A Prospective Observational Study on Prescription Patterns for Medical Conditions During Pregnancy in a Teritiary Care Teaching Hospital

Swetha Bejugam*

Department of Pharmacy, Malla Reddy College of Pharmacy, Hyderabad, Telangana, India

Research Article

ABSTRACT

Prescribing medications during pregnancy is complex task and takes many factors into account. The main factor which needs to be taken into account are the physiological changes which are associated during pregnancy, their effect on drug's pharmacology and the impact of these drugs on the benefits and risks in treatment of mother and the growing foetus. This situation becomes even more important and complicated when pregnancy is associated with comorbid conditions.

A Prospective Observational study was conducted in the department of Obstetrics and Gynaecology in Malla Reddy College Of Pharmacy from November 2019 to April 2020. Approximately 350 patients are to be considered from the department of OBG who were pregnant and diagnosed with medical complications (Thyroid dysfunction, Hypertension and Diabetes). The data collected in the case collection form was then analysed using Ms-Excel and statistical interpretation was done to decipher the objective analysis.

The study concluded that mineral and vitamin supplements are the most prescribed drugs in pregnancy It can also be observed that the medications relating to comorbid conditions are adjusted as per the diagnostic parameters. It is also identified that although prescribing tendency by usage of generic names is less, prescribing drugs from essential drug list is more. Also, usage of injections and antibiotics is less in line with the National drug policy to promote rational drug therapy. The most important recommendation is the usage of more category A drugs and avoidance of self-medication.

INTRODUCTION

Drugs play an important role in improving human health and promoting well-being. However to produce the desired effect, they have to be safe, efficacious and have to be used rationally. In general, drugs unless absolutely necessary should not be used during pregnancy because drugs taken by a pregnant woman can reach the foetus and harm it by crossing the placenta, the same route taken by oxygen and nutrients, which are needed for the growth and development of foetus [1]. While avoiding medications when pregnant may be desirable, it is often not possible and may be dangerous because some women enter pregnancy with medical conditions that require ongoing and episodic treatment (e.g. asthma, epilepsy, and hypertension). Also during pregnancy new medical problems can develop and old ones can be exacerbated (e.g. migraine headache) requiring pharmacological therapy. Failure to manage conditions like these may affect the health of both the mother and her infant. More than 90% of pregnant women take prescription or non-prescription (over-the-counter) drugs or use social drugs such as tobacco or alcohol or illicit drugs at some time during pregnancy. The fact that certain drugs given during pregnancy may prove harmful to the unborn child is one of the classical problems in medical treatment. Pregnant women are usually excluded from medical trials and results from animal studies need not apply to human population. Hence treating pregnant women with some drugs is a problem and most clinicians have a rather restricted approach to the use of drugs during pregnancy. Fear of causing foetal harm and death through medication use in pregnancy has resulted in many challenges to clinical research about the safety of drugs in pregnancy. Therefore medication safety information in pregnancy is actually obtained through case reports, epidemiological studies and animal studies; all of which have limitations that make determining risks of a drug use during pregnancy difficult.

Despite the paucity of information on the safety of drugs in pregnancy, the statistics on Over the Counter (OTC) and prescription drugs used in pregnancy indicate that drug use in pregnancy is wide spread. About 2-3% of all birth defects result from use of drugs. However drugs are sometimes essential for the health of pregnant women and foetus. A health care practitioner may recommend that women take certain vitamins and minerals during pregnancy [2]. Drugs are also used for treatment of some common symptoms associated with pregnancy such as aches and pains, nausea and vomiting, and oedema. Medications may also be prescribed to treat conditions occurring during but unrelated to pregnancy such as upper respiratory infections, urinary tract infections and gastrointestinal upsets to name some. Also pregnant woman may be using medications to treat pre-existing chronic conditions such as epilepsy, hypertension or psychiatric disorders or to treat pregnancy related disorders such as pregnancy induced hypertension; to induce labour or to facilitate lung maturity in the foetus expected to be delivered preterm. Also this patient population may be exposed to any other agents that may have an adverse effect on fetus. It therefore becomes important to examine the pattern of drug use in pregnancy to see to what extent there may be room for improvement in the light of current knowledge.

