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Retrospective study pattern of Drug utilization and Antihypertensive Management in Pregnancy

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A B S T R A C T

Pregnancy is a state in which a woman carries a fertilized egg inside her body. Hypertensive disorders affect 10-22% of pregnancies in major population. Pre-Eclampsia is thought to affect 5-8% of pregnancies. Chronic hypertension accounts for approximately 20% of the cases of high blood pressure seen in pregnancy. **A**mong the pregnant women who were admitted to or visited DSR and who records were fully accessed (380) only 40.2% of them had a record for drug and hence analyzed in the study. The low percentage drug prescription (41.02%) is probably due to most pregnant women who were admitted to OBS ward give birth without taking any medication The management of pregnancy with preeclampsia an integrated package care covering admission to hospital, treatment measurement of blood pressure, testing of protenuria and blood tests as indicated and fetal thresholds for elective birth before 34 weeks in women with pre-eclampsia.

Keywords: Pregnancy, Hypertension, Protenuria and fetal

A R T I C L E I N F O

CONTENTS

1. Introduction 277
2. Methodology. 280
3. Results and discussion 280
4. Conclusion 285
5. References. 286

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1. Introduction

The period from conception to birth. After the egg is fertilized by a sperm and then implanted in the lining of the uterus, it develops into the placenta and embryo, and later into a fetus. Pregnancy usually lasts 40 weeks, beginning

from the first day of the woman's last menstrual period, and is divided into three trimesters, each lasting three months.

Description:

Pregnancy is a state in which a woman carries a fertilized egg inside her body. Due to technological advances, pregnancy is increasingly occurring among older women in the United States.

First month:

At the end of the first month, the embryo is about a third of an inch long, and its head and trunk – plus the beginnings of arms legs – has started to develop. The embryo receives nutrients and eliminates waste through the umbilical cord and placenta. By the end of the first month, the liver and digestive system begin to develop, and the heart starts beat.

Second month:

In this month, the heart starts to pump and the nervous system (including the brain and spinal cord) begins to develop. The 1 in (2.5 cm) long fetus has a complete cartilage skeleton, which is replaced by bone cells by month's end. Arms, legs and all of the major organs begin to appear. Facial features begin to form.

Third month:

The fetus has grown to 4 in (10 cm) and weighs a little more than an ounce (28g). Now the major blood vessels and the roof of the mouth are almost completed, as face starts to take on a more recognizably human appearance. Fingers and toes appear. All the major organs are now beginning to form; the kidneys are now functional and the four chambers of the heart are complete.

Fourth month:-

The fetus begins to kick and swallow, although most women still can't feel the baby move at this point. Now 4 oz (112g), the fetus can hear and urinate, and has established sleep – wake cycles. All organs now fully formed, although they will continue to grow for the next five moths. The fetus has skin, eyebrows, and hair.

Fifth month:

Now weighing up to a 1 lb (454g) and measuring 8-12 in (20-30 cm), the fetus experiences rapid growth as its internal organs continue to grow. At this point, the mother may feel her baby move, and she can hear the heartbeat with a stethoscope.

Sixth month:

Even though its lungs are not fully developed, a fetus born during this month can survive with intensive care. Weigh in g1-1.5 lbs (454-681g), the fetus is red, wrinkly, and covered with fine hair all over its body. The fetus will grow very fast during this month as its organs continue to develop.

Seventh month:

There is a better chance that a fetus born during this month will survive. The fetus continues to grow rapidly, and may weigh as much as3lb (1.3kg) by now. Now the fetus can suck its thumb and look around its watery womb with open eyes.

Eighth month:

Growth continues but slows down as the baby begins to take up most of the room inside the uterus. Now weighing 4-5 lbs (1.8-2.3 kg) and measuring 16-18 in (40-45 cm long, the fetus may at this time prepare for delivery next month by moving into the head-down position.

Ninth month:

Adding 0.5 lb (227 g) a week as the due date approaches, the fetus drops lower into the mother's abdomens and prepares for the onset of labor, which may begin any time between the 37^{th} and 42^{nd} week of gestation. Most healthy babies will weigh 6-9 lb (2.7-4kg) birth, and will be about 20 in. Long.

