



A Prospective Observational Study of Drug Utilization Evaluation in Pregnant Women at a Tertiary Care Teaching Hospital

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ABSTRACT

Pregnancy is a profound physiological change in a woman's body that requires special care and concern towards the selection and prescription of drugs. Pregnant women are prescribed with a large number of drugs to treat their medical conditions or to help improve their nutritional requirements. The interactions between these prescribed drugs may show effect on their actions and sometimes lead to toxicity. Hence this study is put forth to have an objective of promoting the safe use of drugs and examining the pattern of the drug utilization evaluation and interactions of drugs found while in use.

Methods:

A prospective observational study on drug utilization Evaluation was conducted in the department of gynaecology at a tertiary care teaching hospital NELLIMARLA, VIZIANAGARAM. Prescriptions of 200 pregnant women were evaluated. The data collected was analysed on an MS –EXCEL sheet.

Results:

Majority of patients 64(32%) belong to an age group between 24-26 years and 64% were PRIMI GRAVIDA. Majority of women (47.15%) were in third trimester followed by second trimester (35%). Out of 200 patients included in the study 152(76%) patients were having at least one co-morbid condition. Most commonly observed condition in this study was hypothyroidism. A total of 1416 drugs prescribed were included, majority of drugs belonged to 523(37%) vitamins, 208(14.16%) antibiotics, 108(7.62%) gastric acid secretion inhibitors and others. According to US-FDA pregnancy risk categories, 40.6% drugs were prescribed from category A, 37.14% drugs were from category B, 17.16% drugs were from category C, and 5.08% drugs were from category D. No drugs were prescribed from category X. Most commonly prescribed drugs in this study were mostly VITAMINS 180(90%) followed by PANTOP 90(40%), METRONIDAZOLE 72(36%), THYRONORM 52(26%), METFORMIN 42(21%).

Conclusion: By the above study conducted, the drug prescription pattern in the current study was found to be rational.

Key words: Drug utilization, pregnancy, US-FDA, interactions.

Introduction

Pregnancy, often referred to as gestation is a period during which one or more Offspring develop inside a female's body. The time that is required for an offspring to completely develop in the womb typically occurs around 40 weeks, from the start of the last menstrual period.

Trimesters:

A full-term pregnancy completes around 40 weeks and can range from 31- 42 weeks. It is divided into 3 trimesters. The trimesters last up to 12 and 14 weeks or about 3 months. In each trimester there occur various hormonal and physiological changes.

Physiological Changes In Pregnancy:

A process of bodily development takes place in the mother during pregnancy to nurture the needs of the developing fetus. These changes are physical, hormonal, and Psychological.

Physical Changes:

- There is an observed enlargement of breasts, uterus, and vagina to support the growth and supply nutritional requirements for the fetus.
- The blood vessels and blood supply through them are increased to supply oxygen and other essential needs to the fetus.
- The color of the vagina turns pink to purple and gets more elastic during the second trimester.
- The cardiac output usually increases and the blood pressure drops by 10-15mm Hg in the first trimester and returns normally during the second trimester.
- Physical exercise is of greater importance during pregnancy as it keeps away certain health ailments like back pain, constipation, and bloating and helps the mother to sleep better.
- Pregnancy also greatly alters the changes in smell, taste, and sight. Some women experience nearsightedness and get back to normal vision after the delivery.
- They also crave more salty and sweeter foods compared to non pregnant women while some experience sensitivity to a variety of odours.

Psychological Changes:

- Due to the hormonal changes there are a greater episodes of mood swings and anxiety.
- The brain functions get altered resulting in forgetfulness of little things but is temporary and returns to normal post-pregnancy.
- As pregnancy leads to weight gain and increased posture there is low thinking of their physical appearance and may feel depressed.
- Pregnancy also makes a woman feel excited about their young ones and take care of the new addition to their family.

Hormonal Changes:

- During pregnancy the estrogen and progesterone levels in female's body tend to increase.

- These hormonal changes lead to an increase in the blood supply for nutritional supplements and oxygen supply to the fetus.
- The increased levels of human chorionic Gonadotropins (HCG) lead to nausea and vomiting referred to as morning sickness.
- The amount of blood that is pumped from the heart each minute is increased during pregnancy.
- The low progesterone levels lead to a drop in blood pressure during pregnancy.
- Due to high levels of Estrogen, it leads to increased skin pigmentation in some women known as Melasma.

Precautions to Be Followed During Pregnancy:

- The pregnant women should be completely aware and take care of their health to support the growth of the fetus.
- A well healthy diet of fruits, nuts, and fresh vegetables must be included in the diet for nutritional supply.
- Physical exercise is a must during pregnancy and after pregnancy as it relieves back pain, depression, and induces a very fine delivery.
- Music therapy is one of the best choices to relieve stress, anxiety, and depression.
- Intake of required amounts of water is necessary as it protects from getting dehydrated and also improves the fetal blood circulation, and amniotic fluid, and also prevents more blood loss during delivery
- A regular consultation is required to treat in case any health ailments and monitor the fetal conditions.

