynaecology. Patients satisfied inclusion criteria were enrolled after the informed consent and Patient's data was recorded and analysed. WHO prescribing standards were used to study drug utilisation pattern and rationale use of drugs. the drugs prescribed to the patients were categorized according to the USFDA classification and prescriptions with polypharmacy were also observed and analyzed.

Results: A total of 740 drugs were prescribed which mainly included minerals and vitamins 299 (40.40%), Vaccines 148 (19.97%), Folic acid 91 (12.28%), Protein powder 64 (8.63%) and so on. Average number of drugs per prescription was calculated as 3.7. Polypharmacy (Drugs above 6 in prescription) was observed in 10 (5%) prescriptions. All the drugs prescribed were rational as

majority of drugs are nutritional supplements and were essential for growth and proper development of fetus. Drugs prescribed according to the USFDA categories were observed as Category A 653 (88.24%), Category B 61(8.24%), Category C 25(3.37%), Category D (0.0%) and Category X (0.1%). Average age of the patients observed was 25.81 years.

Conclusion: From the results it can be concluded that Minerals and Vitamins are the most commonly prescribed drugs. Overall drugs prescribed were rationale with average number of drugs per prescription 3.7, was under the standards of WHO. Majority of drugs were prescribed as per USFDA category A, the safest category during pregnancy. Prescriptions with polypharmacy were found only in 5% of the prescriptions. Thus, the prescribing practices of the Obstetricians at tertiary care center were similar to that of western countries.

Keywords: Drug utilisation pattern, pregnancy, obstetrics and gynaecology, USFDA Drug Categories, polypharmacy, rational drug prescribing.

1. Introduction and Background

According to World health Organization (WHO) rational use of medicine means drugs appropriate to patient's pathological condition in therapeutic doses, for an adequate period of time, and at the lowest cost [1]. The World Health Organization (WHO) has reported that throughout the world specifically in developing countries like India around 50% of all medicines are inappropriately prescribed, dispensed or sold [2]. Drugs which are ineffective, unnecessary, not related to diagnosis, medically inappropriate, expensive and multiple drugs are prescribed commonly not only in developing countries but also in developed countries [3, 4]. Use of irrational drugs increased the incidences of morbidity and mortality, emergence of microbial resistance, financial loss to patient and community, loss of patient's confidence in the doctor, lowering of health standards of patients and community [5]. Effects of irrational prescriptions are more in underdeveloped or rural regions since such regions are comparatively having less health care facilities. Factors which are responsible for prescribing irrational drugs are vigorous drug promotion by pharmaceutical industries, unethical inducement to doctors and pharmacists and pill for every ill belief of patients. Drug utilization studies which include prescription audit and retrospective analysis of medical records can be conducted to assess the rational prescribing skills of clinicians. Such types of studies are helpful for the assessment of beneficial and adverse impacts of the prescribed drugs [1, 3].

1.1 FDA Categorisation of Drugs Use during Pregnancy

Food and Drug Administration (FDA) developed a system in 1979 that explained the teratogenic risk of drugs on the basis of data obtained from animal and human studies. It provides therapeutic guidance for the Gynaecologists and other Clinicians. According to the system, drugs prescribe during pregnancy were classified into 5 categories

according to their effects on the developing fetus. These categories are summarized in Table 1. [6, 7]

Table 1: Represents Different Drug Categories as per USFDA Classification

Category	Details of Each Categories	Examples of Drugs
A	Safest category, No evidences of risk in first or later trimesters	Folic acid, Doxinate, Iron etc.
B	No fetal risk in first and later trimesters	Azithromycine, Ranitidine, etc.
C	Animal studies demonstrated adverse effects on fetus, drugs should be used only if potential benefits justifies the potential risks to the fetus.	Albendazole, Ascorbic acid, Domperidone etc.
D	Positive evidences of human fetal risks, drugs should be used only in life threatening condition or absence of any other safer drug.	Streptomycin, Tetracycline, carbamazepine etc.
X	Studies demonstrated fetal abnormalities; these drugs are contraindicated in pregnancy.	Warfarin, methotrexate

