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DRUG PRESCRIBING PATTERN IN 3RD TRIMESTER OF PREGNANCY IN ANTENATAL CARE IN OBSTETRICS DEPARTMENT IN A TERTIARY CARE HOSPITAL, MANDYA: A CROSS SECTIONAL STUDY

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ABSTRACT

Prescribing pattern studies in pregnancy is unusual risk benefit situation due to irrational drug use in pregnancy may leads to teratogenic risk to fetus. The World Health organization (WHO) estimates that pregnant women receiving antenatal care can help in early spot and treat the both drug induced and pregnancy related conditions. The aim of our study is to describe the prescribing pattern among antenatal care and classifying in FDA (Food and Drug Administration) categorization in a tertiary care hospital, Mandya, Karnataka, India. **Objective:** To describe the drugs prescribing pattern in 3rd trimester of pregnancy of antenatal care and also describe the type, dose, route, indications etc. of Antenatal care (ANC) prescribed drugs comes under FDA categorization in obstetrics department of MIMS, Mandya. **Methodology:** A cross sectional study was conducted at the obstetrics department of MIMS. Required data was collected from157 outpatient case who were satisfying the inclusion criteria, for the period of six months. A well-designed patient data collection form was used for collecting the details. The information's were documented and subjected to suitable statistical methods**. Results:** A prospective study was conducted to describe the drug prescribing pattern in 3rd trimester of pregnancy in antenatal care in obstetrics department in a tertiary care hospital, Mandya. A total of 157 cases were included based on inclusion criteria. The present study comprised of 157 cases showed a higher incidence of Thyroid and anemia (10.83%), infection (8.92%), UTI (6.37%), gastroesophageal reflux (5.10%). Nutritional supplements (71.18%), antibiotics (6.30%), gastric suppressants (93.44%), antithyroid (3.24%), antiemetics (3.05%), hormonal preparation (2.86%), antipyretic (1.72%) are prescribed more in ANC. Based on FDA category, majority of drugs were A category, 74.24% and B category, 18,13% were found in our study. **Conclusion:** Findings of our study showed that all pregnant women were provided with prophylactic iron and folic acid, calcium therapy. The occurrence of contraindicated medicines was desirably low, thereby minimizing overall risk of developing fetus. Thus, prescribing pattern observed in our study sets a good example, as selection of drugs was rational in most of the cases.

KEYWORDS: Antenatal care, Obstetrics, Gynecology, Drug use, Pregnant, Prescription.

INTRODUCTION

Antenatal care (ANC) is a type of preventive health care, an indicator of access and use of health care during pregnancy and antenatal period presents opportunities for reaching pregnant women with interventions that may be vital to their heath that is to determine whether mother has anemia, diabetes, other medical conditions and wellbeing and that of their infants. ANC profile tests also help the doctor monitor the growth of fetus and provide treatment if required 3rd trimester is from week 27 to end of pregnancy (6-9 months). It is provided in the form of medical checkups, consisting of recommendations on managing a healthy lifestyle and provision of medical information such as maternal physiological changes in pregnancy, biological changes, and prenatal nutrition including prenatal vitamins, which prevents potential health alike. ANC availability of routine prenatal care, including prenatal screening and diagnosis has played a part in reducing the frequency of maternal death, miscarriages, birth defects, low birth weight, neonatal infections and other preventable health problems.[1]

Drug prescription pattern studies is to monitor, assess and if necessary, suggest modifications in the prescribing

behavior of medical practitioners to make cost effective, helps to identification of polypharmacy and main focus on the rational use of drugs in populations. Irrational prescribing has a serious impact on health, economy and resulting in wastage of resources. The definition of rational use of medicines by world health organization (WHO) – "Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period, and at the lowest cost to them and their community".[2]