Teratogenicity:

TERATOGENICITY is the ability of a TERATOGEN to cause defects in the fetus. TERATOGENS are referred to as the drug substances that can cause a defect. The study of the side effects caused by drugs came into view only after the thalidomide tragedy had happened. Initially, Thalidomide was used to treat morning sickness in pregnant women. But later on, the effects caused by the drug came into the world after the babies were born with severe birth defects termed PHOCOMELIA. Later on, with the thalidomide tragedy, the studies are being conducted for assessing the safety and efficacy of the drugs during pregnancy but very few

studies have proven the complete safety and efficacy of fewer drugs during pregnancy.

Pregnancy is a unique period in a woman's life (1). Pregnancy is a profound physiological change in a woman's body which require special care & concern towards the selection & prescription of drugs. The selection of drug is utmost important as it may show some TERATOGENIC effects on the foetus. TERATOGENICITY has been reported in the past with thalidomide (1960) and DI ETHYL STILBESTEROL (1971) (1). The placenta is an organ of exchange allowing the mother to pass nutrients and medications to the foetus. Therefore, medications administered to pregnant women have the potential to affect the growing foetus. The foetus is generally at greatest risk of developing TERATOGENIC effect from medications during the first TRIMESTER, but it is drug specific. Pregnant women exposed to TERATOGENS are referred for ultrasound evaluation to detect malformation. Apart from environmental factors, Dangerous life-style factors seem to be a greatest hazard for the development of foetus due to common practice of consuming alcohol & smoking tobacco. The use of medication in pregnancy should be evaluated for the benefits & risk to both mother & foetus. Upon evaluation, some medications may be used sparingly during some trimester & contraindicated in other. There is no possibility of avoiding all drugs during pregnancy. Some of the pregnant women with chronic conditions like DM, epilepsy, high BP, thyroid conditions, PRE ECLAMPSIA definitely require medications. It can be dangerous if medications are stopped. E.g., : 1) if epilepsy medications are stopped there is a risk of developing seizures, 2) if in case asthma medications are stopped there is a risk of slowing down growth of unborn baby. It can be all efforts should be made to optimize the risk benefit ratio. Worldwide studies on drug use in pregnancy shows that upto 95.5% of pregnant women were exposed to drugs. In order to promote the safe use of drugs during pregnancy, the US FDA categorized the drugs into 5 pregnancy risk categories: A, B, C, D, X.

Category A: controlled studies in women have failed to demonstrate a risk to the foetus in the first trimester and there is no evidence of risk in

later trimesters. Medications in this class is considered to be safe to use in pregnancy. Examples of the medications in this class include vitamins, LEVOTHYROXINE.

Category B: animal reproduction studies have failed to demonstrate a risk to the foetus and there are no adequate and well – controlled studies in pregnant women. Medications in this class are generally considered to be safe. Examples of the medications in this class are ACETAMINOPHEN and AMOXICILLIN.

Category C: studies in animals have revealed adverse effects on the foetus and there are no controlled studies in woman, or studies in women and animals are not available. Drugs from this class can be given to the pregnant women if the benefit to the mother outweighs the risk to the foetus. Examples of the medications in this class are DILTIAZEM, SPIRONOLACTONE.

Category D: Evidence of human foetal risk has been documented, but the benefits to the mother may be acceptable despite the risk to the foetus. Drugs in this class may be used in pregnancy if the benefits to the mother outweigh the risk to the foetus. Examples of medications in this class are PHENYTOIN and VALPROIC ACID.

Category X: Studies in animals or humans have demonstrated TERATOGENIC effects. The risk to the foetus clearly outweighs any potential benefit to the mother. Drugs in this category are contraindicated in pregnancy. Examples in this class are THALIDOMIDE and WARFARIN.

It is a common practice to prescribe supplements like Fe, Ca, folic acid and other nutritional substances during pregnancy to must meet the enhanced needs of the mother. In addition, the drugs may also be prescribed for treating other health conditions of the mother. Unnecessary drug use is also found to be a common practice in certain parts of the world to treat minor conditions like back pain, nausea, vomiting etc., which need to be analysed properly .

Drug Interactions:

A drug interaction is an interaction between two or more drugs or food, beverages, etc., resulting in unwanted reactions or side effects. There are 3 types of drug interactions namely:

- Drug-Drug Interactions.
- Drug – Food Interactions.
- Drug – Condition Interactions.