1.3 Drugs Used During Pregnancy

Pregnancy is the crucial time in which there is a development of one or more offspring inside a woman. It is the time when many physiological changes occur in women body [8]. Pregnancy requires careful assessment of health for both mother and fetus. Thus, awareness about the use of drugs is mandatory for the pregnant women and child [9]. Normally if not necessary, drugs should be avoided during pregnancy because drugs taken by a pregnant woman cross the placenta and reach to the fetus which may be harmful for fetus. The placenta is responsible for the proper growth and development of the fetus by providing oxygen and nutrients to the fetus[10]. There are many drugs like minerals, iron, folic acid, calcium, vitamins, and other dietary supplements which are essential during pregnancy and for the fetus health [11].

Mullana has predominant rural and lower socio-economic population. In this background the present study was planned to assess the status of drug utilization, prescription pattern and rational prescribing skills of medical practitioners in Obstetrics and Gynaecology Department of Maharishi Markandeshwar Institute of

Medical Sciences and Research (MMIMSR) which is the only tertiary care centre of the area.

2. Methodology

Study Design: It was a prescription based prospective study aimed to assess the drug utilisation pattern and to determine whether the drugs prescribed to the pregnant women were rational or not. This study was conducted in Department of Pharmacology in collaboration with Department of Obstetrics and Gynaecology at MMIMSR, Mullana, Ambala. A total of 200 patients were taken as sample size who attended Out Patient Department (OPD) and fulfilled the inclusion criteria.

Inclusion Criteria: All the pregnant women attended OPD above 18 years and who have informed consent to access their prescription were included in this study.

Exclusion criteria: Pregnant women who were not attended regularly for health checkups and the patients who provided incomplete information were excluded from the study.

Hospital Background: It is a tertiary care hospital in rural area which receives referrals from other private clinics, hospitals and general physicians. The hospital is well established and well known for its services to the people in the area and nearby districts. The institution has diverse specialities like Medicine, Surgery, Paediatrics, Psychiatry, Orthopaedics, Obstetrics and Gynaecology, Ophthalmology, ENT and other various specialities. Most of the women visit this centre for antenatal services belong to lower socioeconomic group.

Ethics Committee Approval

The Institutional Ethics Committee permission was taken prior to initiation of the study (Approval Letter No. MMIMSR/IEC/1143/2018-19). Written Informed Consent was taken from all the pregnant women before their prescriptions were analyzed.

Study Method:

All 200 patients attended OPD in the obstetrics and Gynaecology department were observed. Patients satisfied the Study Inclusion Criteria were enrolled after taking Informed Consent (IC). A thorough review of patient's medication charts was done to understand and analyze demographic profile, prescription pattern of drugs according to USFDA category, number of drug group used, average number of drug per prescription, calculation of Polypharmacy, most commonly prescribed drug group and rational use of drug. Data was analyzed in the form of average and percentage using Microsoft Office Excel 2007.

3. Results

Data of various demographic variables and the data of the prescription order of all 200 patients were collected, documented, analyzed and following results were obtained-

3.1 Results Related to Prescription Order

3.1.1 Distribution of Drugs Prescribed According To US-FDA Category

Drugs prescribed to the 200 patients were grouped according to the USFDA categories as shown in the Table 2 .

Table 2: Representing Drugs Prescribed According To US-FDA Category

US FDA Drugs Pregnancy Category	No. of Drugs Prescribed	Percentage (%)
A	653	88.24%
B	61	8.24%
C	25	3.37%
D	0	0.00%
X	1	0.13%

From the Table 2, it was observed that majority of drugs prescribed were belong to the Category A, followed by the Category B and Category C. According to USFDA guidelines, Category A is considered as the safest category of drugs prescribed to the pregnant women.

3.1.2 Drugs Prescribed According To Different Groups

Drugs that were prescribed to 200 patients were grouped into different categories as shown in the Table 3.

Table 3: Representing Drugs Prescribed According To Different Groups.