Causes and symptoms

The first sign of pregnancy is usually a missed menstrual period, although some women in the beginning. A woman's breasts swell and may become tender as the mammary glands prepare for eventual breast feeding. Nipples begin to enlarge and the veins over the surface of the breasts become more noticeable. Nausea and vomiting are very common symptoms and are usually worse in the morning and during the first trimester of pregnancy. They are usually caused by hormonal changes, in particular, increased levels of progesterone. Women may feel worse when their stomach is empty, so it is a good idea to eat several small meals throughout the day, and to keep things like crackers on hand to before getting out of bed in the morning.

Signs & Symptoms:

- Abdominal pain
- Rupture of the amniotic sac or leaking of fluid from the vagina
- Bleeding from the vagina
- No fetal movement for 24 hours (after the fifth month)
- Continuous head aches
- Marked, sudden swelling of eyelids, hands, or face during the last three months
- Dim or blurry vision during last three months
- Persistent vomiting

Common Symptoms:

- Tiredness
- Constipation
- Pelvic pain
- Back pain
- Edema

Types of Pregnancy:

a. Abdominal pregnancy ectopic pregnancy within the abdominal cavity.
b. Ampullar pregnancy ectopic pregnancy in the ampulla of the uterine tube.
c. Cervical pregnancy ectopic pregnancy within the cervical canal.
d. Combined pregnancy simultaneous intrauterine and extra uterine pregnancies.
e. Cornual pregnancy in one of the horns of a bicorn ate uterus.

Determining gestational age:

Since these are spread over a significant period of time, the duration of pregnancy necessarily depends on the date selected as the starting point chosen. As measured on a reference group of women with a menstrual cycle of exactly 28 days prior to pregnancy, and who had spontaneous onset of labor, the mean pregnancy length has been estimated to be 283.4 days of gestational age as timed from the first day of the last menstrual periods recalled by the mother, and 280.6 days when the gestational age was retrospectively

estimated by obstetric ultrasound measurement of the fetal biparietal diameter (BPD) in the second trimester. Other algorithms take into account a variety of other variables, such as whether this is the first of subsequent child the mother's race, parental age, length of menstrual cycle, and menstrual regularity, but these are rarely used by health care professionals. In order to have a standard reference point, the normal pregnancy duration is generally assumed to be 280 days (or 40 weeks) of gestational age.

Table 1: The testes involved during the period of pregnancy

Assessment of pregnant women for alcohol misuse and tobacco use
HIV antibodies (blood test)
Chlamydia and gonorrhea (antigen or culture) tests
Hepatitis B virus (blood test)
Rh incompatibility (blood test)
Syphilis (blood test)
Urinalysis for asymptomatic bacteriuria
Nutritional assessment

Timing of child birth:

Table 2: Stages of pregnancy term

Stage	starts	Ends
Preterm	-	at 37 weeks
Early term	37 weeks	39 weeks
Full term	39 weeks	41 weeks
Late term	41 weeks	42 weeks
Post term	42 weeks	-

In the ideal child birth labor begins on its own when a woman is "at term" pregnancy is considered at term when gestation has lasted between 37 and 42 weeks. Unless is a medical reason to do so, planned delivery of a child should not happen until after the completion of 39 weeks of pregnancy.

Events before completion of 37 weeks are considered pre term. Pre term birth is associated with a range of risks and problems and whenever possible should be avoided of giving birth when the pregnancy is at term. Babies born between 39 and 41 weeks gestation have better out comes than babies born either before of after range. This special time period is called "full term".

Hypertension in Pregnancy

Hypertensive disorders affect 10-22% of pregnancies and have been classified in to four conditions, reflecting potential differences in etiology and pregnancy outcomes:

Signs and Symptoms:

- Severe head ache.
- Visual problems: blurred vision or flashing before the eyes.
- Severe epigastric pain.
- Vomiting.
- Sudden swelling of the face, hands or feet.
- Such women's are those with:
- Hypertension in past pregnancy.
- Chronic kidney disease.

Classification of Hypertension in Pregnancy:

a. Chronic hypertension
b. Gestational hypertension
c. Pre-eclampsia-eclampsia
d. Pre-eclampsia super imposed on chronic hypertension

The incidence of these disorders is not entirely clear, but pre-eclampsia is thought to affect 5-8% of pregnancies. Chronic hypertension accounts for approximately 20% of the cases of high blood pressure seen in pregnancy.

