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Research Article

PATTERN OF DRUG UTILIZATION DURING PREGNANCY AT A TEACHING HOSPITAL – A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Objectives: The objectives of the study were (1) to assess the drug utilization pattern in pregnancy and (2) to assist in ensuring rational drug therapy.

Methods: A prospective, cross-sectional observational study was conducted at the Obstetrics and Gynecology Outpatient Department of KRIMS, Karwar. 546 pregnant women aged 18–40 years were included. Data collected from prescriptions were analyzed for adherence to the World Health Organization core prescribing indicators and classified as per the US Food and Drug Administration (FDA) pregnancy categories.

Results: The average age of study participants was 26.96 years with an urban preponderance (77.65%). Morning sickness (35.71%) and upper respiratory tract infections (20.7%) were the most frequent ailments encountered. 6383 drugs were prescribed in 2555 prescriptions with an average of 2.5 drugs per prescription. Iron and calcium supplements (28.75% each) were the most common drugs prescribed. 12.25% of prescriptions had fixed-dose combinations. 86.28% of drugs were from the National List of Essential Medicine (NLEM) and the majority of drugs belonged to FDA pregnancy category B (39.02%).

Conclusion: Rational prescribing was demonstrated in our study by a fewer number of drugs per prescription and lesser utilization of antibiotics and injections. Generic names were commonly used and drugs were selected from NLEM. It is essential to prescribe medicines with established efficacy and safety to ensure maternal and fetal well-being.

Keywords: Pregnancy, US Food and Drug Administration, Drug utilization, World Health Organization core indicators.

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INTRODUCTION

Pregnancy is a unique physiological condition where drugs administered to pregnant women can affect the developing fetus after crossing the placental barrier [1,2]. The consequences of thalidomide and diethylstilbestrol use during pregnancy have led to the apprehension regarding the use of medicines during pregnancy and lactation. Subsequently, the demonstration of efficacy and safety of any drug before marketing became mandatory [3].

In spite of being in a physiological state, it is essential to supplement various vitamins and minerals during pregnancy which are important to prevent morbidities in mother and fetus [4]. It is not feasible to completely avoid medicines during pregnancy as some women might have medical conditions that necessitate continuous or episodic treatment such as asthma and epilepsy. New diseases can occur and existing ones can aggravate during pregnancy necessitating pharmacological treatment [1]. Therefore, it is necessary to assess the risk-benefit ratio of drugs before prescribing them.

It is reported that about 8% of pregnant women need long-term treatment for a range of chronic diseases and conditions associated with pregnancy [5]. However, it is unfortunate that drugs used as self-medication far exceed the prescribed drugs resulting in adverse drug responses and drug interactions during pregnancy. These are due to easy access to pharmaceuticals and underdeveloped health infrastructure [3]. Drugs account for 1% of reported cases of congenital abnormalities, necessitating the consideration of the safety of prescribed medicines during pregnancy [2].

Drug utilization study (DUS) is defined as, "the study of marketing, distribution, prescription, and use of drugs in a society, with special emphasis on resulting medical, social, and economic consequences" [6]. The prescriptions should be reviewed regularly to minimize adverse effects, optimize treatment efficacy, and give feedback to prescribers. Inappropriate drug prescription is a global concern, particularly in developing nations [7]. These studies can be done in two ways – studies that are focused on specific drugs or classes of treatments and highlight their efficacy and safety or on patterns of drug utilization aimed at improving the quality of treatment through instructional intervention [8].

Rational drug use requires that "appropriate medicines are prescribed according to patient's clinical needs, in appropriate doses, for adequate duration and at the lowest cost to the individual and the community" [8]. Irrational prescribing raises the risk of adverse drug responses, cost of treatment, development of drug resistance, depletion of health-care resources, and also reduces the quality of drug treatment [7]. With this background, we have conducted this study to assess the drug utilization pattern in pregnancy and to ensure rational drug therapy.

METHODS

A prospective, cross-sectional observational study was carried out from June to November 2019 at the Outpatient Department (OPD) of Obstetrics and Gynecology (OBG), KRIMS, Karwar, after obtaining ethical clearance. 546 pregnant women aged between 18 and 40 years who came for antenatal check-ups (ANCs) and gave written informed consent were included. All the drugs prescribed to a pregnant woman from the time of conception to the day of data collection were noted.