Name of Drug Group	No. of Drugs Prescribed per Group	Percentage (%)
Minerals and Vitamins	299	40.40
Vaccines	148	19.97
Folic Acid	91	12.28
Protein Powder	64	8.63
Hormonal Drugs	46	6.21
Drugs acting on GIT	44	5.94
Antimicrobial Drugs	28	3.78
Drugs Acting on Blood	14	1.89
Cold/Cough	4	0.53
Antihistaminic Drugs	1	0.13
Anti-inflammatory Drugs	1	0.13
Sedative Hypnotics	1	0.13

From the Table 3, it was observed that out of total 740 drugs, majority of drug group prescribed was minerals and vitamins 299 (40.40%), Vaccines 148 (19.97%), Folic acid 91 (12.28%), Protein powder 64 (8.63%), Hormonal drugs 46 (6.21%), drugs acting on GIT 44(5.94%), Anti microbial agents 28 (3.78%), Drugs acting on blood 14 (1.89%), Cough/Cold 4 (0.53%), Sedative and Hypnotics 1 (0.13%), Anti-Histaminics 1 (0.13%), Anti-inflammatory drugs1 (0.13%) etc. Figure 1 represents the chart of the different drug groups prescribed to the patients.

Figure 1: Represents the Chart of the Different Drug Groups and Number of Drugs in Each Group Prescribed to the Patients.

3.1.3 Drugs Prescribed According To Trimester of Pregnancy

Out of the total 740 drugs prescribed, the number of drugs prescribed to the patients of different trimester is shown below in the Table 4-

Table 4: Representing the Distribution of Drugs Prescribed According to Trimesters

Trimesters	Number of Drugs	Percentage
First Trimesters	123	16.62 %
Second Trimesters	307	41.48 %
Third Trimesters	310	41.89 %

From Table 4, it was observed that out of total 740 drugs, majority of drugs were prescribed to the patients of third trimester 310 (41.89%) followed by patients of second trimester 307 (41.48%) and first trimester 123 (16.62%).

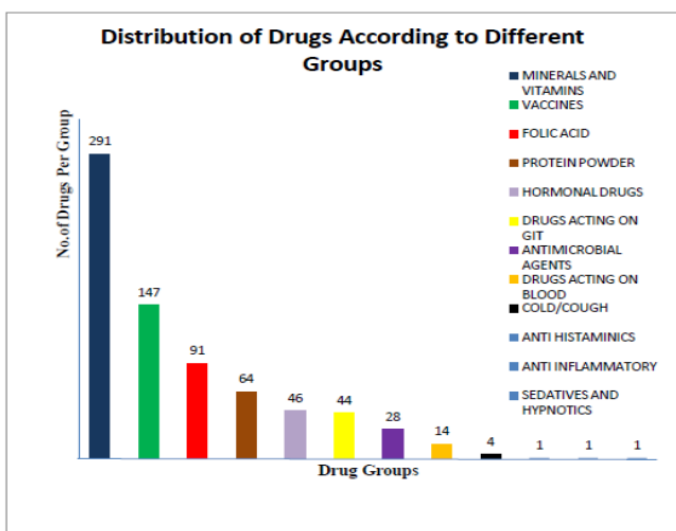
Other results related to the prescription order were –

- Average number of drugs per prescription was calculated as 3.7.
- Out of 200 prescriptions, 42(21%) prescriptions were observed with less than 3 drugs, 148 (74%) prescriptions were observed with 3 to 6 drugs and 10 (5%) prescriptions were observed with more than 6 drugs prescribed to the patients. Thus, polypharmacy observed was only 5% prescriptions.
- All the drugs prescribed to the patients were according to the diagnosis, medically appropriate and were rational.

3.2 Results of Demographic Data

The demographic data of the patients according to the different variables is expressed in the Table 5.