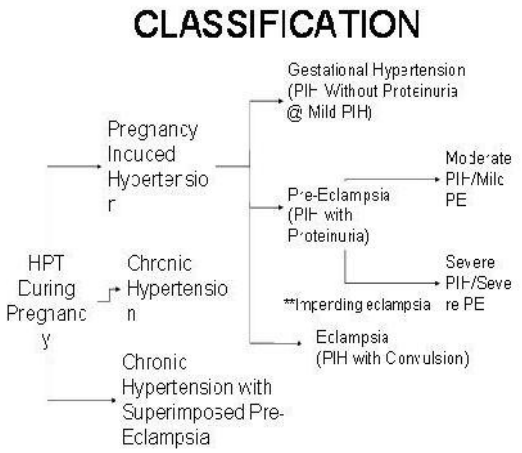

Figure 1: Classification of hypertension in pregnancy

Chronic Hypertension:

1. Chronic hypertension is diagnosed when hypertension is confirmed before pregnancy or before20 weeks gestation (blood pressure>140mmHg systolic and/or >90mmHg diastolic).However, chronic hypertension is frequently diagnosed when high blood pressure fails to resolve postpartum. Women with chronic hypertension require careful monitoring during pregnancy as they have an increased risk of adverse events, including superimposed pre-eclampsia, placental abruption, fetal growth restriction, premature delivery and still birth.
2. Pre-pregnancy counseling and management of chronic hypertension is essential. Some commonly prescribed anti hypertensive drugs are contraindicated or best avoided before conception and during pregnancy. These include in ACE inhibitors, Angiotensin receptor antagonists, diuretics and most beta blockers.
3. Were indicated, it is advisable to look for secondary causes of hypertension before conception, as normal physiological changes in pregnancy can make many of these screening tests difficult to interpret. It is not possible, with the exception of phaeochromocytoma; further investigation is often best deferred until the postpartum period. In all cases, preconception assessment for proteinuria (with urine protein: creatinine ratio) is recommended as a baseline measurement.

2. Methodology

a. Retrospective study was conducted to pregnant women, for during drug utilization pattern in pregnant women.
b. Required information like patient age, address, gravidae drugs prescribed, dosage form,. Route of administration, main diagnosis, and the trimester during drug administration.
c. The collection data was checked manually for then the data was coded and analyzed using FDA pregnancy drug category and WHO core prescribing indicators.
d. The pregnant women who visited greater than or equal to the two times in their gestational period and the prescribed drugs which clearly corresponds with the trimester were included in the study.
e. The nature of service delivered, and the trimester and the Gestational age during drug administration and other related issued were collected from PMR.
f. Collection of prescriptions of patient attending the ANC and diagnosed as a care of hypertensive disorder by the treating physician were analyzed.
g. The study was conducted after obtaining permission from the institutional ethics committee and the obstetrics and gynecology department.
h. The study was conducted after obtaining permission from the Gynecology department.
i. The following steps were taken to maintain the confidentiality of the study population.
j. The pregnant females attending the ANC clinic and registered with department of obstetrics and Gynecology.
k. The counseling was given to the patients and then leaflets for drug utilization pattern. And counseling about the patients and reduce the adverse effects from the patients.

Ethical consideration:

Research on pregnant women raises a unique set of ethical concerns therefore before starting to collect the data and sample for the study a formal letter was obtained from the department of pharmacy and medical director of hospital.