Pregnant women are prescribed a large number of drugs to treat their medical conditions or help improve their nutritional requirements. The interactions between these prescribed drugs may show the effect on their actions and sometimes lead to toxicity. The placental-mediated interactions are also possible as the placenta not only acts as a passive diffusion barrier but also efflux and influx a variety of drug-metabolizing enzymes. Hence the physicians must cross-check the drugs before prescribing to avoid the drug interactions and the effects caused by them on the mother and fetus.

Hence this study is put forth to have an objective in promoting the safe use of drugs and to examine the pattern of drug evaluation and interactions of drug found while in use.

Material and Methods:

Study area, design, population:

This study was conducted in the Department of Gynaecology at Maharaja Institute of Medical Sciences, NELLIMARLA, and VIZIANAGARAM. Permission had been approved from the hospital authority and ethical committee. The study conducted was a prospective and observational study. This study was conducted for a period of 8 months.

Study population:

A total of 200 medical records of pregnant women attending to the antenatal care hospital were considered as study population. Pregnant women who were willing to participate in the study were included.

Data collection:

Data was collected from medical records by using structurally organized data collection form. Data was collected after signing by the pregnant women in the informed consent form. A detailed explanation is given to uneducated pregnant women about the informed consent form. This data collection form contains age, gravidity, trimester, disease conditions, drugs prescribed, drug interactions observed etc.,

Eligibility criteria:

• Inclusion criteria :

1. All pregnant women attending OP & IP above 19 years.
2. Pregnant women who were willing to participate in this study.
3. Patient prescribed with at least one medication.

• Exclusion criteria :

1. Patient providing incomplete information.
2. Patient who were not willing to participate in this study.
3. Age less than 18 years.

Results:

A total of 200 patients from the department of obstetrics and gynaecology were included in this study. The study was conducted from October to March 2022 at Maharaja Institute of Medical Sciences, a tertiary care hospital in VIZIANAGARAM.

Age distribution of patients:

Out of 200 patients enrolled in this study, majority of patients 64 (32%) belonged to the age group between 24 – 26 years. Less number of patients 36 (18%) between age group of 30 -33 years.

Table 1: Age distribution in patients

S.NO	Age	Frequency	Percentage
1	20-23	45	22.5%
2	24-26	64	32%
3	27-29	55	27.5%
4	30-33	36	18%

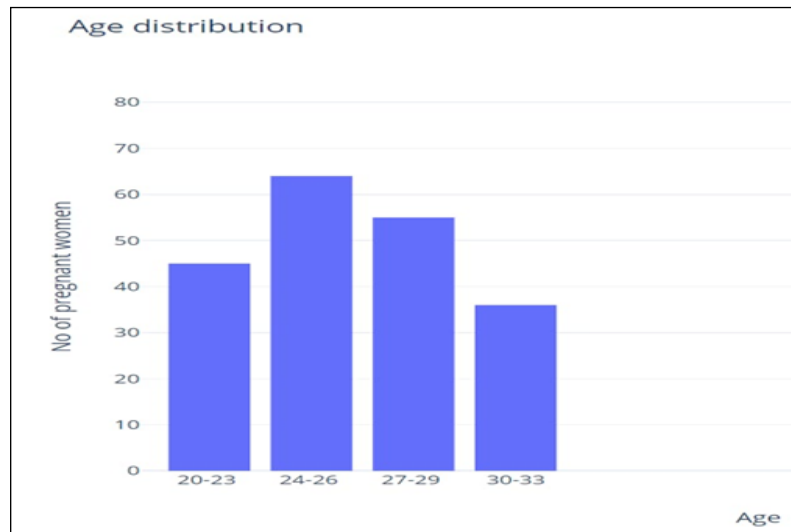


Figure 1: Age distribution in patients

2) Educational Status in Pregnant Women:

From a total of 200 patients majority of members 123 (61.5 %) were illiterates while 77(38.5%) patients were educated.

Table 2: Educational Status in Pregnant Women

S.NO	Variables	Frequency	Percentage
1	Illiterates	123	61.5%
2	Educated	77	38.5%

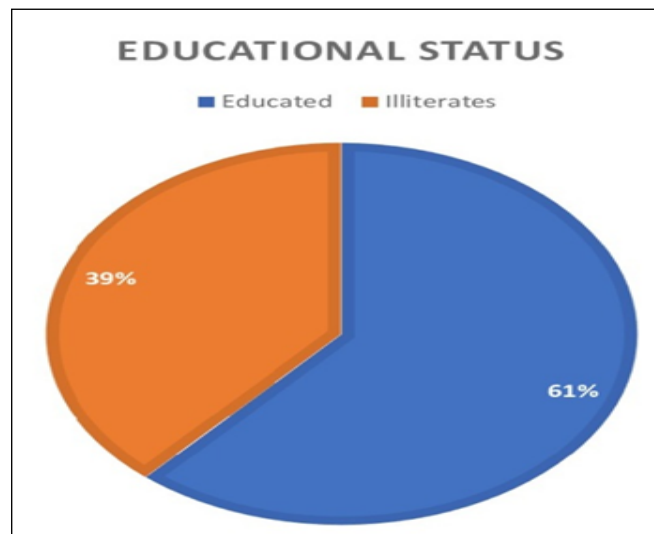


Figure 2: Educational Status in Pregnant Women

3) Residency:

From a total of 200 patients majority of members 118(58%) were rural residents while 82(42%) were urban residents.