To promote safe use of medications during pregnancy, the US Food and Drug Administration (FDA) categorized drugs into five pregnancy risk categories: A, B, C, D and X, among these groups, D and X medications are those with available evidence of significant harm in pregnancy. Category A drugs are those with no risk to fetus from well adequate controlled human studies in pregnant women fail to demonstrate a risk, it's a safe class of drugs in pregnancy and very few drugs are seen in this category. For Category B drugs, "best" no evidence of risk from animal studies has been documented, but there are no controlled studies/trials in pregnancy women. Category C drugs are "caution" those associated with harm to fetus in animal studies but no adequate and well controlled studies in pregnant women. Category D drugs are "danger" well documented, evidence of human fetal risk for life threatening diseases, avoided in except occasional use when maternal benefit outweighs the fetal risk. Category X drugs are with prominent fetal harm, strong evidence of fetal abnormalities, no therapeutic indications in pregnancy and are contraindicated in pregnancy. Teratogenic drugs: "most teratogenic FDA – approved medications are in categories D or X, some drugs in C categories.[3]

Despite limited information on its safety, drug use in pregnancy is common such as vaccine, supplementary drug treatment like iron, folic acid, calcium and vitamins are prescribed commonly to improve overall nutritional status of mother and fetus. In additional, drugs may be used to treat pregnancy related conditions like back pain, headache, heartburn, nausea and vomiting and also treat acute conditions not related to pregnancy or pre-existing chronic conditions such as diabetes, hypertension, epilepsy or to treat pregnancy induced anemia, thyroid disorders, hypertension, respiratory tract infections, preeclampsia, mental illness and gestational diabetes and genitourinary infections.[4]

During ANC, the medications like anti-emetics, antacids, analgesics, antibiotics, anti-bacterials, anti-psychotics, anti-microbials, antihistamines, diuretics, anti-diabetics, anti-hypertensives, pain killer, de-worming etc. are prescribed in 3rd trimester of pregnancy. Currently, drug prescribing studies mainly involves assessing disease prevalence, drug consumption, rational use of drugs and adherence to evidence-based guidelines. The primary objectives of drug prescribing study to promotes safe and effective use of medicines and also improve prescribing practices.[5]

OBJECTIVES

1. To describe the drug prescribing pattern in 3rd trimester of pregnancy of antenatal care in Obstetrics Department of MIMS Teaching hospital, Mandya.
2. To describe the types, dose route, indications etc. of ANC prescribed drugs comes under FDA categorization in Obstetrics and Gynecology Department.

MATERIALS AND METHODS

This was a Institutional Based Cross-Sectional study conducted in Mandya Institute of Medical Sciences (MIMS) Teaching Hospital, Mandya for a period of 6 months. The data collected from pregnant women's medical records who were attended in the antenatal care in obstetrics department. The sample size was 157. Age between 18 – 45 years,3rd trimester of pregnancy cases, adult pregnant women attended in obstetrics department and given written informed consent form was included. When pregnant women had incomplete medical records, they were excluded from the study. A suitably designed data collection form was used to collect the necessary data including name, age, details regarding presenting complaints, history of present illness, laboratory findings, diagnostic tests and prescribed medication. The collected information was documented and subjected for analysis using suitable statistical method.

Analysis: For the analysis of the results, simple percentage calculation was done. Microsoft word and Microsoft excel are used to generate graphs and tables where ever required.

RESULT

The cross-sectional study was conducted in obstetrics department at MIMS Teaching hospital, Mandya. A total of 157 out-pregnant cases who are attaining antenatal care in 3rd trimester in obstetrics department of MIMS were enrolled in the study based on study criteria. The socio-demographic details like patients name, age, father/husband name and data regarding present complaints, history of present illness, professional diagnosis, laboratory findings, diagnostic tests and prescribed medications. and FDA categories of drugs prescribed in 3rd trimester of antenatal care in obstetrics department were recorded in a suitably designed patient profile form.

DISTRIBUTION OF PATIENTS BASED ON AGE

Among 157 cases involved in the study, the maximum number of pregnant women attaining antenatal care were found in the age group of 18-22 years (43.31%) followed by 23-27 years (36.31%), 29-32 years (18.47%) and minimum number of patients were found in the age group of 33-35 years (1.91%). Pregnant women receiving antenatal care in the age 36-45 years during study period was not found in obstetrics department of

MIMS, as shown in Table 1.