MATERIALS AND METHODS

A Prospective Observational study was conducted in the department of Obstetrics and Gynaecology in Malla Reddy College of Pharmacy from November 2019 to April 2020. Approximately 350 patients are to be considered from the department of OBG who were pregnant and diagnosed with medical complications (Thyroid dysfunction, Hypertension and Diabetes). The inclusion criteria were set as pregnant women who are presented to the outpatient department of Obstetrics and Gynecology ward, the inpatients who are admitted in to the OBG ward after referral from outpatient department, pregnant ladies who have been diagnosed with hypothyroidism, hyperthyroidism, hypertension and Gestational diabetes and age above 20 years and below 40 years. Based on the inclusion and exclusion criteria subjects are chosen. Data will be collected and analyzed for demographics, various cardiovascular disease and various drugs prescribed. Further identification of adverse drug effects and drug interactions will be done, if found. The collected data was incorporated in Pre designed patient pro-forma and information regarding, social history, comorbidities, adverse effects and relevant data was collected was then analysed using Ms-Excel and statistical interpretation was done to decipher the objective analysis.

Institutional Human Ethics Committee [IHEC] approval was obtained for initiating and conducting the study. The IHEC approval code of the study is IEC/MRIMS/07/2019.The protocol of the study which includes the aim, objectives, methodology and plan of work was submitted to the Ethics Committee of the hospital. The authorization was obtained and permission was given to utilize the hospital facilities to conduct the study and the follow up of the patients in the selected department.

RESULTS AND DISCUSSION

The Age wise distribution of patients (n=350) shows majority of the patients belonged to the age group of 18-20 years (n=158) and the least number of the patients belonged to the over 35 years age group (n=15) as shown in (Table 1).

Table 1. Age wise distribution of selected patients.

Age group	Number of patients
18-20	158
21-25	82
26-30	73
31-35	22
>35	15

A pie chart distribution shows that the patients selected for the study majorly belonged to second trimester (n=189), followed by third trimester (n=98) and the least in the first trimester (n=63) as shown in (Figure 1).

Figure 1. Distribution of the patients on the basis of Gravidity.
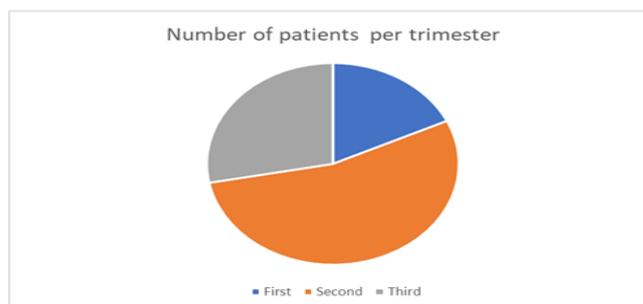
Table 2. Distribution of the patients according to the selected study comorbid condition.

Comorbid condition	Number of patients
Hyperthyroidism	121
Hyperthyroidism	0
Gestational Diabetes	138
Gestational HYN	91

Total distribution of study population (n=350) as per their comorbid condition is depicted statistically. The table shows that most of the patients have gestational diabetes (n=138), followed by those with hypothyroidism (n=121), then gestational hypertension (n=91). There were no patients reported with hyperthyroidism (Table 2).

Category of drugs prescribed to patients in the antenatal ward

The table representation shows that the majorly prescribed drugs in the ward are the vitamins and mineral preparations constituting highest number accounting to 57%, followed by IV fluids (13%), anti-emetics (8%), anti-microbial (7%), thyroid drugs (6%), hypertensives, analgesics and anti-ulcer drugs accounting to 3% each.

Prescription of drugs according to dosage forms in patients of ANW

The table shows the distribution of drug formulations in the antenatal ward. Amongst all the formulations, tablets were given commonly (46.72%). 19.77% were injections constituting both intravenous fluids and Insulin drip. Capsules also occupy 19.27% of the total formulations (N=1030). Infusions (12.57%), powders/granules (1.39%) and syrups (0.28%) follow the list (Table 3).