Table 3: Residency of Patients

S.NO	Variables	Frequency	Percentage
1	Rural	118	58%
2	Urban	82	42%

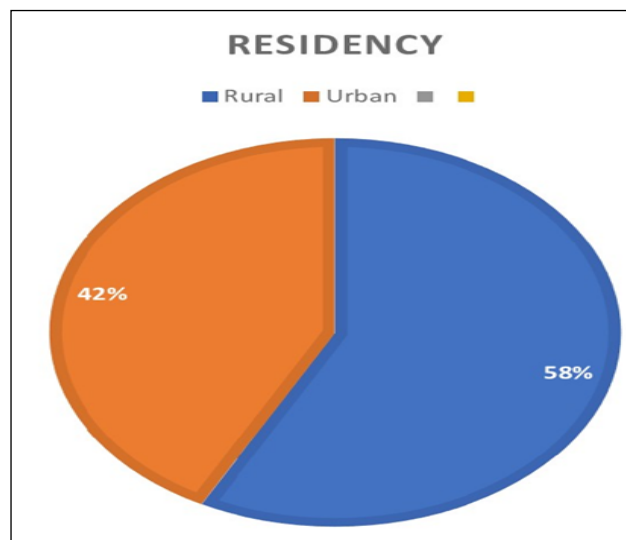


Figure 3: Residency of Patients

4) Gravid Condition in Patients:

Out of 200 study patients, majority 112 (56%) were PRIMI GRAVIDA and 88 (44%) patients were MULTI GRAVIDA.

Table 4: Gravid Condition in Patients

S.NO	Variable	Frequency	Percentage
1	Primi Gravida	112	56%
2	Multi Gravida	88	44%

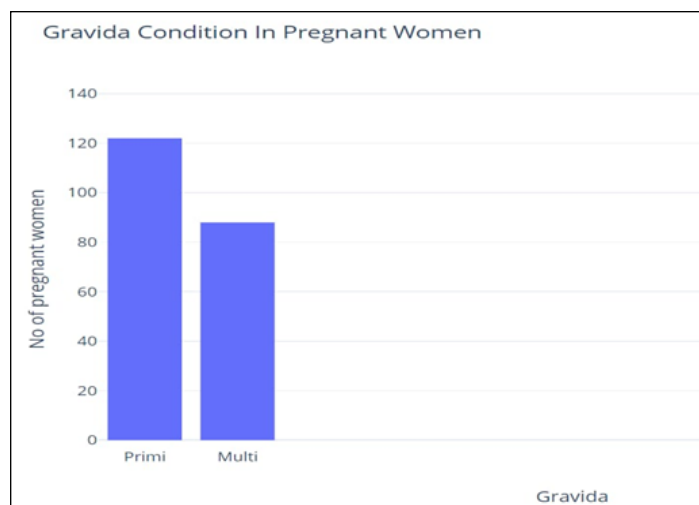


Figure 4: Gravida Condition of Patients

5) Trimester Distribution of Patients:

Out of 200 patients, most of the patients 95 (47.5 %) belonged to third trimester. Rest of the members 70 (35 %) belonged to second trimester, 35 (17.5%) belonged to first trimester.

Table 5: Trimester Distribution of Patients

S.NO	Trimester	Frequency	Percentage
1	First trimester	35	17.5%
2	Second trimester	70	35%
3	Third trimester	95	47.5%

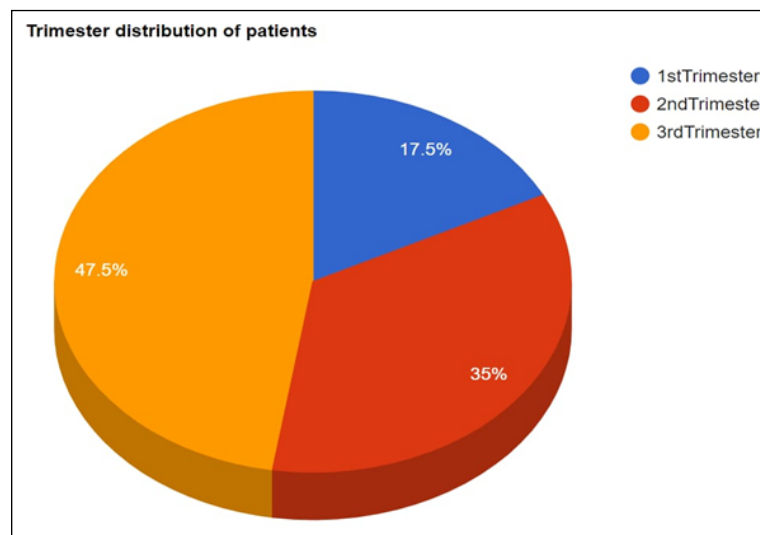


Figure 5: Trimester Distribution of Patients

6) Co Morbid Condition of Patients:

Out of 200 patients included in this study, 152(76 %) patients were having at least one co morbid condition while 99 (24 %) patients admitted on the basis of fresh complaints, the most common co morbid condition is hypothyroidism.

Table 6: Co Morbid Conditions of Patients

S.NO	Co Morbidities	Frequency	Percentage
1	GHTN	20	10%
2	GDM	24	12%
3	Hypothyroidism	52	26%
4	Anaemia	28	14%
5	Preeclampsia	28	14%

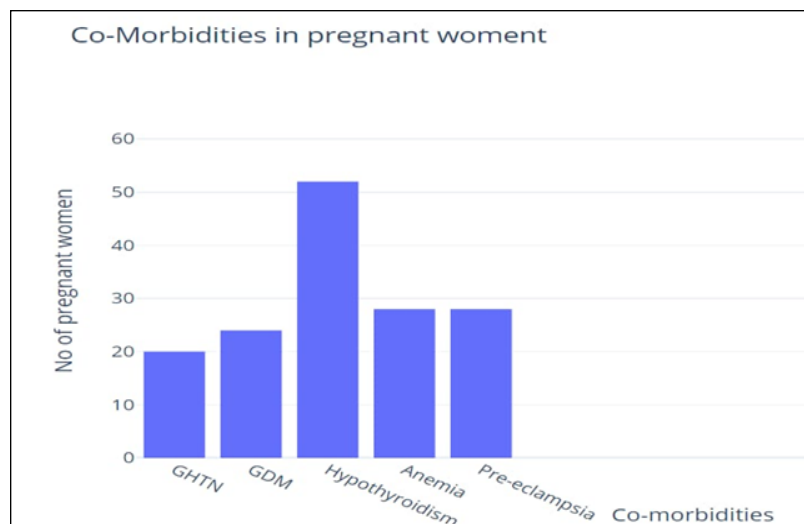


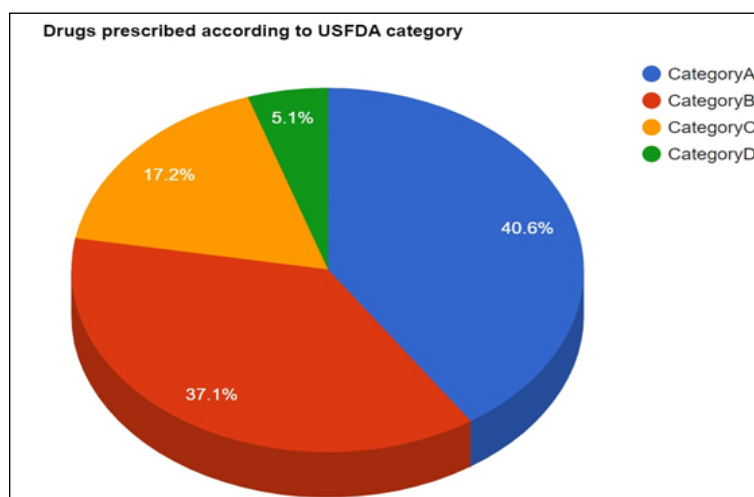
Figure 6: Co Morbid condition of patients

7) USA- FDA drug risk category:

Drugs prescribed in pregnant women, were classified according to US FDA drug risk category. A total of 1416 drugs were prescribed for pregnant women. Among these, 575 (40.6 %) were prescribed from FDA pregnant risk category A; 526 (37.14%) were from category B, 243 (17.16 %) drugs were from category C, rest of the drugs 72 (5.08 %) were prescribed from category D. No drugs were prescribed from category X.

Table 7: US FDA Drug Risk Categories

S.NO	Categories	Frequency	Percentage
1	A	575	40.6%
2	B	526	37.14%
3	C	243	17.16%
4	D	72	5.08%

**Figure 7: US FDA Drug Risk Categories****8) Classification of Drugs Prescribed In Pregnant Women:**

From a total of 200 pregnant women, 200 had taken at least one medication. A total of 1416 drugs were prescribed for such pregnant women. From which supplemental drugs accounted for about 523 (37 %) and rest of the drugs were non – supplemental drugs named as antibiotics (14.6%), anti – ulcer(7.62%), anti - thyroid (3.67%)etc.