Eligibility criteria

Inclusion criteria

Pregnant women aged 18–40 years who attended the OPD for ANCs.

Exclusion criteria

Pregnant women diagnosed with acute and/or chronic medical conditions requiring hospitalization.

The following data were collected from prescriptions given to pregnant women:

1. Demographic data
2. Pregnancy-related details:

Gestational age, trimester, gravidity, total number of ANCs, diagnosis, and comorbidities (if any).

3. Data about medications:

Name of the drugs prescribed, their dose, frequency, duration, and route of administration.

4. Data regarding investigations:

Hemoglobin, random blood sugar, thyroid-stimulating hormone.

5. Adverse drug events

The prescriptions were analyzed to check whether they met the World Health Organization (WHO) core prescribing indicators and the US Food and Drug Administration (FDA) pregnancy categories. The collected data was tabulated and analyzed using descriptive statistics with Statistical Package for Social Sciences software 26.0.

RESULTS

A total of 546 pregnant women were enrolled. The average age of the study participants was 26.96 years. Most of them were in the age group of 26–30 years (39%). There was a preponderance of urban population (77.65%) (Table 1). 50.2% of the participants were multigravida (Table 2). Morning sickness (35.71%) and upper respiratory tract infection (URTI) (20.7%) were the most frequent ailments encountered (Fig. 1).

A total of 6383 drugs were prescribed in 2555 prescriptions with an average of 2.5 drugs/prescription. Iron and calcium supplements (28.75% each) and folic acid (8.55%) were the most common drugs prescribed apart from doxylamine with pyridoxine (8.18%) and antibiotics (2.02%) (Fig. 2). 12.25% prescriptions had fixed-dose combinations (FDC). 86.28% of drugs were from the National List of Essential Medicine (NLEM) and the majority of drugs belonged to FDA pregnancy drug category B (39.02%) followed by category C (32.93%) (Fig. 3). The WHO core drug prescribing indicators are tabulated in Table 3. Total number of drugs prescribed per antenatal visit is tabulated in Table 4.

Table 1: Demographic details of the study population

Trimester	1st	2nd	3rd	Total (%)
Age group				
≤20	9	23	7	39 (7)
21–25	43	88	47	178 (32.6)
26–30	47	110	56	213 (39)
31–35	21	54	25	100 (18.4)
>35	3	6	7	16 (3)
Residence				
Rural	19	60	43	122 (22.3)
Urban	104	221	99	424 (77.7)
Literacy				
Primary	17	40	10	67 (12.3)
Secondary	113	120	100	333 (61)
Graduation and above	89	40	17	146 (26.7)
Occupation				
Home-maker	323	117	72	512 (93.8)
Working	17	10	7	34 (6.2)

Table 2: Antenatal check-ups parameters

Parameters	Number (%)
Gravidity	
Primigravida	272 (49.8)
Multigravida	274 (50.2)
Time of first antenatal visit	
1st Trimester	431 (78.94)
2nd Trimester	100 (18.31)
3rd Trimester	15 (2.75)
Total number of antenatal visits	
≤3	232 (42.49)
4–12	308 (56.41)
≥13	6 (1.1)
Married life	
<5 years	438 (80.22)
>5 years	108 (19.78)

DISCUSSION

The primary aim of DUS is to aid the rational use of medications in populations [6]. Rational drug usage in pregnancy involves not only weighing the advantages and potential side effects of the drug but also aids maternal recovery and fetal development [5]. In our study, the antenatal data of 546 women were collected and analyzed. 39% of the study population who attended the antenatal clinic (ANC) were within the reproductive age range of 26–30 years. In our study, most of the participants were in the second trimester (51.47%), which is similar to a study by Savitha *et al*. [10].

A total of 384 individuals (70.33%) had an associated ailment during their pregnancy which was in contrast to a study by Rajan *et al*. where it was only 32% [11]. Morning sickness (35.71%) and URTI (20.7%) were the most commonly associated ailments in our study. This is in contrast to a study by Rajan *et al.* [11] who reported that hypothyroidism (9.5%) and anemia (9%) were the most common illnesses.