Table 1: Distribution of patient based on Age.

AGE GROUP	NUMBER OF PREGNANT WOMEN	PERCENTAGE (%)
18-22	68	43.31
23-27	57	36.31
28-32	29	18.47
33-35	3	1.91

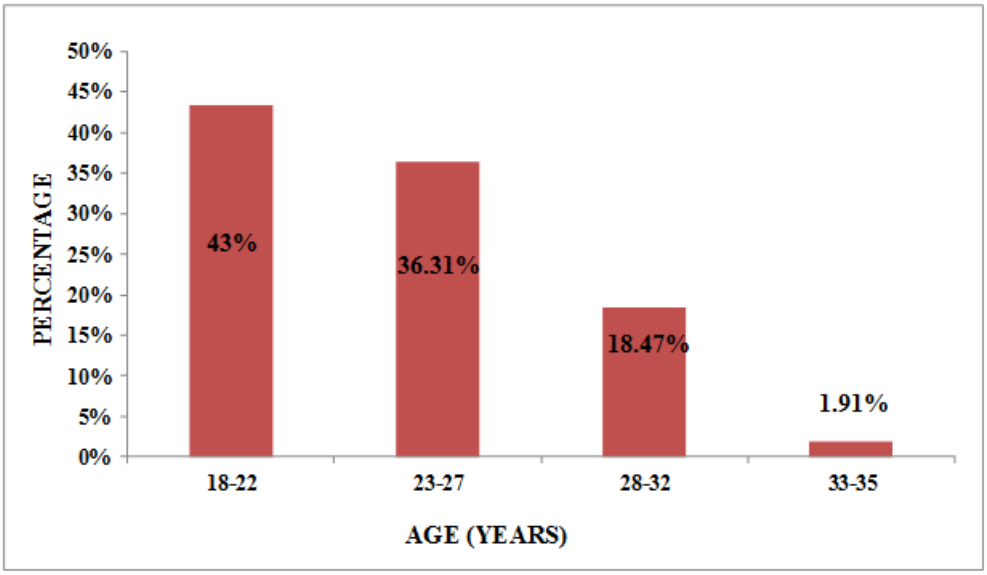

Figure 1: Distribution of patients based on Age.

GROUPING BASED ON HEALTH STATUS OF PREGNANT WOMEN

Out of 157 prenatal women outpatients with the high risk of Antenatal care, in which 48 (30.57%) were normal/healthy pregnant women and remaining 109 (69.43%) were with complications/diseases, as shown in Table 2.

Table 2: Based on health status of pregnant women.

PREGNANT WOMEN	NO OF PREGNANT WOMEN	PERCENTAGE (%)
Normal/Healthy	48	30.57%
Complication/Diseases	109	69.43%