Table 8: Classification of Drugs Prescribed in Pregnant Women

S.NO	Drug Class	Frequency	Percentage
1	Vitamins	523	37%
2	Anti-biotic	208	14.6%
3	Anti-ulcer	108	7.62%
4	Anti-thyroid	52	3.67%
5	Anti-diabetic	66	4.66%
6	Anti-epileptic	48	3.38%
7	Anti-emetic	16	1.12%
8	Anti protozoal	72	5.08%
9	Steroids	76	5.36%
10	NSAID	84	5.93%
11	Anti HTN	84	5.93%
12	Others	79	5.48%

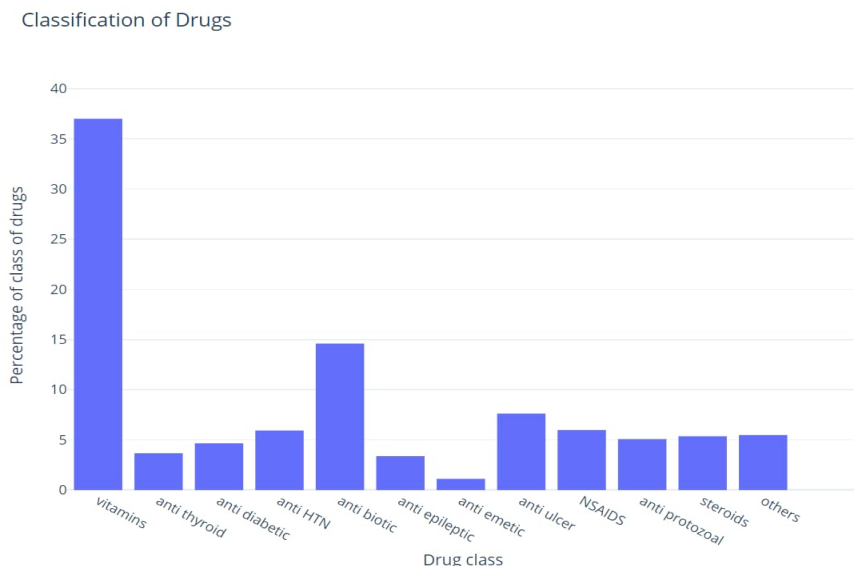


Figure8: Classification Of Drugs Prescribed In Pregnant Women:

9) Commonly Prescribed drugs:

Most commonly prescribed drugs in this study were mostly vitamins 180(90%) followed by PANTOP 90(45%) , METRONIDAZOLE 72(36 %) , THYRONORM 52(26 %) , METFORMIN 42(21%).

Table 9: Commonly Prescribed Drugs in Pregnant Women

S.NO	Drugs	No of Patients	Percentage
1	VITAMINS	180	90%
2	LEVO THYROXINE	52	26%
3	METFORMIN	42	21%
4	AMOXICILLIN	60	30%
5	PANTOPRAZOLE	90	45%
6	PARACETAMOL	80	40%
7	METRONIDAZOLE	72	36%

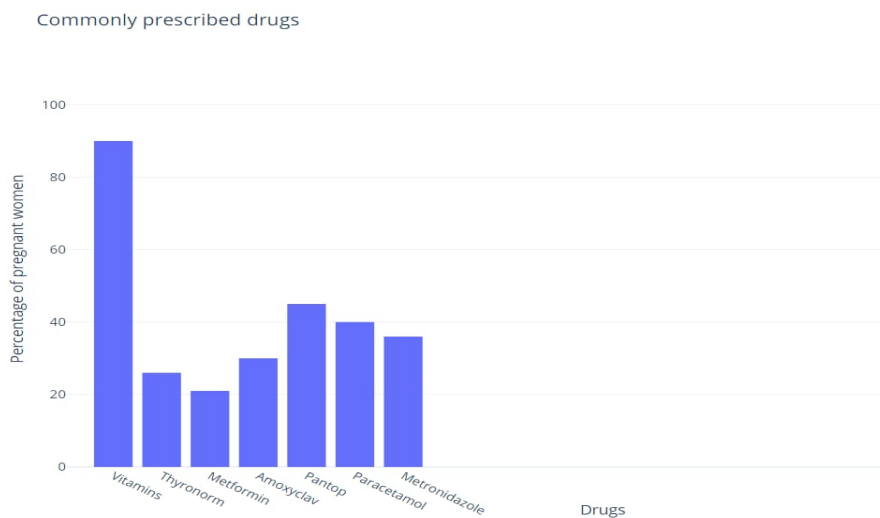


Figure 9: Commonly Prescribed Drugs in Pregnant Women:

10) Risk category of drugs:

A total of 1416 drugs were prescribed for the pregnant women, among these 72(5.08 %) of drugs were prescribed from category D. None of the drugs were prescribed from category X.