Among 6383 medications administered, iron and calcium supplements (28.75% each) were most commonly prescribed followed by folic acid (8.55%) which was similar to studies by Savitha *et al*. [10] and Patel *et al*. [12]. The prevalence of anemia is very high in India with 50% of pregnant women being anemic [13]. In India, 20–40% of maternal deaths are estimated to be due to anemia. Calcium supplementation is recommended in those with low dietary calcium. The WHO recommends iron, calcium, and folic acid supplementation during pregnancy, particularly in developing nations like India to reduce perinatal mortality, preterm delivery, and low birth weight and to improve infant outcomes [6].

Nausea and vomiting constitute one of the commonest symptoms of early pregnancy seen in 70–85% of pregnant women [14]. A combination of doxylamine+pyridoxine is the first-line treatment for this condition as per the American College of Obstetricians and Gynecologists guidelines [15]. Their efficacy and perinatal safety have been well established. Metoclopramide and ondansetron are the alternative drugs with good risk: benefit profile and belong to FDA pregnancy category B [15-17]. In our study, doxylamine with pyridoxine was the most commonly prescribed drug for morning sickness.

Antibiotics contributed to 2.02% of total drugs prescribed which is much lesser than that reported by Savitha *et al.* [10] (26%). However, Chaudhari *et al*. [8] reported only 1.72% of antibiotics usage. URTI (20.7%) and urinary tract infections (UTI) (6.04%) were the most frequent infections encountered in our study. URTI can affect the fetus adversely and is associated with preterm labor. In developing countries, UTI affects about 12–40% of pregnant women which carries a higher risk of low birth weight and preterm labor as well as serious maternal complications such as sepsis and acute respiratory distress syndrome. Hence, it is important to treat both these infections with antibiotics, if needed [18].

Table 3: The WHO core drug prescribing indicators

Indicator	Value	WHO recommended optimal value [9]
Average number of drugs per prescription	2.5	1.6–1.8
Percentage of drugs prescribed by generic name	77.13%	100%
Percentage of encounters with an antibiotic prescribed	4.03%	20.0–26.8%
Percentage of encounters with an injection prescribed	0.82%	13.4–24.1%
Percentage of drugs prescribed from essential drug list	86.28%	100%