Table 5: Representing the Demographic Variables of the Patients



Variables	Number and Percentage	
Age (Years)	18 - 23 years	53 (26.5 %)
	24-29 years	120 (60.0 %)
	30 - 35 years	24 (12.0 %)
	36 – 41 years	3 (1.5 %)
Educational Status	Illiterate	11 (5.5 %)
	Primary Education	11 (5.5 %)
	Secondary Education	68 (34 %)
	Sr. Secondary Education	44 (22 %)
	Graduate	58 (29 %)
	Post Graduate	8 (4 %)
Employment Status	House wife	188 (94%)
	Working	12 (6%)
Gravida Condition	Primi-Gravida	72(36%)
	Second-Gravida	69(34.5%)
	Multi-Gravida	59(29.5%)
Distribution of Patients according to Trimester	First-Trimester	59(29.5%)
	Second- Trimester	97(48.5%)
	Third- Trimester	44(22%)

From the Table 5, following results were observed -

1. Out of 200 patients included in the study, majority of patients, 120 (60.0%) belonged to age group of between 24-29 years. The average age of the patients was calculated as 25.81 years.
2. Out of 200 patients included in the study majority of patients, 68 (34%) belonged to secondary education category.
3. Out of 200 patients 188 (94%) pregnant women are house wives.
4. Out of 200 study patients, majority of patients, 72(36%) belonged to primi-Gravida.
5. Out of 200 study patients, majority of patients, 97(48.5%) belonged to second trimester.

4. Discussion

This study was planned to get the knowledge of the current status of prescriptions and drug utilisation in the department of Obstetrics and Gynaecology in MMIMSR, Mullana, Ambala. With the help of this study we can improve the drug utilisation and prescription system in this tertiary care centre located in the rural area of Ambala city. A total of 740 drugs were prescribed by the Gynaecologists to 200 patients. Deshagani M *et. al* [12] reported that majority of pregnant women under study belong to the age group of 18-23 years(25) and 24-29

years (22). In our study, majority of pregnant women belong to the age group of 24-29 years 120 (60 %). Rohra DK et al [13] found majority of drugs prescribed during the 3rd trimester of pregnancy (55.4%). Our study also indicates the same result that majority of drugs prescribed during third trimester of pregnancy 310 (41.89%). IlyasMd. et. al [14] reported the average number of drug per prescription was 6.25, majority of patients were primary literate 142 (35.5%), majority of patients were unemployed 353 (88.25%) and majority of patients were belong to Primigravida 150 (37.5%). Our study indicates the same and the better results, the average number of drug per prescription was calculated as 3.7, majority of patients were secondary literate 68 (34%), majority of patients were housewives 188 (94 %), and majority of patients were belong to primigravida 72 (36%). In the study of Das B et al [15], most prescribed group of drugs included was nutritional supplements like iron, vitamins (72.8%), In our study, majority of drugs prescribed were also minerals and vitamins 299 (40.40%). Polypharmacy was also reported by Kumari R et al [16] in their study. Our study also reports Polypharmacy in only 10 (5%) prescriptions. But all the drugs prescribed to the pregnant women were according to the diagnosis, medically appropriate and were rationale as all the prescriptions contained 4 – 5 nutritional supplements. Agarwal M et. al [17] explained the differentiation of drugs prescribed to pregnant women according to USFDA and found that most of the drugs prescribed belong to the category A. In our study most of the drugs prescribed were also belong to the category A 653(88.24%).

5 Conclusion

Pregnancy requires careful assessment of health for both mother and fetus. From the results it can be concluded that Minerals and Vitamins are the most commonly prescribed drugs which are essential for the proper growth and development of fetus. Overall drugs prescribed were

rationale with average number of drugs per prescription 3.7, was under the standards of WHO. Polypharmacy was observed in only 10 (5%) prescriptions. Majority of prescriptions contained 3 – 4 nutritional supplements; this is the only reason for polypharmacy. As majority of the drugs were Nutritional supplements, rational prescribing pattern was followed under the tertiary care center. Majority of drugs were prescribed as per USFDA category A, the safest category during pregnancy. Thus from the above results we can conclude that the drugs prescribed in the Obstetrics and Gynaecology Department of MMIMSR, Mullana, Ambala were according to the WHO and USFDA guidelines and according to the drugs prescribed in the developed countries.

