Morbidity Pattern and Drug Prescribing Study in Pregnant Women of Rural Part of Charotar Region

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ABSTRACT

Background: Pregnancy is a normal physiological condition where drug treatment presents a special concern because certain drugs that harm to the fetus due to the potential teratogenic effects of drugs. Therefore, the present study was planned to carry out with the objective to evaluate the drug prescribing pattern, morbidity and categories of safe drug prescribing among all the pregnant women. Materials and Methods: A cross-sectional observational study was carried out in 400 pregnant women who attended inpatient and outpatient department at CHARUSAT Hospital during 8 months of study. Demographic details, prescribed drugs, medical history and diagnosis were recorded in CRF. The prescription pattern was assessed and drugs were classified based on USFDA Risk Classification. Results: In present study, iron (82.65%), folic acid (53.62%), calcium (58.51%) and vitamins (82.84%) were found the most frequently prescribed drugs during pregnancy. Anti-emetics, PPIs and H2 blockers, Antibiotics, Anti-hypertensive agents prescribed drugs during labor. The majority of drugs (49.05%) prescribed were from category B. Anemia (66.75%) was found to be a top most morbidity in pregnant women. Other obstetric morbidities like PIH, Breech presentation, Oligohydramnios, Meconium stain Lycor were observed during study period. Conclusion: Majority of the drugs (49.05%) prescribed as per FDA category B. No drug was prescribed belonging to the category X in study. Anemia was found in (66.75%) of pregnant women. Whereas PIH was found in (4%) of pregnant women.

Key words: Drug prescribing, Antenatal, Maternal morbidity, Pregnancy, Anemia, Pregnancy Induced Hypertension.

INTRODUCTION

Pregnancy is defined as the 'High-risk' when there is a probability of an adverse outcome to the woman and to the baby that is greater than the incidence of that outcome in the general pregnant population. A high-risk pregnancy is with a notable for poor maternal or fetal outcomes. High risk patients need sophisticated maternal and fetal surveillance and in occurrence difficult management. A high-risk pregnancy can be recognized only if the woman has access to the prenatal care.¹

Pregnancy is a normal physiological condition where drug treatment presents a special concern because physiology of pregnancy affects the pharmacokinetics of medications used and certain drugs that cause harm to the fetus due to the potential teratogenic effects of drugs.² There is

increase in the volume of distribution of some soluble drugs. Teratogenic drugs may act directly on the fetus causing damage or abnormal development or can also alter the physiological function of the placenta affecting fetal growth.^{3,4}

The rationale for medication used during pregnancy needs to be extra strong. In other words, benefits to the mother and risks to the fetus need to be continuously monitored. Drug utilization review is the authorized, structured, ongoing review of prescribing, dispensing and use of medication. 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

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categories B, C and D are also used during pregnancy. Category X is the only rating that denotes a drug that is contraindicated for use during pregnancy.⁵ The USFDA had laid strict regulations appraising drug labeling, use of medications in pregnancy, requiring proper demonstrations of safety and efficacy of any drug before it comes to the market.⁶ Monitoring of prescriptions and drug utilization studies can help in the comparing observed patterns of the drug use with recommendations, can identify problems and provide feedback to prescribers to create awareness about the irrational use of drugs.⁷

WHO report 2005 shows that one woman dies of pregnancy and childbirth related problems every minute, i.e. more than half a million every year. While most of the pregnancies and births are uneventful, all pregnancies are at risk. Around 15% of all pregnant women develop a potentially life-threatening complication that calls for skilled care and some will require major obstetrical intervention to survive (WHO, 2000).8 In India every year 8 million babies are born underweight and born with certain morbidities. Complications of pregnancy, childbirth and postpartum period may lead to death or cause perpetuity of morbidities that affect a woman's health for short or long-term periods during and after pregnancy and even throughout her life.9