Table 10: Risk Category of Drugs

S.NO	Risk Category	Frequency	Percentage
1	D	72	5.08%

11) Drug interactions of drugs:

Drug- interactions occur when a drug mechanism action is disturbed by the concomitant administration of substances such as food, beverages & other drugs.

A total 200 of prescriptions were collected in which 1416 drugs were prescribed. In this study we observed 76 drug interactions of which 20 (26.31%) were found to be minor interactions, 48 (63.15 %) to be moderate i.e., which are to be monitored closely and 8(10.5 %) drug interactions to be severe.

By the above results, the drug interactions in prescription to the pregnant women were carefully and appropriately made to avoid the greater incidence of Drug interactions which in turn decrease the risk of TERATOGENECITY.

Table 11: Drug Interactions of Drugs:

S.NO	Type Of Interactions	Frequency	Percentage
1	MINOR	20	(26.31%)
2	MODERATE	48	(63.15%)
3	SEVERE	8	(10.5%)

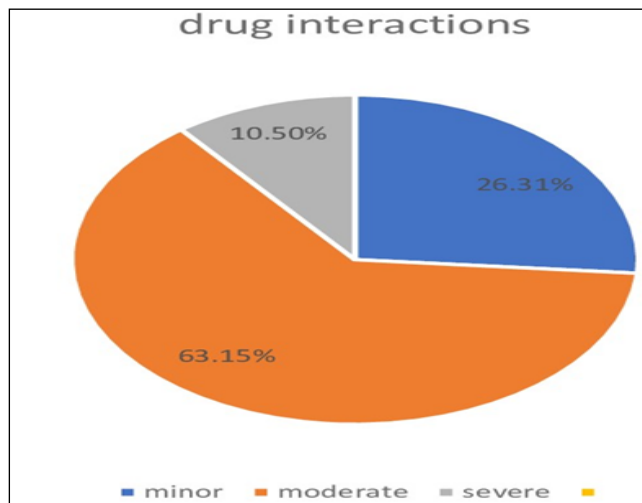


Figure 11: Drug Interactions of Drugs

Discussion:

From a total 200 pregnant women, most of the patients 32.5% were between the age group of 23-26. Majority of them were illiterates 123 (61.3%) and 118 (58%) of pregnant women were residents of rural area. This study indicated that well- educated patients were on less number of drugs due to prone for side effects. Our result was similar to the previous studies conducted in

Northern Ethiopia[4]. Majority of pregnant women, 112 (56%) in this study were PRIMIGRAVIDA while the rest of them were MULTI GRAVIDA (44%). The study specified that MULTI GRAVIDA women had taken large number of drugs compared to PRIMIGRAVIDA because a greater number of risk complications were observed in MULTI GRAVIDA. It is similar to the study conducted by Niguse Meles

Alema in Northern Ethiopia [4], by Adefolarin Aamu in SWAZILAND [11]. However, this finding was different to the study conducted by Fantahun molla who concluded that PRIMI GRAVIDA women had taken large number of drugs compared to MULTI GRAVIDA women in Southern TIGRAI region [16].

Most of the pregnant women (47.5%) admitted in the third trimester followed by second

trimester. This study showed result similar to the previous study conducted by Adefolarin Aamu in Swaziland [11] but this result is in contrast to the previous study conducted by Gudeta Duga Geresu who concluded that most of the pregnant women admitted in second trimester followed by third trimester in ETHIOPIA [3].

From this study most commonly, prescribed medications were supplemental drugs (37%) followed by non-supplemental drugs. Among the supplemental drugs, Iron & Folic acid is the most commonly prescribed in pregnant women similar to the previous study conducted by Niguse Meles Alema in Northern Ethiopia[4], by Neim Bedewi in Eastern Ethiopia[5], by Kumarjith in Karnataka[7], by Kinnari B thacker in Ahmadabad[8], by Kasaye Etefa in Addis Ababa[14]. The reason behind the common usage of iron & folic acid in our study was anemia which is found quite a common co morbid condition in pregnant women. However, this study showed high percentage of Anemia (14%) compared to the study conducted by Kumarjith in Karnataka (5%) [7] and by Fereshteh Makiabadi in Bangalore (12.6%)[9]. A study conducted by Niguse Meles Alema in Northern Ethiopia [4] showed a higher iron & folic acid drug prescription (95%). Among non-supplements, antibiotics (14.6%) most commonly prescribed drug is anti-ulcer agents (7.62%). This result is concurrent to the previous study conducted by Fereshteh Makiabadi in Bangalore[9], JAZAN[15], by Gudeta Duga Geresu in Ethiopia[3]. In this study the most common co morbid condition is HYPOTHYROIDISM which is in contrast to the study conducted by Fereshteh Makiabadi who concluded that most comorbid condition was anemia in Bangalore[9]. The next common co-

morbid conditions in this study are as follows: preeclampsia (14%), anemia (14%).