3. Results and Discussion

- **A**mong the pregnant women who were admitted to or visited DSR and who records were fully accessed (380) only 40.2% of them had a record for drug and hence analyzed in the study.
- The low percentage drug prescription (41.02%) is probably due to most pregnant women who were admitted to OBS ward give birth without taking any medication.
- Moreover the impact of the lost records should not be underestimated. The highest drug utilization recorded in the hospital was during third trimester the number pregnant women admitted to/visited DSR this trimester accounts for 75%(179) of all the pregnant women visiting the hospital(table1b).
- Additionally the women took many drugs including different ivfluids in OBS ward(the average number of drugs per pregnant women was 2.50).our findings also reveal that the highest average number of medications prescribed women was recorded in the GYN ward.
- This is probably due to almost all of the pregnant women were admitted for the hyper emesis gravidum (HG) in which they took different parental drug such as anti emetics, anti pain, ivfluids, antibiotics and others per drug encounter.
- Among the total drugs prescribed during ANC 2.5% were category D namely tetracycline and doxycycline these drugs were prescribed for upper respiratory tract infection in the first and second trimester.
- The prescription was inappropriate as both drugs can cross the placenta and their use late in pregnant cause's permanent discoloration of teeth, enamel, hyperplasia and impaired fetal skeletal growth. There were also categories x drugs (2%) prescribed in the second and third trimester. the drug were Misoprostol (to terminate pregnancy) and oxytocin (to induce labor) and this was appropriate. Number of iron and folate supplements prescribed in this study was only 12 (out of 280 drugs totally prescribed (table3).
- Globally pregnant women and young children are at high risk of anemia with iron deficiency. Contributing to 48.9% of this risk. WHO has estimated that prevalence of anemia during pregnant in developed countries is 13% and developing countries50% nearly all women are to some degree iron deficient and more than half of pregnant women in developing countries suffer from iron deficient anemia.
- Therefore it is mandatory to consider iron supplement during pregnancy so as to minimize the risk associated with anemia, among 420 drugs prescribed in OBS ward, most of them were under category B(40.13%) category C (27.3%) and category X(12.4%) respectively.
- A total of 66 category X labor inducing drugs (misopostol and oxytocin) were also prescribed (table5and 6 Figure2).moreover category D like diclofenac (if given for third trimester mother), diazepam and spironolactone were prescribed in the third trimester. Diazepam was used for the treatment to mild to severe preeclampsia. If diazepam is used for long during pregnancy or at high doses, it might be associated with a high incidence of physiological depression when maternal doses exceed 30mg the babies being likely to have a tendency to apnea, reluctance to feed and impaired hermogenesis.
- Our result had shown that spironolactone (category D) was used for the patient with congestive heart failure, high dose of this drug is contraindicated during pregnancy before determine the sex of the fetus because of its anti androgenic effects

resulting in feminization of male fetuse. The same is true for higher dose of cimetidine prescribed for patients with dyspepsia, which may lead to gynecomastia in male. However their use may be acceptable if the benefit out weights the associated risk. Hence either safe alternatives should be used or close monitoring of the patients is required.

- According to our results, diclofenac was used in third trimester for pregnant women in labor however this can cause early closure and constriction of ductus arteriosus with subsequent neonatal pulmonary hypertension and transient right sided hypertrophic cardiomyopathy.
- Therefore it is very important to search for other alternatives that could alleviate pain during labor. pregnant women who were admitted to the GYN ward in DSR took a total of 55 drugs (33%) under category B(28.5%) under category C and (14%) under category A/C category include pyridoxine and vitamin B complex (table7and8).the A/C stands for manufacturer difference and B/C/D indicates safety differs according to the trimester.Fgure1and 2and3 it was difficult to exactly know the category of such drugs because only generic name was written on the patient medical record. most of the drugs in OBS ward were given parental (table2a and b) this may due to the nature of the diagnosis in which they can't take drugs orally. Most common diseases recorded were urinary tract infection, peptic ulcer diseases and abdominal discomfort. Hence the majority of medications prescribed were drugs used against gastrointestinal disorders such as Metoclopromide, metronidazole, magnesium trisilicate, cimetidine, omeprazole, mebendazole, chlorpromazine, and Hyoscine.
- Moreover, most of the patients were admitted to OBS ward for labor and they underwent cesarean section for delivery in which they took different iv fluids and anesthetics parental.
- The high value for the injectables prescribed in GYN ward may be due to nature of the diagnosis observed. For orally administered drugs the role of pharmacist working at the hospital pharmacy is very crucial to identify medication related problem.
- To discuss the other antihypertensive treatment with the health care professionals responsible for managing their hypertension.
- In pregnant women with uncomplicated chronic hypertension aim to develop blood pressure lower than 150/100mmHg.
- The patients having the gestational hypertension an integrated package of care covering admission to hospital, treatment, measurement of blood pressure, testing protenuria and blood tests indicated.
- The management of pregnancy with preeclampsia an integrated package care covering admission to hospital, treatment measurement of blood pressure, testing of protenuria and blood tests as indicated and fetal thresholds for elective birth before 34 weeks in women with pre-eclampsia.
- Most of the patients who admitted DSR came from rural area; this may indicate inadequate health care service provided in rural areas and/or bias by mothers for being safe when treated in DSR hospital.