The common cause of maternal death includes Hemorrhage, Hypertension, Infection, Obstructed labor and unsafe abortion. Also, other particular etiology can be due to early marriage during teens, often pregnancies, motherly malnutrition issues, respiratory obstacles, etc. Complications can arise any time during pregnancy, childbirth and postnatal period and in the absence of the skilled interventions, there is high feto-maternal morbidity and mortality. In India, data shows that 70% of mothers, who had four or more antenatal check-ups, delivered in institutions compared with 7% for those who had no antenatal check-ups. The burden of maternal morbidity is still unknown⁸

Pharmaco-epidemiological studies including drug utilization reviews can help to minimize the use of potentially dangerous drugs in pregnancy by establishing a profile of drug consumption, by monitoring the health services and by investigating interventional measures. Morbidities in pregnancy will be a considerable cause for the use of medications and eventually create problems of accidentally exposed to harmful or teratogenic drugs. With this background, the present study was planned to carry out with the objective of to evaluate the drug prescribing pattern, morbidity and categories of safe drug prescribing among all the pregnant women attending the

Obstetrics and Gynecology department, irrespective of the duration of pregnancy, at CHARUSAT hospital, CHANGA.

MATERIALS AND METHODS

A cross-sectional observational study was conducted on pregnant women attending to outpatient and inpatient department of Obstetrics and Gynecology, at CHARUSAT Hospital, Changa over period of 8 months from July 2019 to February 2020.

Ethical Consideration

The protocol of the study was approved by Ethics Committee, before the commencement of the study. Written informed consent of all pregnant women were taken before inquired their data collection. Confidentiality of the women's identity is maintained.

Protocol Number: RPCP/IECHR/2/2019-2020/PG/R-01

Sample size: As per the use of Qualitative variable for cross-sectional studies⁹ total 376 sample size was considered as sufficient, hence we have collected 400 sample for the present study.

Data Collection process: All newly registered pregnant women attending to hospital were interviewed personally and the necessary information such as age, presenting complains, medical history, diagnosis, prescribed medication, diet history, family status, housing area were recorded in Case Record Form. Pregnant women were enrolled in the study as per the following study Criteria:

Inclusion Criteria: All newly registered pregnant women who were attended inpatient and outpatient department of Obstetrics and Gynecology department, irrespective of the duration of pregnancy. Those willing to give consent for the study.

Exclusion Criteria: Patient admitted to hospital with IVF pregnancy and patient attending to Gynecologic department other than pregnancy were excluded.

Statistical Analysis: Descriptive analyses were performed using Microsoft Excel 2007. Data were expressed as number and percentage.

RESULTS

Socio-Demographical Data

Table 1 showed out of 400 antenatal women population, the mean age of pregnant women was 24.07±4.04

years with a minimum of 20 years to maximum up to 35 years. The majority of patients were from the age group between 20-35 years which constituted 90% of the study population. Duration of pregnancy, out of 400 pregnant women, 40 (10%) women were in first trimester, 82 (20.5%) women were in second trimester and 123 (30.5%) were in third trimester. Whereas, 155 (38.75%) women referred to Inpatient department were also included in the study. In case of Gravida, out of 400 pregnant women, 173 (43.25%) women had primigravida and 227 (56.75%) women had multigravida. Education status of pregnant women showed that 313 (78.25%) out of 400 women were literate. In that 201 women had primary education, 96 women had secondary education, 12 women had higher-secondary education and 4 women were graduated. Total pregnant women 87 (21.75%) were illiterate. In our study, out of 400, the majority of the pregnant women 377 (94.25%) were vegetarian and 23 (5.75%) were non – vegetarian. In our study, all patients were from joint family and came from rural area.

Table 2 and Figure 1 showed pattern of drug prescribing during trimester of pregnancy along with, an average drugs per pregnant women. During first trimester- a 14 different therapeutic class of drugs were given to 132 patients in first trimester. Likewise, during second trimester-13 (24.51%) therapeutic class of drugs given

to 335 patients. Furthermore, during third trimester-A total of 26 (49.05%) therapeutic class of drugs had been given to 422 patients.