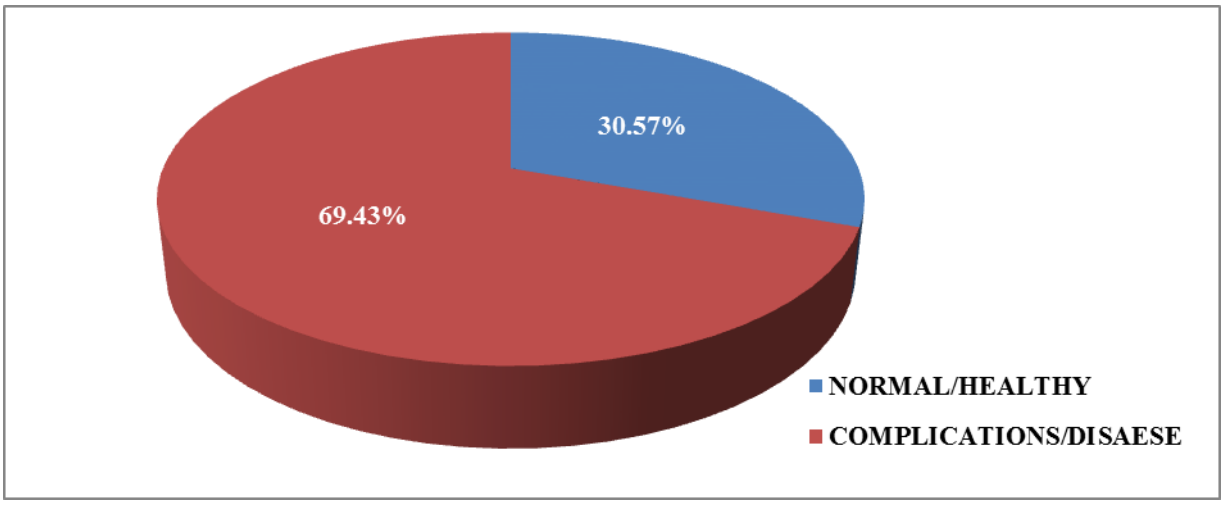

Figure 2: Based on health status of pregnant women.

CATEGORIZATION OF PREGNANT WOMEN BASED ON CONDITION

Various types of pre-existing health issues or pregnancy induced conditions or diseases were observed during the study. All the pregnant women were assessed for different condition and classified, out of 157 cases, 17 (10.83%) pregnant women were affected with hypothyroidism, 4 (2.55%) were affected with hypertension, 6 (3.82%) were affected with pre-eclampsia, 2 (1.27%) were affected with diabetes mellitus, 1 (0.64%) were affected with seizure, 8 (5.10%) were affected with gastro-esophageal reflex condition, 10 (6.37%) were affected with urinary tract infection, anemia is seen in 17 (10.83%) pregnant cases, other conditions like RVD, psychiatry, ectopic fetal right kidney, insomnia, OCD, kidney stone each were seen in 1 (0.64%), infection 14 (8.92%) case and common conditions like PCOD, cough, constipation each were seen in 2 (1.27%), fever 6 (3.82%), body pain 5 (3.19%), loose stools 4 (2.55%) and skin infection 3 (1.91%) , as shown in Table 3.

Table 3: Categorization of pregnant women based on conditions.

CONDITION/COMPLICATION	NO OF PATIENT	PERCENTAGE (%)
Hypothyroidism	17	10.83
Hypertension	4	2.55
Pre-Eclampsia	6	3.82
Diabetes mellitus	2	1.27
Seizure	1	0.64
Gastro esophageal reflex	8	5.10
Urinary tract infection	10	6.37
Anemia	17	10.83
Skin infection	3	1.91
PCOD	2	1.27
Fever	6	3.82
Loose stool	4	2.55
Body pain	5	3.19
Infections	14	8.92
Other conditions: RVD, psychiatry, ectopic fetal right kidney, insomnia, OCD, kidney stone	6	3.82
Common conditions: cough and constipation	4	2.55