Table 3: Number of pregnant women with trimester wise distribution

Trimesters	NO. of Pregnant Women	Percentage (%)
FIRST	11	3.9
SECOND	116	41.4
THIRD	153	54.6
TOTAL	280	100

Table 4: Number of pregnant women with gravidity wise distribution

Gravida	NO. of Pregnant Women	Percentage (%)
PRIMIGRAVIDA	115	41
GRAVIDA2	115	41
GRAVIDA3	42	15
GRAVIDA>4	8	2.8
TOTAL	280	100

Table 5: percentage distribution of medical conditions of the pregnant: in first trimester

Diagnosis	Frequency
CAP	25
DYSPEPSIA	30
UTI	25
AFI	22
TRACHOMA	11

Table 6: Percentage Distribution of Medical Conditions Of the Pregnant Women: In Second Trimester

Diagnosis	Frequency
UTI	22
DYSPEPSIA	20
CAP	8
AFI	9
ABDOMINAL DISCOMFORT	7
PUD	3
HEG	2

Table 7: percentage distribution of medical conditions of the pregnant women: in third trimester

Diagnosis	Frequency
HEG	13
UTI	10
ABDOMINAL DISCOMFORT	12
PUD	9
ANAEMIA	7

Table 8: Distribution of dosage forms prescribed to pregnant women in all trimesters

Dosage form	First trimester	Second trimester	Third trimester
Tablet	100	68	25
Capsule	11	13	8
Syrup	14	11	4
Gels	4	3	1
Vaginal cream	1	2	0
Solution	33	16	22
Ointment	11	2	0

Table 9: the route of administration of prescribed drugs for pregnant women in first trimester

Route of Administration	Frequency
PO	120
IV	24
IM	6
VAGINAL	5
TOPICAL	9

Table 10: The route of administration of prescribed drugs for pregnant women in second trimester

Route of administration	Frequency
PO	98
IV	13
IM	2
VAGINAL	4
TOPICAL	2

Table 11: Route of administration of prescribed drugs for pregnant women in third trimester:

Route of Administration	Frequency
PO	42
IV	20
IM	2
VAGINAL	1
TOPICAL	0

Table 12: FDA category of drugs prescribed to pregnant women

FDA Drug Category	Representative Drugs
A	Ferrous sulphate, Folic acid, Multivitamin, pyridoxine, Vitamin B complex.
A/C	Magnesium trisilicate, Magnesium sulphate.

B	Amoxicillin/clavulinic acid, erythromycin, cephalexin, cloxacillin.
C	Cimetidine, omeprazole, dexamethasone eye ointment, mebendazole, hyosine, ketoconazole.
C/D	Ibuprofen, enalapril, diclofenac.

Table 13: FDA category of drugs prescribed during pregnancy in first trimester

FDA Category	Drug name	Frequency
A	Iron folate	13
A/C	Vitamin B	10
B	Amoxicillin	20
B*	Metronidazole	8
B/C/D	Dilcofenac	6

Table 14: FDA category of drugs prescribed during pregnancy in third trimester

FDA Category	Drug name	Frequency
A	Iron folate	8
A/C	Vitamin B	7
B	Amoxicillin	5
B*	Metronidazole	4
B/C/D	Diclofenac	3
C	Omeprazole	5

Table 15: Drugs prescribed for pregnant women at OBS ward:

FDA Category	Drug Name	Frequency
A	Iron folate	10
A/C	Vitamin B	15
B	Amoxcillin	12
B*	Metronidazole	9
B/C/D	Dilcofenac	5
C	Omeprazole	10

Table 16: FDA category of drugs prescribed during pregnancy in third trimester:

FDA Category	Drug Name	Frequency
A	Iron folate	8
A/C	Vitamin B	7
B	Amoxicillin	5
B*	Metronidazole	4
B/C/D	Diclofenac	3
C	Omeprazole	5

Table No 17: Drugs prescribed for pregnant women at OBS ward:

Drugs prescribed	Frequency
Insulin	1
Metronidazole	14
Pethidine	5
Iv fluids	50
Ketamine	6
Hyoscine	5
Spironolactone	3
Frusemide	2
Propranalol	3
Magnesium sulphate	22
Nifedipine	2