Table 3 showed pattern of drug prescribing during labor, a total of 526 numbers of drugs were prescribed during labor pain. Anti-emetics-Ondansetron (99,18.82%), PPIs and H2 blockers- Pantoprazole (100,19.01%), Ranitidine (55,10.45%), Antibiotics-Amoxicilin + Clavulanic acid (85,16.15%), Metronidazole (108, 20.53%), Ceftriaxone (64, 12.16%), Anti-Hypertensive agent- Magnesium sulfate (6,0.62%), Labetolol (9,0.94%) drugs were prescribed during labor pain.

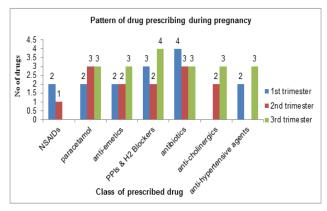


Figure 1: Pattern of Drug Prescribing during Pregnancy.

Table 1:	Socio-Demographical Data	a.	
Sr. No	Variables	Frequency	Percentage
1	Age (Years)	24.07±4.04	
	<20	036	9%
	20-35	360	90%
	>35	004	1%
2	Duration of Pregnancy		
	First Trimester	040	10%
	Second Trimester	082	20.5%
	Third Trimester	123	30.75%
	*Labor	155	38.75%
3	Gravida		
	Primigravida	173	43.25%
	Multigravida	227	56.75%
4	Education Status		
	Primary	201	50.25%
	Secondary	096	24%
	Higher-Secondary	004	3%
	Graduation	012	1%
	Literate	313	78.25%
	Illiterate	087	21.75%
5	Diet History		
	Vegetarian	377	94.25%
	Non-vegetarian	023	5.75%
6	Family History		
	Single	000	
	Joint	400	100%
7	Housing Area		
	Urban	000	
	Rural	400	100%

Table 4 and Figure 2 showed categories of drug prescribing during pregnancy, total 11 drugs were belongs to the category of C and D, which indicated that majority of drugs were safely prescribed and only 3.77% of drugs implied risk to fetus. Drugs such as Nifedipine, Methylergonovine maleate, Isoxsuprine, Caffeine, Phenylephrine, Levofloxacin, Alprazolam, Amikacin were prescribed according to category C and D and found to be harmful. We can say that, according to USFDA category, the C and D categories of drugs can be used because benefits overweigh the risks.

Figure 3 and 4 showed obstetric and non-obstetric maternal morbidities, in present study, total 18 types of obstetric morbidities were found. Total 69 (17.25%) women had minimum one obstetric morbidity. The Obstetric morbidities reported were Pregnancy induced Hypertension 16 (4%), Breech presentation 8 (2%), Oligohydramnios 9 (2.25%) and total 270 (67.5%) women had minimum one non-obstetric morbidity. Majority of the pregnant women were having Anemia 267 (66.75%) and only 3 (0.75%) of pregnant women were having LRTI 1 (0.25%), Viral fever 1 (0.25%), Renal calculi 1 (0.25%).

DISCUSSION

In present study, Out of 400 pregnant women, the mean age of pregnant women 24.07±4.04 years, the highest number of ANC 90% (n=360) were between

the age group of 20-35 years which is accordance with the prospective study done by Bency Mary Varghese, et al.2 The mean age of the participants was found to be 24.51±3.81 years. In our study, majority of the pregnant women 30.5% (n=123) were in their third trimester which is similar with the retrospective study, in that the research established that women in their third trimesters attended the antenatal clinics more than those in the first and second trimesters reported by Abubakar K, et al.11 Gravida means the total number of confirmed pregnancies a woman has had regardless of the outcome of the pregnancy, a woman who is pregnant for the first time will be termed a primigravida and a woman who is pregnant for more than one time will be termed a multigravida.¹² In the study, the highest number of the pregnant women 56.75% (n=227) had multigravida which was compared with institution-based cross-sectional study 61.5% of the pregnant women were multigravida by Fantahun Molla, et al.13

