

Medication Safety in Obstetrics and Gynecology Ward in Tertiary Care Hospital, Bangalore, India

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Abstract

Objective: The present study is aimed to access medication safety in pregnant patients involving drug utilization pattern, therapeutic inappropriateness and drugs related problem in Tertiary Care Hospital. **Methodology:** It is a prospective observational study, conducted in inpatient obstetrics and gynecology ward. The data was collected in a predesigned data collection form 150 pregnant patients who are assessed during the period of six months of the study. Data were collected about their socio-demographic background, medication use during pregnancy, medication/pregnancy risk awareness, sources of drug information and beliefs about medications. Analyzed data included drug utilization pattern, drugs related problem and potential drug-drug interaction. **Result:** Among the study patients most of them 75.33% were in the age group of 21-30 year. Most of them 20.67% and 14.67% had hypertension and gestational diabetes mellitus as comorbidities. On the review of 150 prescriptions, the average number of drugs prescribed was found to be 7.62. Iron, folic acid, calcium and vitamins were most frequently used drugs during the pregnancy. Other drug include paracetamol, prostaglandin analogs, antibiotics and H2 receptor blocker. Most of the used drug were from Category A (54.50%). Only 0.1% of drug were from Category X. There were 161 possible risks of major potential drug interactions. The most common interaction was between Metronidazole and Ondansetron. The management for the most of adverse drug interaction was monitoring and time spacing. Most women had a positive attitude toward medications in general but they believed pregnant women should be more cautious regarding drug-use during pregnancy. About 32.67% of the participants were able, individually, to name some medications to be avoided during pregnancy. The primary information sources were from gynecologists followed by general practitioner and pharmacists. **Conclusion:** The study was indicative of the influence of the characteristics of pregnant women in the Indian community on the medication intake. Polypharmacy was higher and generic prescribing should be encouraged. Early signals of irrational use of drugs can be detected by frequent prescription auditing. There is a need to educate women regarding the medication usage during pregnancy.

Keywords: Obstetrics Ward, Gynecology Ward, pregnant patients, drug utilization pattern, therapeutic inappropriateness, drugs related problem

INTRODUCTION

Pregnancy is a special physiological condition where drug treatment presents a special concern because the physiology of pregnancy affects the pharmacokinetics of medications used and certain medications can reach the fetus and cause harm^[1]. The worry about prescription use during pregnancy and lactation has been affected by chronicled occasions, remembering thalidomide emergency for the 1960's and the teratogenic impacts found identified with the utilization of diethylstilbestrol in 1971.^[2] The one of a kind physiologic changes of pregnancy influence the pharmacokinetics of prescriptions utilized by pregnant ladies. During pregnancy a lady's plasma volume increments by 30-half and cardiovascular yield and glomerular filtration rate additionally increment in comparative extent. These components add to bring down coursing convergence of certain medications (particularly those discharged by kidney) in a pregnant lady and potentially to sub restorative medication levels. Additionally, there is increment in muscle to fat ratio during pregnancy; which expands the volume of

dispersion of fat-solvent medications. A reduction in plasma egg whites fixation during pregnancy expands the volume of appropriation for profoundly protein bound medications for example But the unbound drugs are excreted out more rapidly by the kidney and liver; and this offset the effect of increased volume of distribution. Due to the effect of progesterone,

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gastric emptying time is decreased particularly in the third trimester thus delaying the onset of effect of the drug [3]. Simultaneous utilization of other regular meds during pregnancy, for example, stomach settling agents, iron and nutrients could likewise tie and inactivate a few medications. Intramuscular assimilation of medication is commonly progressively quick because of expanded blood stream; which upgrades foundational tranquilize ingestion and the pace of beginning of activity. In conclusion estrogen and progesterone adjust hepatic chemical movement; which can build sedate collection or abatement disposal of certain medications [4]. The placenta; the product of conception is the functional unit between fetal blood and maternal blood. The functions of the placenta include nutrition, respiration, metabolism, excretion and endocrine activity to maintain fetal and maternal wellbeing. In order for a drug to cause a teratogenic or pharmacological effect on the fetus, it must cross from maternal circulation to fetal circulation through the placenta by diffusion [5]. The rate of transfer depends on the chemical properties of the drug such as protein binding, pH difference, lipid solubility and molecular weight of the drug [6]. 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 [7]. By and large, drugs except if totally essential ought not be utilized during pregnancy since drugs taken by a pregnant lady can arrive at the embryo and damage it by intersection the placenta, a similar course taken by oxygen and supplements, which are required for the development and advancement of baby [8].