Table 18: Drugs prescribed for pregnant women at GYN ward

Drugs prescribed	First trimester	Second trimester	Third trimester
Vitamins	15	5	0
Iron folate	2	1	1
Antibiotics	8	2	6
Nsaids	0	1	0
Antacids	3	1	3
Anti emetics	10	3	0
Ppi/h2blocker	3	0	0
Chlorpromazine	3	0	3
Iv fluids	10	2	0
Promethazine	1	0	0

Table 19: Distribution of FDA categories d and X drugs prescribed for pregnant women

Drugs	Indication	Fda category
Doxycyline	UTI	D
Gentamicin	UTI	D
Chloropromazine	HEG	D
Tetracycline ointment	TRACHOMA	D
Diazepam	PREECLAMPSIA	D
Phenobarbital	EPILEPSY	D

Table 20: Nature of the service and residence of patients admitted to DSR

Name of the ward	Rural	Urban
ANC	**50**	**10**
OBS	**100**	**60**
GYN	**30**	**70**
TOTAL	**180**	**140**

Table 21: who core drug prescribing indicator

S. No	Indicator	Value
1	Average number of drugs per prescription	3.01
2	Percentage of drugs prescribed by generic name	21.51
3	Percentage of encounters with antibiotic prescribed	11.17
4	Percentage of encounters with an injection prescribed	2.17
5	Percentage of drugs prescribed from essential drug list	58.97
6	Percentage of drugs prescribed from hospital drugs list	24.50

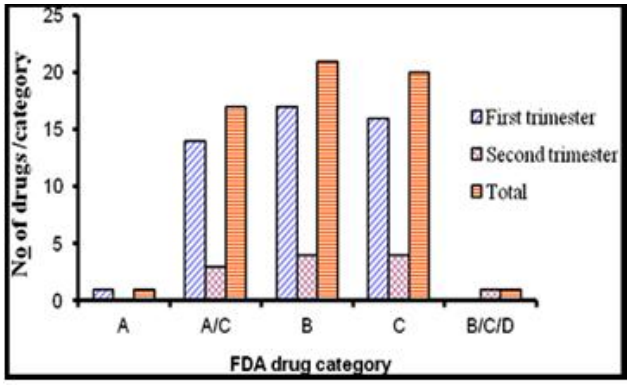

Figure 2: Graphical representation of distribution of the FDA category of drugs in pregnancy patients in different trimester

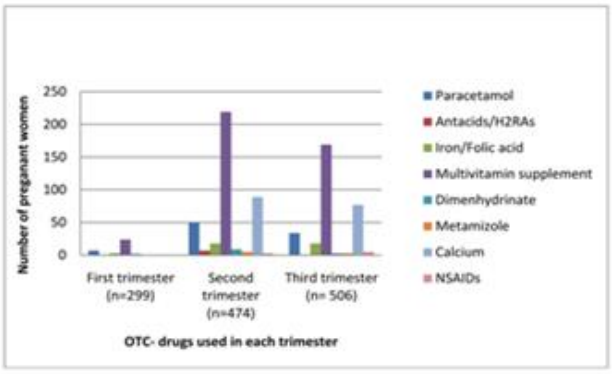

Figure 3: the graph between OTC drugs used in each trimester vs. number of pregnant women