Women's education is more important for the purpose of educating the next generation. ¹⁴ In our study, out of 400 pregnant women, the majority of pregnant women 78.25% (n=313) were literate and 21.75% (n=87) pregnant women were illiterate, which is comparable with the study of wealth, education and urban-rural inequality in that majority of ANC. The previous study found that education up to primary school by SanniYaya, *et al.* ¹⁵

Table 2: Pattern of drug prescribing during pregnancy.							
Parameter	First trimester	Second trimester	Third trimester				
Total no of drugs	132	335	422				
Average drug per ANC	3.3	4.08	3.43				
Drug Prescribed during pregnancy							
Iron	37 (28.03%)	79 (23.58%)	131 (31.04%)				
Folic acid	37 (28.03%)	81 (24.17%)	006 (1.42%)				
Calcium	06 (4.54%)	80 (23.88%)	127 (30.09%)				
Vitamins	36 (27.27%)	79 (23.58%)	135 (31.99%)				
NSAIDs (Diclofenac)	02 (1.51%)	01 (0.29%)	-				
Paracetamol	02 (1.51%)	03 (0.89%)	003 (0.71%)				
Isoxsuprine	-	02 (0.59%)	004 (0.94%)				
Anti-emetics (Ondansetron)	02 (1.51%)	02 (0.59%)	003 (0.71%)				
PPIs and H2 blockers (pantoprazole, Ranitidine)	03 (2.27%)	02 (0.59%)	004 (0.94%)				
Antibiotics (metronidazole, ceftriaxone)	04 (3.03%)	03 (0.89%)	003 (0.71%)				
Anti-cholinergic (Dicyclomine)	-	02 (0.59%)	003 (0.71%)				
Misoprostol	01 (0.75%)	01 (0.29%)	-				
Anti – Hypertensive Agent							
Labetolol	01 (0.75%)	-	001 (0.23%)				
Nifedipine	01 (0.75%)	-	002 (0.47%)				

Table 3: Pattern of drug prescribing during labor.							
Parameter	Dose	No. of ANC received (n)	Frequency (%)				
Anti-emetics							
Ondansetron	4 mg	099	18.83%				
PPIs and H2 blockers							
Pantoprazole	40 mg	100	19.02%				
Ranitidine	25 mg	055	10.46%				
Antibiotics							
Amoxicilin + Clavulanic acid	1.2 gm	085	16.15%				
Metronidazole	500 mg	108	20.53%				
Ceftriaxone	1 gm	064	12.16%				
Anti – Hypertensive Agent							
Magnesium sulfate	5 gm	006	1.14%				
Labetolol	20 mg	009	1.71%				
Total no of Drugs		526	100%				

Table 4: Categories of drug prescribed during pregnancy.							
Categories of drug according to USFDA	First trimester (N=14) (n,%)	Second trimester (N=13) (n,%)	Third trimester (N=26) (n,%)	Total (N=53) (<i>n</i> ,%)			
Α	06 (11.32%)	04 (7.54%)	06 (11.32%)	16 (30.14%)			
В	07 (13.20%)	07 (13.20%)	12 (22.64%)	26 (49.05%)			
С	01 (1.88%)	02 (3.77%)	06 (11.32%)	09 (16.98%)			
D	-	-	02 (3.77%)	02 (3.77%)			
X	-	-	-	-			
Total	14 (26.4%)	13 (24.51%)	26 (49.05%)				

USFDA: United States Food and Drug Administration Category A: Safest drugs, Category B: Failed to demonstrate a risk to the fetus, Category C: Can be used it benefits overweigh the risks, Category D: implies risk, Category X: contraindicated

A vegetarian diet might prevent some morbidity. Plant-based diets are at risk of nutritional deficiencies such as Proteins, Iron, Vit D, Calcium, Vit B₁₂, the available authentication shows that well planned vegetarian diet may be contemplating safe during pregnancy and it can impact on fetal development. In our study, out of 400 ANC, 377(94.25%) were vegetarian and 23(5.75%) were non-vegetarian. Morbidities like prolonged labor pain and hypertension were shown in non-vegetarian ANC which is in accordance with the study by Giorgia Sebastaini, et al. And Studies reported by Babita Gutam, et al. Tound that the majority of the patients were non-vegetarian and the results suggested that hemoglobin level in vegetarian

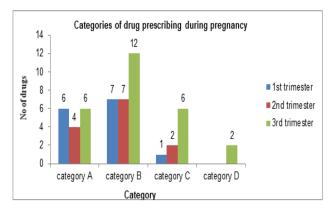


Figure 2: Categories of Drug Prescribing during Pregnancy.