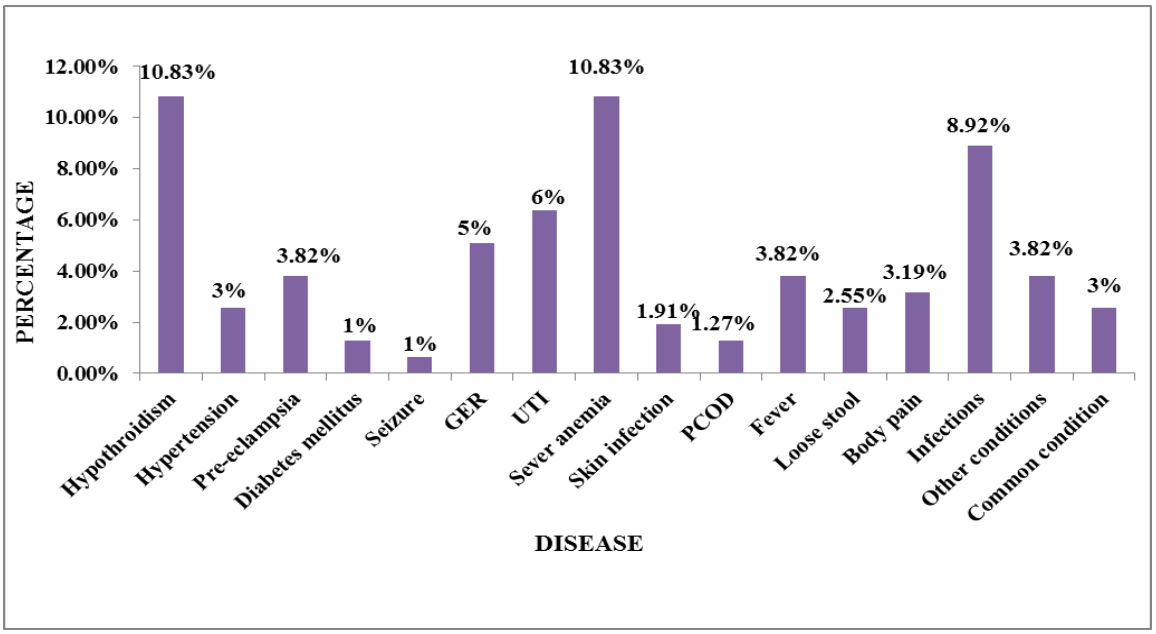

Figure 3: Categorization of pregnant women based on conditions.

DIFFERENT DOSAGE FORMS PRESCRIBED

The dosage form of drugs prescribed in maximum were found to be tablets (85.69%) and powder (4.58%). This was followed by syrups (2.29%), capsules (1.15%), injection (3.05%), other dosage like sachets, ORS, pessaries, gel and soap (3.05%) and cream (0.38 %) respectively, as shown in Table 4.

Table 4: Different dosage forms prescribed.

DOSAGE FORMS	NUMBER OF DRUGS	PERCENTAGE (%)
Tablets	449	85.69
Powder	2	4.58
Capsules	6	1.15
Syrups	12	2.29
Injection	16	3.05
Cream	2	0.38
Other dosage	16	3.05
Total	524	100