Table 3. Prescription of drugs according to dosage forms in patients of ANW.

Drug formulations	Numbers (%)
Tablets	46.72%
Injections	19.77%
Capsules	19.27%
Infusions	12.57%
Powders/granules	1.39%
Syrups	0.28%
Total	1030.00%

WHO core drug prescribing indicators among patients in ANW

A pie chart indicating the core drug prescribing indicators in the antenatal ward is depicted below. The percentage of drugs ordered from essential drug list is 59.56%, percentage of antibiotics prescribed accounts for 22.13%, percentage of drugs prescribed from hospital drug list accounts for 21%, drugs ordered by generic name were less and accounted for 21%. The average number of drugs per prescription accounts to 4.97% and the antibiotics prescribed accounted to 8.79%.

Prescription pattern according to FDA drug risk category

A tabular column indicating the percentage of FDA category drugs prescribed in the study population. Category B drugs were prescribed up to 70$, category A drugs were prescribed to 18.5%, category C drugs were prescribed up to 8% and category D drugs accounts to 3.13%. None of the incidents of prescribing Category X drugs were reported (Table 4).

Table 4. Statistics of prescription pattern of drugs in accordance to FDA drug risk category.

Category	Numbers (%)
Category A	18.53%
Category B	70.34%
Category C	8.00%
Category D	3.13%
Category X	0.00%

There are many studies that confer that there is less knowledge and awareness in pregnant women regarding the safety of drugs used in pregnancy. In spite of this, there are many studies that suggest that pregnant women take different drugs without prior consultation, not knowing the adverse effects to both, the mother and the baby. In this context, constant monitoring of the prescriptions by the clinical pharmacists is necessary to reduce contraindications and adverse events/effects in the women [3]. There are many studies being conducted across the world for this reason and this present study was conducted in a tertiary care teaching hospital for analysing the demographic details of the pregnant women, the incidence of the reported comorbid conditions, their compliance to medication, their adherence to the treatment, their awareness towards Over the counter medication and other

safety protocols during pregnancy. In order to analyse the prescription of the study population, WHO core drug prescribing indicators is used along with the risk of drugs on pregnancy by categorising them as per FDA guidelines.

In the present study, the mean age of the patients was reportedly 25.33 ± 3.66 years, the most common age group being 18-20 years, which is in accordance to most of the similar prospective studies done in these healthcare settings. Among the women, most of them were in their second trimester and majority had second gravida. These observations are contradictory to the studies done earlier as in those studies, women belonged to first trimester. Also, in many studies, the antenatal mothers were primi gravida, which is again contradictory to the observation made in these settings.

DISCUSSION

It was also observed that majority of the pregnant women with comorbid conditions were educated about regular check and change of medicines according to the diagnostic parameters as per the hospital policy. However, our study identified that the attendance to the routine check-up was based on their literacy and awareness. The study identified that mostly illiterate women made sure to have more than 5 ANC visits (65%) when compared to their literate counterparts (1.20%). The gap was identified as gaining knowledge over medication through self-medication practices and excessive usage of online sources for their wellbeing during pregnancy. It was therefore identified that awareness programs are necessary to all the pregnant women at every visit, irrespective of their education status.

Discussing about the drugs used in pregnancy during the entire course, it was identified that the most frequently used drugs are vitamins and mineral supplements which is in accordance to the WHO guidelines and previously conducted prospective studies [4]. Among the vitamins prescribed, folic acid, iron and calcium supplements were prescribed as most of the women had commonly associated medical condition apart from the comorbid condition under study, as anaemia. The prevalence of severe anaemia in the study population was identified as poor nutritional habits of pregnant women and hence, education regarding healthy eating and complete diet during pregnancy is advocated during the study. After the vitamins, the second most prescribed are IVF (RL, DNS and NS), RL being prescribed majorly among women who have hyper emesis condition accompanied along with the comorbid status.