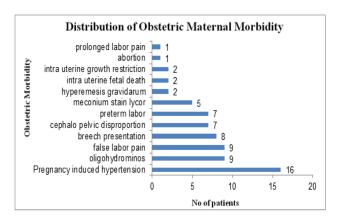


Figure 3: Distribution of Obstetric Maternal Morbidity.

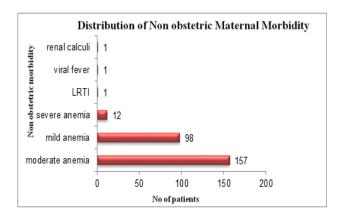


Figure 4: Distribution of Non-obstetric Maternal Morbidity.

women is significantly the same than non-vegetarian female. Whereas, the majority of pregnant women 267(66.75%) were having anemia as major findings in study.

In our study, all ANC were from a rural area. This could be the one factor that may cause maternal health issues in our pregnant population. Patience A. Afulani. 18 a study reports that, in rural area, during pregnancy, mothers are likely to face multiple stressful life events, including lone-mother, teenage pregnancies, unemployment, more crowded or polluted physical environment.

In first trimester- supplements like Folic acid helps to make new cells, produce DNA, normal growth and organ development of baby and it helps to prevent neural tube defects, Iron helps to increase in red blood cell mass, Vitamins (Vitamin B₁₂ helps to develop nervous system of baby, Vitamin C helps to improve to adsorption of iron) are mostly given to pregnant women. 19,20 In our study, Folic acid, Iron, Calcium and Vitamins were prescribed in first trimester which is in accordance with the prospective study by I. F. Inamdar, et al.21 Reported data suggested that in second trimester of pregnancy women need supplements like folic acid, iron and calcium. Hence, they are regularly prescribed as a supplement course of treatment. Folic acid is essential for the developing brain as areas such as the hippocampus, striatum and auditory and visual cortices rapid growth and to become functionally active, Iron requirements begin to increase because an increase in oxygen consumption by both mother and fetus is associated with major hematologic changes, Calcium helps in fetal bone mineralization and to prevent a reduction in maternal bone density, Vitamins are given to pregnant women for the proper growth and development of a fetus. 19,22 In present study, Folic acid, Iron, Calcium and multivitamins were prescribed in second trimester which is similar to the prospective study by I. F. Inamdar, et al.21 Likewise, in third trimester pregnant women required Iron requirements for fetal growth. Furthermore, the need rise steadily in proportion to the weight of the fetus, Multivitamins intake increased by 35% from the 1st and 2nd trimester because as the pregnancy progresses, body size increases, alongside the nutritional requirements of the developing fetus also increases. 19,23 In the current study, iron, calcium, vitamins and folic acid were prescribed during the third trimester to pregnant women, which is in accordance with the prospective study by I. F. Inamdar, et al.21 During the first trimester of pregnancy doctor prescribed the folic acid and iron tablets while as pregnancy matures to 3rd trimester doctor gradually add calcium supplements and reduces the iron supplements. However, multivitamins are supplemented throughout all trimester.

In present study, a total 526 number of drugs were prescribed during labor. Oxytocics are given for uterine contraction during labor. In present study, oxytocics is not highly prescribed which is not similar with the study by S. R. Gawde. ²⁴ In which oxytocics was not prescribed during labor. Antibiotics are used to treat maternal infection during labor. In present study, antibiotics like metronidazole, amoxicillin+clavulanic acid combination and ceftriaxone were prescribed which are in accordance with the study by S. R. Gawde. ²⁴ In which a greater number of antibiotics were prescribed for upper respiratory tract infection and UTI.