WHO: World Health Organization

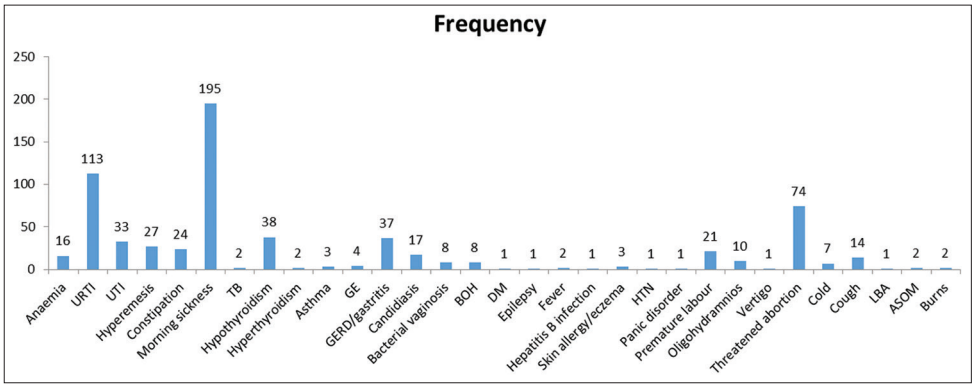

Fig. 1: Associated medical ailments in pregnancy

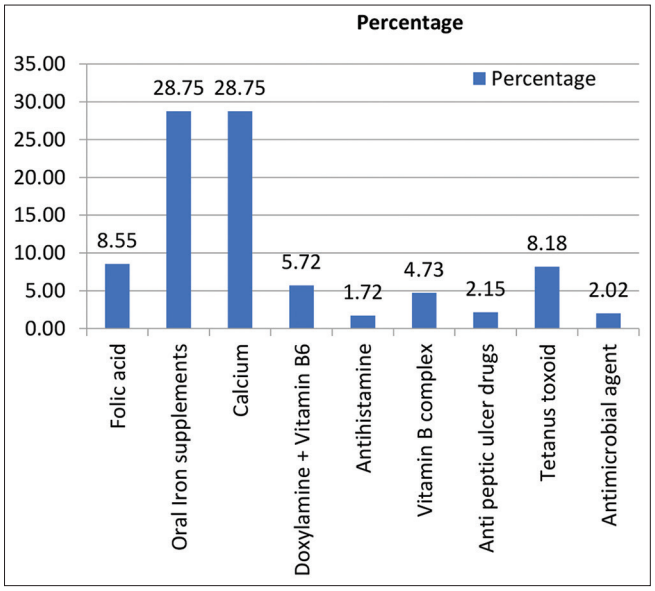

Fig. 2: Antenatal drug utilization pattern

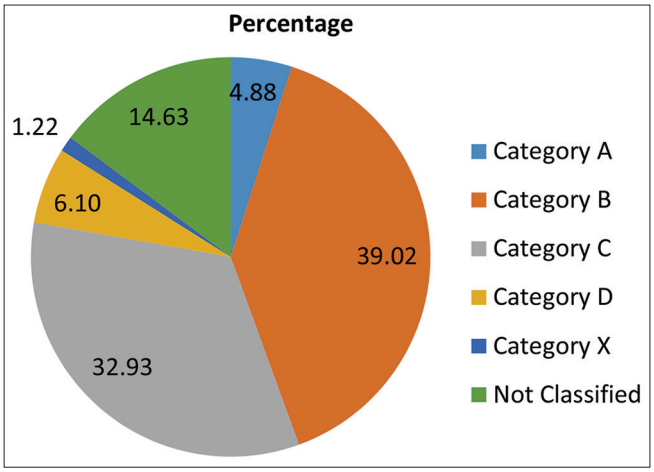

Fig. 3: Food and Drug Administration drug categories in pregnancy

We have compared the WHO core drug prescribing indicators of our study with the WHO reference values (Table 3). The WHO core prescribing indicators are helpful metrics for evaluating the efficacy of prescriptions. They aid in the avoidance of expensive therapies, antibiotic misuse, and polypharmacy [19]. In the present study, we observed that majority of pregnant women were prescribed with 2 drugs per antenatal visit (Table 4). This implies that there was no polypharmacy.

In the present study, the average number of drugs per prescription was 2.5, which was slightly greater than the WHO reference value because of the associated illnesses. Generic names were used in 77.13% of drugs. Prescribing drugs by their generic names will decrease the treatment cost. Only 0.82% and 4.03% of encounters were prescribed with an injection and an antibiotic, respectively, which were much less than the WHO reference values. This indicates that antibiotics and injections were not misused. 86.28% of drugs were prescribed by NLEM. Prescribing from the essential medicines list will improve access to drugs by streamlining the procurement and help in the proper distribution of quality-assured medicines. It also aids in rational prescribing and thus reduces health-care costs [20].

The percentage of FDC prescribed in our study was 12.25%. The risk profile of the prescribed medicines was assessed as per the US-FDA pregnancy categories. In our study, Category B drugs were the most commonly prescribed. FDA categories A, B, and C are considered safe. In the present study, category D drugs, such as hydroxyprogesterone, fluconazole, propylthiouracil, betadine powder, and carbimazole were prescribed as their benefits were more than their risks. 14.63% of drugs prescribed in our study were "not-classified" which refers to drugs which are not having any established evidence or that are still under research.

Table 4: Total number of drugs prescribed per antenatal visit

Number of drugs prescribed per antenatal check-ups visit	Number of pregnant women (%)
1	62 (11.36)
2	278 (50.92)
3	178 (32.6)
4	22 (4.03)
5	4 (0.73)
6	2 (0.37)

CONCLUSION

In our study, vitamins and mineral supplements accounted for the majority of the prescriptions. Rational prescribing was demonstrated by a fewer number of drugs per prescription and lesser utilization of antibiotics and injections. Most of the drugs were prescribed using generic names and were selected from NLEM. In addition, medicines with established efficacy and safety should be preferred as they impact the health of both mother and child.

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CONFLICTS OF INTEREST

None declared.

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