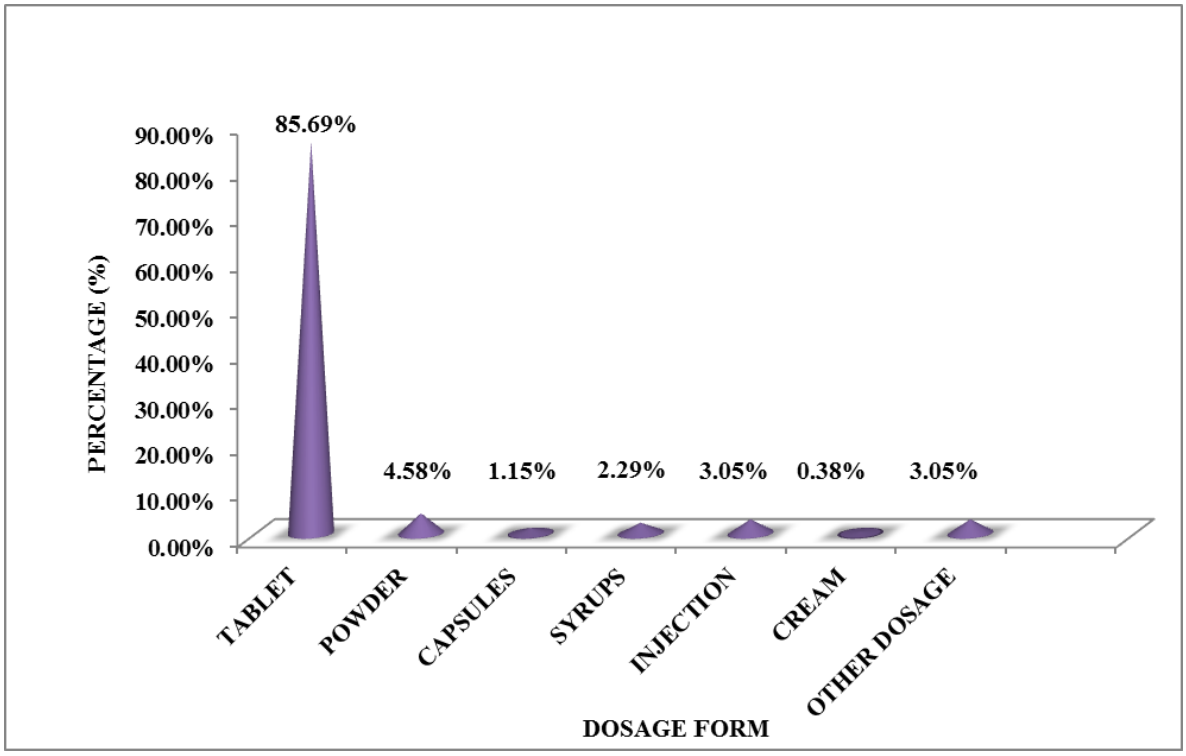

Figure 4: Different dosage form prescribed.

COMMONLY PRESCRIBED CLASS OF DRUG

Among the different class of drugs prescribed during pregnancy, the commonly prescribed class of drug is nutritional supplements 373 (71.18) which includes Folic acid, Ferrous sulphate, Calcium, Protein powder, Vitamin-C, B-complex, Iron sucrose, Hermin forte, Orofer, Systole active, Dexorange, and Spectrofer, followed by Antibiotics 29 (5.53%) which includes Cephalosporin, Clindamycin, Clotrimazole, Tinidazole, Amikacin, Clavulanic acid, Azithromycin, Metronidazole, Linezolid, Gentamycin, Vancomycin, Ciproflaxacin, and Nitrofurantoin, Gastric supplements 18 (3.44%) which includes Pan, Rantac, Antacid, Omeprazole, Rablet, and Mucaine gel, Anti-Hypertensive 4 (0.76%) Labetalol, NSAIDS 4 (0.76%) which includes Diclofenac gel, Sumo cold, Zerodol-p, Mefenamic acid, Antipyretic 9(1.72%) Paracetamol, Oral Hypoglycemic agents 3 (0.57%) which includes Metformin, and Glimeperide, Subcutaneous Hypoglycemic agent 1 (0.19%) Human – Actrapid, Hormonal preparation 15 (2.86%) which includes Susten, Nidagen, and Maintain ,Anti-emetics 16 (3.05%) Ondem, and Domperidone, Steroids 2 (0.38%) which includes Betamethasone and Dexamethaxone, Antidepressants 2 (0.38%) which includes Biopreg and Clominex, Barbiturates 1 (0.19%) Phenobarbitone, Anti helminthics 3 (0.57%) Albendazole, Urinary alkalizer 1 (0.19%) Cital syrup, Antihistamine 6 (1.14%) Chlorpheniramine, Antithyroid 17 (3.24%) Thyronorm, Laxative 2 (0.381%) Cremaffin syrup, Emollient 1 (0.19%) Dermadew caloe cream, Antiplatelet 6 (1.14%) Eospirin, Cough suppressants 2 (0.38%) Cough syrup, Appetite stimulant 1 (0.19%) Apimore syrup, Antibacterial 1 (0.19%) Triclosan soap ,Antifungal 1 (0.19%) Nuforce soap, Pessaries 2 (0.38%) which includes Clingen forte vaginal and Betadine vaginal and Vaccines include tetanus toxoid and covid vaccine 100% are given in 3rd trimester of Antenatal care.

FDA CATEGORIZATION OF NUTRITIONAL SUPPLEMENTS AND DRUGS

The study on Antenatal care assess the obtained data on drug prescribed pattern in 3rd trimester of pregnant women in obstetrics department reveals that category A

drugs are safe during pregnancy 389 (74.24%) are commonly prescribed, followed by category B drugs 18.51%, category C drugs 5.15%, category D drugs 1.72% and category X drug 0.38%, as shown in Table 5.