The US-FDA pregnancy risk classification system was used to evaluate the risk levels of drugs prescribed during pregnancy. USFDA Category A to X indicate evidence of safety level in human. Studies, adequate well-controlled or observational, in animals or pregnant women have demonstrated positive evidence of fetal abnormalities. The use of the product is contraindicated in women who are or may become pregnant.²⁵ In present study, the majority of category B drugs 26(49.05%) were prescribed which included ondansetron, paracetamol, ceftriaxone, metronidazole, labetalol, cetirizine, dicyclomine, ranitidine, pantoprazole, chlorpheniramine maleate, rabeprazole, domeperidone and metoclopramide. Only 2 (3.77%) drugs were prescribed from category D. Alprazolam and Amikacin were prescribed from category D. Fortunately, in present study no drug was prescribed from category X. Similar findings were reported by the study carried out by Fantahu Molla, et al.13 In which the majority of prescribed drugs were from category A and B.

In our study around 339 (84.75%) pregnant women had obstetrics or non-obstetrics morbidities. Total 18 morbidities were reported in our study. Out of 18 morbidities, 12 morbidities were obstetrics and 6 morbidities were non-obstetrics. In obstetric morbidities, Pregnancy induced Hypertension 4% (n=16) was reported high. In present study, Nifedipine, Labetalol and Magnesium sulfate was prescribed for pregnancy induced hypertension which is similar to the study carried out by Manjusha Sajith, et al.26 In which anti-hypertensive drugs such as Methyldopa, Nifedipine and Labetalol were given. In present study, Betamethasone was prescribed for preterm labor which is in accordance with the study by Dimitrios M. N. et al.27 in which preterm labor was treated by steroid therapy. In present study, Ondansetron and Metoclopramide were prescribed for hyperemesis gravid arum which is not similar to our study by Michael P. Nageotte, et al.²⁸

In non-obstetric morbidities, Mild anemia (98,24.5%), Moderate anemia (157, 39.25%), Severe anemia (12,3%) were found high. Oral iron therapy was given for anemia and for severe anemia IV iron sucrose was given which is similar to the study carried out by Christian Breyman, *et al.*²⁹ In which intravenous (IV) iron therapy is an alternative therapeutic option in patients who do not respond to oral iron therapy. A rural population may be a reason for the high prevalence of anemia which is similar to the study by Jalpa Suthar, *et al.*⁸ In which reported higher prevalence anemia and a lower prevalence of urinary tract infections. Similarly, study by Singh R, *et al.*³⁰ Reported a high prevalence of anemia, Pre-eclampsia, abnormal presentation and Hyperemesis Gravidarum.

CONCLUSION

The extensive usage of pregnancy supplements is warranted as there is evidence of beneficial effects on maternal health and fetal outcome. Iron, Calcium, Folic acid and Vitamins were the most frequently prescribed drugs during pregnancy. Majority of the drugs (79.19%) prescribed as per USFDA category A and B, which are safe to be prescribed during pregnancy. Category C and D drugs can be used because benefits overweigh the risks and most importantly it was observed that there were no drugs belonging to category X which are supposed to be contraindicated during pregnancy. Anemia was found to be a top most morbidity in pregnant women with a prevalence of 66.75% in the rural population. Other morbidities like PIH, Breech presentation, Oligohydramnios, CPD, IUFD, IUGR, Meconium stain Lycor were observed during the study period.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

USFDA: United States of Food and Drug Administration; **WHO:** World Health Organization; **CRF:** Case Record Form; **IVF:** *In vitro* Fertilization; **ANC:** Antenatal Care; **PIH:** Pregnancy induced Hypertension; **LRTI:** Lower Respiratory Tract Infection; **UTI:** Urinary Tract Infection; **CPD:** Cephalo Pelvic Disproportion; **IUFD:** Intra Uterine Fetal Death; **IUGR:** Intra Uterine Growth Restriction.

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