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 ones can worsen (e.g. migraine, headache, hyperacidity, nausea and vomiting) requiring drug therapy [9].

The safe prescribing, use, administration, and monitoring of medications are an important component of patient safety efforts and are of particular importance to the obstetrician/gynecologist. Safe use of medications requires a team-based approach focused on medication safety with effective 2-way communication, use of technology to prevent and identify errors, diligent monitoring of the medication's effects on the patient, and use of standardized protocols to decrease the likelihood of a medication error [10]. Improving the medication use process initiated in obstetrics and gynecology department is an important step to improving medication safety for the women. To fulfil the objective of medication safety in hospital, various parameters discussed above has to be actively monitored. The drug utilization studies will help to identify the basic drug related problems. A precise knowledge of how drugs are being prescribed and used is essential to initiate a discussion on rational drug use or to suggest measures to improve prescribing habits. This research will help the hospital to access medication safety in pregnant patients involving drug utilization pattern,

therapeutic inappropriateness and drugs related problem in Tertiary Care Hospital.

MATERIALS AND METHODS

The study was conducted in all the major departments of Tertiary Care Hospital, Bangalore, India. Study was conducted in Obstetrics and Gynecology ward at Tertiary Care Hospital, Bangalore. And it is a 400 bedded secondary care hospital. The study method involves selection of patients based on the inclusion and exclusion Pregnant/lactating mothers were taken. The patient demographics and all medically relevant information was noted in a predefined data collection form. On the other hand, these case graphs were looked into for remedy decipherability and culmination, unaccepted truncations, catch of pertinent data on the off chance that sheet, contraindication, sedate collaborations and antagonistic medication occasions. The progressions and the everyday notes for the situation sheets were followed until the patient was released or moved to different wards. The remedy rules, Micromedex, Medscape and references books were utilized as devices to audit the solution and case graphs. The patient interview was done using predefined questionnaires with their consent to assess the usage, attitude and beliefs about medication usage during pregnancy. The data were stored confidentially and subjected to further analysis using appropriate software. The data was subjected to descriptive analysis using statistical tool IBM SPSS version 22.0 and data was entered in Microsoft excel version 16. And statistical Results were expressed in percentages and mean-standard deviation (SD).

RESULT AND DISCUSSION

This study enrolled 150 pregnant patients in which mean age of patients were 26.38 (± 4.39). Among the study patients most of them 75.33% were in the age group of 21 - 30 year. out of 150 the study population, 93 [62 %] were multigravida, and 57 [38 %] were primigravida.

Table 1: Obstetric History

Obstetric History	Number of Patient	Percentage
Multi	93	62
Prime	57	38
Total	150	100

20.67% had Hypertension, 14.67% had Gestational diabetes mellitus, and 8.67% had urinary tract infection as major comorbidities.

Table 2: Prevalence of Pregnancy Risk Factors

Pregnancy Risk Factors	Number of subjects	Percentage of subjects
Oligohydramnios	31	20.67
Preeclampsia	18	12