The percentage reported suggests that the settings comparatively use very less antimicrobials, which is favourable in accordance to the WHO indicators. Among the antimicrobials used, all of the drugs in the hospital essential drug list which are metronidazole and mebendazole, are used more frequently and they belong to category B drugs, which are harmless to the mother and foetus. A specific case where the patient had severe infection and was resistant to these drugs was prescribed Doxycycline, which is a category D drug and should be avoided in pregnancy as it is teratogenic.

In the study, it was also identified that the percentage of drugs prescribed by its generic name was 21%, which is a parameter to consider as it increases the economic burden on the patient. A detailed investigation with the medical staff regarding the same suggested that medicines were prescribed by the brand name considering the quality and effectiveness of the medication, limiting the choice to their financial condition. They also revealed that the hospital's essential drug list was prepared considering these main factors. In other previous studies conducted in Northern India, the percentage was more. The percentage of antibiotics prescribed to the patient was 8.79% which was in line with the previous study results and the percentage also reveals that the patients are avoided with unnecessary financial burden and also avoided with development of widespread resistance [5]. The percentage of injection encounters was reported as 22.13% which is considerably high according to the drug policy. On the other hand, the percentage of drugs prescribed from the essential drug list is 79.56%, which indicates that hospital prescription policy is in accordance to the national drug policy.

Discussing about the prescribing pattern of drugs as per the FDA categorisation, it is identified that most of the patients were prescribed from category B, followed by Category A and then Category C and D. This pattern of prescribing was contrary to the studies conducted in developed countries where the drugs mostly belonged to Category A. More rational use of Category A drugs should be encouraged in use to promote rational drug prescription and improve efficacy of treatment.

It is also reported from previous studies that intake of folic acid supplementation reduces pregnancy complications, which is why folic acid intake is observed to be more and recommended in the settings. Observations from the studies reveal that every patient is treated on the basis of their governing diagnostic parameters and the dosage of the medication in the comorbid conditions is adjusted accordingly every visit. The dosage of thyroxine, insulin drip and labetalol are adjusted as per the diagnosis presented on the visit of the patient.

CONCLUSION

Often drugs play a very important role in improvement of human health and in promotion of overall wellbeing. The main parameters for the drugs to show effect are safety profile, efficacy and rational usage. In pregnancy, rational usage of drugs is not limited to safeguarding of maternal health but also in healthy development of foetus. Treating the comorbid conditions like gestational diabetes, gestational hypertension and thyroid disorders necessarily, using the appropriate treatment guidelines ensures maternal health and avoids preterm deliveries or abortions.

It can be concluded that mineral and vitamin supplements are the most prescribed drugs in pregnancy and necessary usage of medications relating to comorbid conditions is essentially practiced in the hospital settings. It can also be observed that the medications relating to comorbid conditions are adjusted as per the diagnostic parameters and dosage adjustments are made regularly to safeguard maternal health. Majority of the women belonged to second gravida and most of the women had associated gestational diabetes, needing adequate use of Insulin. It is also identified that although prescribing tendency by usage of generic names is less, prescribing drugs from essential drug list is more. Also, usage of injections and antibiotics is less in line with the National drug policy to promote rational drug therapy. The most important recommendation is the usage of more category A drugs and avoidance of self-medication.

REFERENCES

1. Bunjes H, et al. Characterization of lipid nanoparticles by differential scanning calorimetry, X-ray and neutron scattering. Adv Drug Deliv Rev. 2007;59:379-402.
2. Forman J, et al. Effect of vitamin D supplementation on blood pressure in blacks. Hypertension. 2013;61:779-785.
3. Hasanvand E, et al. Novel starch based nanocarrier for vitamin D fortification of milk: Production and characterization. Food Bioprod Process. 2015;96:264-277.
4. Hategekimana J, et al. Encapsulation of vitamin E: effect of physicochemical properties of wall material on retention and stability. Carbohydrate Polymers. 2015;124:172-179.
5. Makueti JT, et al. Morphological traits of control-pollinated fruits in African plum (Dacryodes edulis (G. Don). Lam.) using multivariate statistical techniques. Int J Agronomy Agr Res (IJAAR). 2012;2:1-7.