Table 5: FDA categorization of nutritional supplements and drugs.

CATEGORY OF DRUGS	NO OF DRUGS	PERCENTAGE (%)
CATEGORY A	389	74.24%
CATEGORY B	97	18.51%
CATEGORY C	27	5.15%
CATEGORY D	9	1.72%
CATEGORY X	2	0.38%

Table 5.1: List of nutritional supplements and drugs under category A.

NAME OF THE NUTRITIONAL SUPPLEMENTS/ DRUGS	NO OF PRESCRIPTION	CATEGORY
Folic acid	10	A
Ferrous sulphate	147	A
Calcium	157	A
Protein powder	24	A
Vitamin – C	5	A
B – complex	3	A
Iron sucrose	5	A
Hermin forte	11	A
Orofer	4	A
Systol active	3	A
Dexorange syrup	2	A
Spectrofer	1	A
Thyronorm	17	A

Table 5.2: List of drugs under category B.

NAME OF THE DRUGS	NO OF PRESCRIPTION	CATEGORY
Cephalosporin	4	B
Clindamycin	2	B
Clotrimazole	2	B
Tinidazole	2	B
Amoxycillin	1	B
Nitrofurantoin	9	B
Azithromycin	3	B
Clavulanic acid	2	B
Pan	7	B
Rantac	3	B
Antacid	1	B
Omeprazole	1	B
Rablet	3	B
Mucaine gel	3	B
Paracetamol	9	B
Metformin and Human Actrapid	3	B
Susten, Nidagen, and Maintain	15	B
Ondem	16	B
Cital syrup and Apimore syrup	2	B
Chlorpheniramine	6	B
Sporolac	2	B
Zerodol – P	1	B

Table 5.3: List of drugs under category C.

NAME OF THE DRUGS	NO OF PRESCRIPTION	CATEGORY
Linezolid	1	C
Gentamycin	1	C
Vancomycin	1	C
Ciproflaxacin	2	C
Labetalol	4	C
Sumo cold	1	C
Mefenamic acid	1	C
Diclofenac	1	C
Glimeperide	1	C
Betamethasone	1	C
Dexamethaxone	1	C
Biopreg	1	C
Clominex	1	C
Albendazole	3	C
Dermadew caloe cream	1	C
Cough syrup	2	C
Triclosan soap	1	C
Nuforce soap	1	C
Domperidone	2	

Table 5.4: List of drugs under category D and X.

NAME OF THE DRUGS	NO OF PRESCRIPTION	CATEGORY
Amikacin	1	D
Phenobarbitone	1	D
Eospirin	6	D
Betadine vaginal pessaries	1	D
Cremaffin syrup	2	X

These are the drugs which were prescribed in 157 cases of pregnant women attended in Antenatal care in their 3rd trimester was analysed based on FDA (food and drug administration) category A, B, C, D and X which is most important to promote rational use of drugs in pregnancy, health of pregnant women, reduces drug-drug interactions, adverse drug reaction, reduces further complications in pregnancy.