6 References

1. Tripathi KD. Aspects of Pharmacotherapy; Clinical Pharmacology and Drug Development. In: Essentials of medical pharmacology. 6th edition. New Delhi: Jaypee Brothers; 2008.P. 68- 71.
2. Thomas JE, Elizabeth PP, Geethu C, Chintu SP, Sivakumar T, Assessment of Drug Use Pattern and WHO Prescribing Indicators in the Department of Obstetrics and Gynaecology Prospectively, *International Journal of Pharmacy and Pharmaceutical Research*, 2016 July; Volume 6(4): 378-385.
3. Bhingare PE, Bashir MSM, Khade A, George S, Prescription Pattern in Gnaecology- A Retrospective study in a South Indian Teaching Hospital. *J Cont Med A Dent* 2014, Volume 2 Issue 2: 51-54.
4. Harsh Joshi, Sejal Patel, Kamlesh Patel, Varsha Patel. Drug use pattern during pregnancy: A prospective study at tertiary care teaching hospital. *NHL Journal of Medical Sciences*. 2012;1(1):13-16.
5. Rathod AM, Rathod RM, Jha RK, Gupta VK, Ahmed Tabish, Santra Diptendu. Prescribing trends in antenatal care at a tertiary level teaching hospital of Vidarbha region. *Research Journal of Pharmaceutical Biological and Chemical Sciences*.2012; 3(3): 865-72
6. Dutta's DC, Text book of Obstetrics Including Perinatology and Contraception, New Central Book Agency (P) Ltd, 6th Edition, pp -64,68,70.
7. Shrestha P and Bhandari SK, Pattern of Drug Prescribing During Pregnancy in Nepalese Women, *International Journal of Pharmacy*, 2013; 3(4): 680-688.
8. EZe UI, Eferakeya AE, Oparah AC, Enato EF. Assessment of prescription profile of pregnant women visiting antenatal clinics. *Pharmacy Practice*. 2007; 5(3): 135-139.
9. Mitchell AA, Gilboa SM, Werler MM, Kelley K.E, Louik C, Hernandez-Diaz S, study T.B.D.P, medication used during pregnancy with particular focus on prescription drugs: 1976-2008. *American Journal of Obstetrics and Gynaecology* 2011; 205(1): 51 e. 1-8.
10. Porter RS, editor. The Merck Manual's Online Medical Library. White House Station: Merck Research Lab; 2004.
11. Sharma R, Kapoor B, Verma U. Drug Utilization Pattern During Pregnancy in North India, *Journal Medical Science* 2006; 60: 277-287.
12. Deshagani M, Ramgalla A, Shaga S, Das SK, Srikanth S, Rao UM. Categorisation of prescription pattern in pregnant women according to US-FDA in a tertiary care hospital. *International Journal of Innovative Pharmaceutical sciences and research*. 2015;3(8):1066-1077.
13. Rohra DK, Das N, Azam SI, Solangi NA, Memon Z, Shaikh AM et al. Drug- prescribing patterns during pregnancy in the tertiary care hospitals of Pakistan: a cross sectional study. *BMC pregnancy and child birth*. 2008;8:1-5.

14. Ilyaz M, Rozati R, Hafeez F, Tahniyath F, Sultana H, Hussain MA. Drug Utilization Pattern in Pregnancy- a scope for improvement in the current prescribing practices. *International Journal of Pharmacy*. 2014; 4(4):156-167.
15. Das B, Sarkar C, Dutta A and Bohra S. A study of drug use during pregnancy in a teaching hospital in western Nepal. *Pharmacoepidemiol Drug Saf*. 2003 Apr-May;12(3):221-5.
16. Kumari R, Idris MZ, Bhushan V, Khanna A, Agrawal M, Singh SK. Assessment of prescription pattern at the public health facilities of Lucknow district. *Indian Journal of Pharmacology*. 2008; 40(6): 243–247.
17. Agarwal M, Nayeem M, Safhi MM, Makeen HA, Sumaily JM, Gupta N. Prescribing pattern of drugs in the department of obstetrics and gynaecology in expecting mothers in jazan region, ksa. *International Journal of Pharmacy and Pharmaceutical Sciences*. 2014;6(1):651-661.