From a total of 1416 drugs prescribed for pregnant women, the most commonly prescribed drugs were Vitamins (90%), THYRONORM ((26%), METFORMIN (21%), AMOXYCLAV (30%), PANTOP (45%), PARACETAMOL (40%), METRONIDAZOLE (36%). Vitamins are most commonly prescribed in pregnant women to enhance and meet the nutritional requirements as indicated above. Iron folic acid is most commonly used to treat co morbid conditions like ANAEMIA (14%). Among antibiotic, AMOXYCLAV is (30%) the most frequently used drug to treat infections. PARACETAMOL (40%) is used to treat fever in pregnant women, which is the symptom of other conditions. PANTOPRAZOLE (40%) is used to prevent gastric irritation which occurred after taking drugs like NSAIDS, antibiotics. THYRONORM (26%), METFORMIN (21%) used to treat HYPOTHYROIDISM and GDM which were found to be common co morbid conditions in this study. From a total of 200 patients (76%) people with co morbid condition find this study in contrast to the study conducted by Fereshteh Makiabadi in Bangalore[9].

According to the US FDA, the drugs used in pregnant women were classified into 5 categories: category A, B, C, D, X. From this study majority of drugs were prescribed from category A (40.6%), category B (37.14%). Similar pattern of drug distribution is observed in previous studies conducted by Adefolarin Aamu in Swaziland[11], by Fereshteh Makiabadi in Bangalore[9], by Neim Bedewi in Eastern Ethiopia, by Niguse Meles Alema in Northern Ethiopia[4], JAZAN[15]. The result obtained is in contrast to the study conducted by Kinnari B thacker who concluded that majority of drugs prescribed from category B (47%) followed by category A (15%) in AHMEDABAD[8], by Danielle Dayse Araujo who concluded that majority of drugs prescribed from category B (39.5%) followed by category A (37.2%) in BRAZIL[12]. Category A drugs (40.6%) in this study was in line with the study conducted by Vanessa Dela Justina (46.8%) in legal Amazon region[13], by Fereshteh Makiabadi (45.5%) in Bangalore[9], by Niguse Meles Alema (42.7%)

in Northern Ethiopia[4]. A high percent of drugs from category A is observed in the study conducted by Neim Bedewi (84.88%) in Eastern Ethiopia[5], by Adefolarin Aamu (64.9%) in SWAZILAND[11], (70.12%) in JAZAN [16]region. This study stated that a less percentage (5.08%) of drugs were prescribed from category D. This finding is similar to the study conducted by Kasaya Etefa in Addis Ababa[14], by Vanessa Dela Justina in legal Amazon[13], by Adefolarin Aamu in SWAZILAND[11], by Fereshteh Makiabadi in BANGALORE[9]. Less percentage of drugs from category D was observed in the study conducted by Neim Bedewi (1.33%) in eastern Ethiopia[5], JAZAN region [15] (1.33%), Gujarat (0.89%), by Fereshteh Makiabadi in Bangalore[9] (2.30%). Drugs belonging to category D were prescribed in our study in the cases of epilepsy. NO drugs have been prescribed from category X. A total 224 drug interactions were found out in this study.

Conclusion:

By the above study conducted, the drug prescription pattern in the current study was found to be rational. The majority of drugs prescribed were found to be supplemental, while the non-supplemental drugs were found to be prescribed only under some co morbid conditions. The most common co morbid condition is hypothyroidism. From the study conducted, the most commonly used drugs were VITAMINS, PANTOP, THYRONORM, METRONIDAZOLE, METFORMIN. There is no trace of drugs prescribed, belonging to category X. Simultaneously, the drug interactions that occur were found to be moderate i.e, cause harm to the patient but were stabilised by taking extra care to the patient. Usually there is a rational selection, prescription and use of drugs but to treat some co morbidities drugs belonging to category D were prescribed. The drug interactions found to be deteriorating the patient's condition were also stabilised and treated to prevent further complications.

Recommendations:

The physicians must prescribe the drugs by assessing the risk – benefit ratio. If a particular co morbid condition is to be treated, the selection

of drugs from category D shall be replaced with less risk percentage drug category. The pregnant women shall have a counsel of intake of drugs that are prescribed as some drugs might have a probability of causing TERATOGENICITY. The benefits and side effects of the prescribed drugs should be explained to the pregnant women. They should be cautioned with the use of home remedies, OTC drugs etc. The pregnant women should be aware of their situation and health & hygiene must be maintained.

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