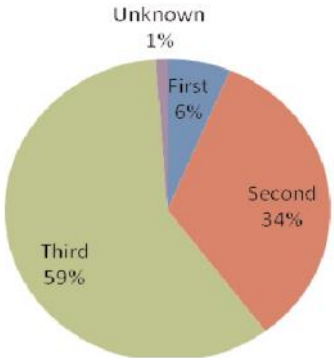

Figure 4: percentage of women at different trimesters of pregnancy

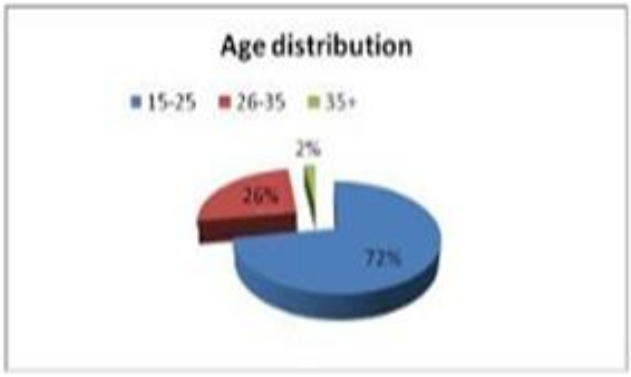

Figure 5: percentage of age distribution

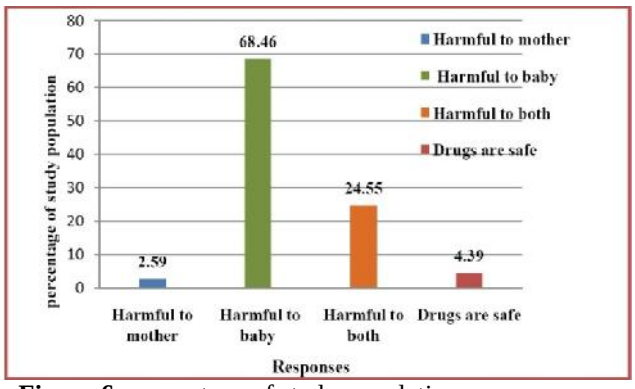

Figure 6: percentage of study population vs. responses

4. Conclusion

- FDA category B drugs were the most frequently prescribed drugs. However, approximately half of the women encountered with drugs from category C, D and X which are thought to cause possible fetal harm. Therefore, intensive assessment of pharmacotherapy given to pregnant women should be done with respect to the FDA risk category, the gestational period, and the risk-benefit balance of drug before its prescription.
- Antibiotics use was not within the range of WHO standard which indicates over use of antibiotics. Moreover, percentage encounter with injection was higher in third trimester.
- The drug utilization pattern observed among the pregnant woman admitted to/visited DSR was good and almost all the teratogenic drugs prescribed to them were labor inducing and they all were prescribed at term and post term.
- However there were some category D drugs like (diclofenac, if given in third trimester, tetracycline, doxycycline, spironolactone and others) and category C (cimetidine) drugs prescribed inappropriately to some of the patients. Such inappropriately prescription drugs should not be underestimated because it definitely affects the life of both mother and fetus.
- Therefore it is recommended that there should be intensive assessment of pregnant women including the FDA risk category. In addition, pharmacist should interact with other members of the health care team to develop, implement, and monitor a therapeutic plan so as to achieve optimal care each pregnant woman.
- It is also recommended to strength use of smart care (electronic medical record system), which is already practiced in the hospital, so that every health care provider including the pharmacist can have access to the patient information and understood the contraindication and ADR effect of the drug.
- Moreover there will be no loss of records and thus any data can be accessed easily. Prescription to pregnant women should be easy known by the pharmacist either by direct communication with the health care provider working in GYN/OBS ward and opd or through the pharmacist working in the drug information centre.
- Preparing check list for commonly prescribed drugs to pregnant women, continuous education on medication during pregnancy to health care provider working GYN/OPD and ward is also very important.
- Pregnancies affected by hypertensive disorder require careful monitoring due to increase risk of adverse pregnancy outcomes.
- New onset hypertension in pregnancy warrants consideration of preeclampsia.
- Anti hypertensive drugs for all forms of hypertensive disorder of pregnancy trend to be reserved for persistent or severe hypertension.
- Many standards anti hypertensive drugs are contraindicated in pregnancy and lactation.
- In women at moderate to high risk for recurrent preeclampsia, prophylaxis with low dose aspirin and calcium supplement in subsequent pregnancies may to be benefit long-term follow-up, particularly in regard to cardiovascular risk, is important in women with a history of hypertensive disorder in pregnancy.
- AS DSR is teaching hospital, interns (medical students) and other maternity, addition to this ANC follow up service should be monitored on regular base. Strengthening the drug information

center in the hospital is the other best possible solutions for medication error during pregnancy.

- Hypertensive disorders of pregnancy are common and represent a spectrum of disease ranging from chronic and gestational hypertension to eclampsia. They are associated with increased risk of both adverse maternal and fetal outcomes.
- Drug treatment is generally reserved for moderate or severe hypertension. pre-eclampsia–eclampsia can belief-threatening and requires urgent investigation and intervention. There are limited data about the safety of many hypertensive drugs in pregnancy. ACE inhibitors and Angiotensin receptor blockers should be avoided.
- Women who have had any hypertensive disorder in pregnancy have an increased cardiovascular risk. They require long-term follow-up.

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