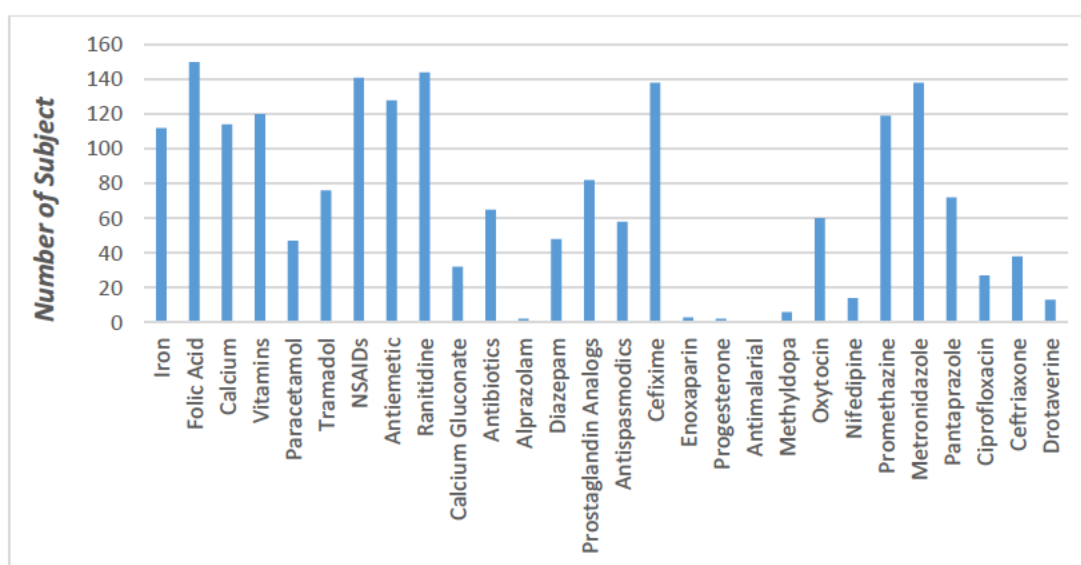
Small for Gestational Age	5	3.33
Preterm birth	3	2
PROM (Premature Rupture of Membrane)	2	1.33
Polyhydramnios	1	0.67

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144(96%) were not having generic name of drugs prescribed. 146(97.33%) prescription had drugs without capital letters followed by 127 (84.67%) were not legible. 148(98.67%) had at least one inappropriate abbreviation. Among 150 prescription analyzed, 9(6%) prescription was without dose followed by 40(26.67%) without dosage form, 13(8.67%) without route and 24(16%) without frequency. Out of 150 prescription, 4(2.67%) prescription had drug substitution. Prescription audit is shown in Table 3.

Table 3: Prescription Audit of Pregnant Subjects

Auditing Parameters	Total Number of Prescriptions	
	N	%
Prescription without generic name	144	96
Prescription without drug capitals	146	97.33
Prescriptions not legible	127	84.67
Prescription with inappropriate abbreviations	148	98.67
Prescription with dose not mentioned	9	6
Prescription with dosage form not mentioned	40	26.67
Prescription with route not mentioned	13	8.67
Prescription with frequency not mentioned	24	16
Prescription with drug substitution	4	2.67

**Figure 1: Pattern of Drug Use during Pregnancy**

Category A drug constituted 623(54.50%) followed by category B drug 398(34.82%) out of 1992 drugs used in pregnant subjects. Another category C, D and X were 6.99%, 3.5% and 0.1% respectively. Category A drugs were multivitamins, iron, folic acid, calcium, thyroxine. Category B drugs were paracetamol, diclofenac sodium, antacids, ranitidine, ampicillin, amoxicillin, cephalosporins, metronidazole, insulin, methyl dopa. Category C drugs were Nifedipine, pantoprazole. Category D were antiepileptic. Category X drug was progesterone. US FDA pregnancy risk categories of drug used in pregnancy were shown in Table 4.

Table 4: US FDA Pregnancy risk Categories of Drug Used

Category of Drug	Number of Drugs	Percentage of Drug
A	1086	54.51
B	694	34.83
C	139	6.97

D	70	3.5
X	3	0.15

Out of 150 inpatients records analyzed during the study period, of which 98(65.33%) prescriptions showed potential drug-drug interaction involving prescribed medications. The study prescriptions comprised 179(49.72%) pharmacodynamics drug interaction, 89(24.72%) were pharmacokinetic drug interaction and 92(25.56%) were by an unknown mechanism. Among them 127(35.28%) comprised of synergistic drug interaction followed by 89(24.72%) absorption related drug interaction. Most of drug interaction 183(50.83%) were major followed by 173(48.05%) moderate and 4(2.67%) contraindicated. The summary of potential drug interaction is given in Table 5.