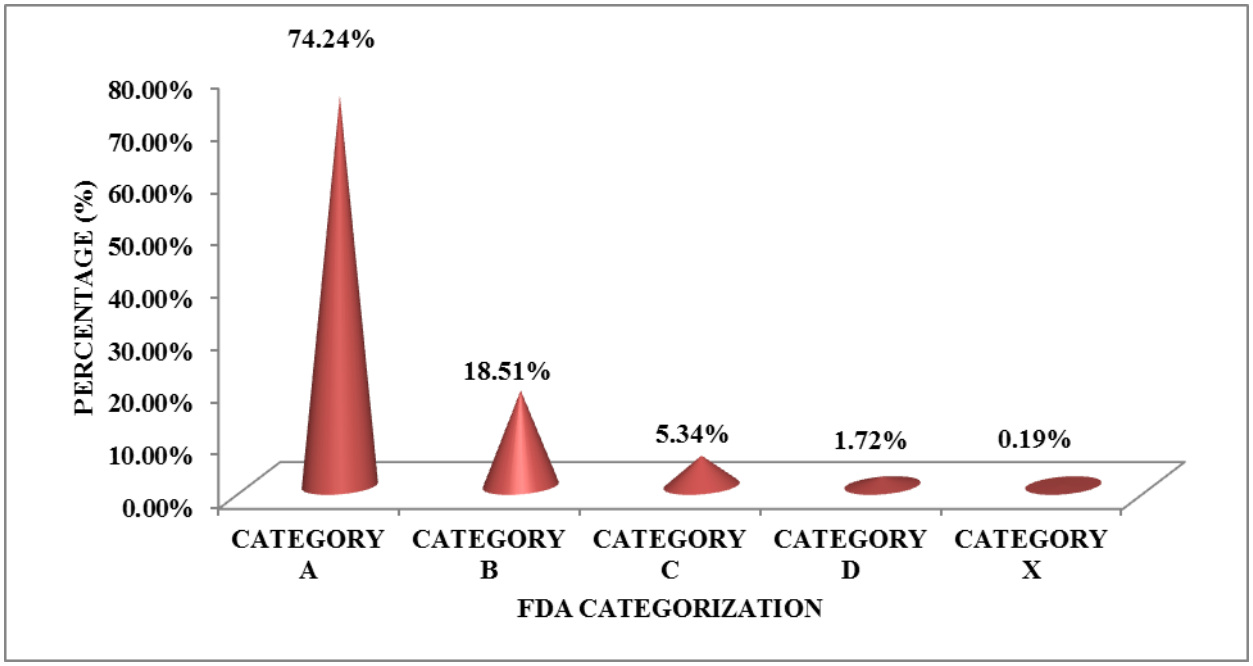

Figure 5: FDA categorization of nutritional supplements and drugs.

DISCUSSION

The cross-sectional study was conducted in obstetrics department at MIMS Teaching hospital, Mandya. A total 157 pregnant cases was collected in 3rd trimester of antenatal care in obstetrics department . Among 157 cases the maximum number of pregnant women were found in the age group of 18-22 years (43.31%) and based on diseases conditions, hypothyroidism 17 (10.83%) , hypertension 4 (2.55%) , pre -eclampsia 6 (3.82%) , diabetes mellitus 2 (1.27%), gastro – esophageal reflex 8 (5.10%) , urinary tract infection 10 (6.37%), anemias 17 (10.83%), common infection 14 (8.92%), fever 6 (3.82%), body pain 5 (3.19%), loose stools 4 (2.55%) and commonly prescribed class of drug is nutritional supplements 373 (71.18%), in which Calcium 157 (29.96%), Ferrous Sulphate 147 (28.05%), Protein powder 24 (4.58%) and other nutritional supplements, followed by Antibiotics 29 (5.53%), Gastric suppressants 18 (3.44%), Anti-Hypertensive 4 (0.76%), Hormonal preparation 15 (2.86%), Anti-emetics 16 (3.05%), Antihistamines 6 (1.15%), Antithyroid 17 (3.24%) and Vaccines include tetanus toxoid and covid vaccine 100% was given in 3rd trimester of Antenatal care and FDA categorization of drugs, the category A drugs 389 (74.24%) was prescribed, followed by category B drugs 97 (18.51%), category C drugs 28 (5.34%), category D drugs 9 (1.72%) and category X drugs 1 (0.19%).

CONCLUSION

Findings of our study showed that all pregnant women were provided with prophylactic iron and folic acid, calcium and other nutritional supplement therapy. The occurrence of contraindicated medicines was desirably low, there by minimizing overall risk to developing fetus. Thus prescribing pattern observed in our study sets a good example, as selection of drugs was rational in most of the cases.

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CONFLICT OF INTEREST: The authors declared no conflict of interest.

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