Table 5: Summary of Potential Drug-drug Interactions

Parameters		Total	
		n	%
Severity	Major	183	50.83
	Moderate	173	48.05
	Contraindicated	4	2.67
	Total	360	100
Pharmacokinetic Interaction	Absorption	89	24.72
Pharmacodynamics Interaction	Synergism	127	35.28
	Antagonism	52	14.44
	Total	179	49.72
Unknown Mechanism		92	25.56

Medication Usage Pattern

The average number of drugs per prescription is an important index of a prescription audit. It is preferable to keep the number of drugs per prescription as low as possible to minimize the risk of drug interactions and hospital costs. The mean number of drugs received by patients in the present study (7.62) was higher compared to report from another study in 2014 which recorded a mean of 3.1 drugs [11]. This may be related to the physician's tendency to polypharmacy and also multi diagnosed prescriptions written for some patients. Polypharmacy is defined as concomitant use of five or more drugs and it could enhance drug interactions and drug related problems [12]. Extensive polypharmacy (81%) that is more than five drugs were prescribed in all the patients. Polypharmacy in some instance becomes necessary especially when the patient has some co-morbid conditions associated with the pregnancy. Moreover, most pregnant women take hematinic and vitamins such as Iron preparations, folic acid, ascorbic acid and vitamin B complex tablets.

Generic prescribing was less compared to other study by Rohra DK30 *et al.* The use of generic drugs is becoming more popular in the world and it is commonly used as an option to reduce the higher costs of treatments with originals. Conventional endorsing is considered as a security safety measure for the patients as it gives clear recognizable proof and empowers simple data trade and permits better correspondence between human services suppliers. The utilization of brand names may prompt expanded expense of medications for these ladies. Components that might be liable for this pattern incorporate the impact of medication special exercises, weights of pharmaceutical detail men, absence of proceeding with training on the standards of objective endorsing and non-nature with conventional names among the prescribers. In my investigation, iron, folic-corrosive, calcium and nutrients were the most every now and again utilized medications in pregnancy. [13]

Isosuprine, progesterone, paracetamol, NSAIDs, antibiotics, anti-emetics, proton pump inhibitors/H2 blockers, antacids and antihypertensive drugs (nifedipine, methyldopa) were the other commonly used drugs. In a prospective survey in Southwestern Finland, iron and vitamin supplementation were the most frequently used drugs, followed by analgesics, tocolytic agents and drugs for chronic conditions and common pregnancy symptoms [14]. In another study from Australia, folate (70%), iron (38%) and multivitamins (27%) were the most frequently taken drugs by pregnant women; along with herbal drugs like, ginger (20%) and raspberry leaf (9%) [15].

Periconceptional folic-acid supplementation can prevent most neural-tube defects and other congenital abnormalities of the cardiovascular system, urinary tract and limb deficiencies. Moreover, folic-acid supplementation in pregnancy is associated with the decreased incidence of habitual spontaneous abortion and pregnancy complications (e.g., placental abruption and preeclampsia) [16]. Percentage encounter with antibiotics was found to be 43.33%, this is higher than the recommended value of 20%. Anti-infection agents are generally endorsed with alert because of the issue of medication obstruction, remembering this the higher level of anti-toxins recommended in the investigation could be because of sharp contaminations, respiratory and urinary tract disease which happen ordinarily among pregnant ladies. Comparable outcome (43.5%) was accounted for by Reddy B. Ret *al.* [17]

Paracetamol was the most prescribed analgesic during pregnancy (>31.33%), this may be due to its affordability, tolerability and lack of the adverse effect of the NSAIDS. Similar studies where paracetamol was the major analgesic anti-inflammatory agent includes the study conducted by Kazeem A *et al* [18] and Gawde SR *et al.* [19]

The majority of the drugs used during pregnancy in the present study, were from category-A, followed by category-B and category-D whereas category-X was 0.1%. There are reports of use of potentially harmful drugs (category D drugs-1.5% to 4.8% and category X drugs-2.3 to 4.6%) during pregnancy from other developed and underdeveloped countries of the world [20].

In a retrospective, register-based cohort study in Finland, it was found that 20.4% of women purchased at least one drug classified as potentially harmful during pregnancy and 3.4% purchased at least one drug classified as clearly harmful [16].

According to the HIMAGE study from France, 4.6% of women were exposed to drugs (mainly NSAIDs), involved in risk during pregnancy [21]. In a study from Bratislava and Nitra, it was reported that a vast majority of prescribed drugs during pregnancy, belonged to category-C [22].

Potential Drug-Drug Interactions:

The study prescriptions comprised 179(49.72%) pharmacodynamics drug interaction, 92(25.56%) were by an unknown mechanism and 89(24.72%) were pharmacokinetic drug interaction. These findings were different from another study reported in the literature where the pharmacokinetic drug interaction was dominant^[13]. The severity assessment of drug interaction in present study showed that most of the interactions were major (183) followed by moderate (173) and contraindicated (4). This trend is different to that found in another report^[23]. The most common drug interaction was found to be between Metronidazole and ondansetron, which may be due to high usage of tramadol and metoclopramide in pregnancy. The most common management plan found in present study for most of the drug interaction was monitoring and time spacing; this is similar to the results reported by Bergk and colleagues^[24]. The result obtained in present study was based on the classification as minor, moderate or major according to the Micromedex-2 drug interaction checker. Sepehri and colleagues⁷⁵ used a similar software detection approach, and found the occurrence of drug interaction in 20% of patients which is lower compared to this study^[25].

Adverse Drug Events Report:

- Among the 150 study populations, the adverse drug reactions were noticed only in 10 patients.
- The adverse drug event accompanied only 6.66% in the study population.
- The adverse drug events were mainly noted in critically ill patients.
- The adverse drug reactions ranged from mild to moderate, no severe adverse drug reactions were noticed.
- Adverse drug reaction assessment was made with NARANJO'S SCALE and WHO PROBABILITY SCALE.

And the adverse drug reactions were resolved on clinical intervention; and some adverse events required de challenging and some conditions required re challenging, and re challenging was successfully achieved to promote the better therapeutic outcome after resolving the adverse events.

CONCLUSION

The study was indicative of the influence of the characteristics of pregnant women in the Indian community on the medication intake. This study results indicated the prevalence of gestational diabetes and eclampsia in pregnant patients. Almost all women are exposed to medication during pregnancy, either because drugs are recommended during this period, or because women are sick and need treatment. Iron, calcium and folic acid were the most frequently prescribed drugs. Overall drug use pattern is rational with few exceptions. Majority of the drugs were prescribed as per FDA category A, the safest category during pregnancy. Less than one percent of the pregnant women attending Tertiary Care Hospitals in Bangalore are prescribed teratogenic drugs. The

average number of prescriptions per encounter was much higher than WHO standard, indicating occurrence of polypharmacy. Generic drug prescribing was low. The drug interaction was found to be potentially harmful so monitoring should be required for appropriate management. The insufficient information regarding drugs in pregnancy from the clinical practitioners, is an area that needs further improvement in the future. Drug specialists, with aptitude in furnishing ladies with positive convictions about prescriptions during pregnancy and in upgrading drug treatment results, are significant segments of the medicinal services group and ought to be progressively associated with general wellbeing endeavors. Social insurance experts ought to know about ladies' mentalities while encouraging them to take prescription during pregnancy. This kind of study can help in assessing the current medication use design and in arranging suitable intercessions to guarantee discerning medication treatment. And the overall impact of the study result sets a benchmark in Tertiary Care Hospital [obstetrics and gynecology ward] in improving the therapeutic outcome of the patients and the enumerated result findings were recapitulated and made into a pamphlet and it was provided to the physicians and the nursing staffs in the obstetrics and gynecology ward to optimize their therapeutic role and to improve the optimal therapeutic outcome in the obstetrics and gynecology ward patients. And the medication safety guide pamphlet was prepared and provided to the patients in obstetrics and gynecology ward, to enhance the patient's knowledge on medication safety and medication use in pregnancy.

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