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Research Article

A study on investigation on the complications associated with pregnancy and its birth defects

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ABSTRACT

We conducted a prospective observational study in coastal area of Andhra Pradesh. We collected a total number of 304 cases from the hospital and observed the risks of developing birth defects in infants. Fisher exact test was performed for birth defects in both the exposed and the unexposed groups and their complications were used to estimate odds ratio, relative risk, attributable risk, sensitivity and specificity. The risk to benefit ratio of various drugs used during the pregnancy was calculated.Fisher exact test is used to calculate the risk assessment parameters. The results obtained from this test include thyroid (OR=3.39, RR=2.194, AR=0.2721, snout= 0.1091, spin=0.9651), preeclampsia (O, R=0.3, RR=0.3636, AR=0.1591, snout=0.01818, spin=0.9419), gestational diabetes mellitus (OR=2.42, RR=1.813, AR=0.1922, snout=0.0545, spin=0.9767), anemia (OR=1.57, RR=1.383, AR=0.0922, snout=0.01818, spin=0.9884), larger maternal weight (OR=infinity, RR=5.095, AR=0.8037, snout=0.2364, spin=1), older maternal age (OR=infinity, RR=4.909, AR=0,7963, snout=0.1698, spin=1), drug abuse (OR=3.25, RR=2.125, AR=0.26, snout=0.05455, spin=0.9826), chicken pox (OR=infinity, RR=4.185, AR=0.76, snout=0.01818, spin=1), toxoplasmosis (OR=6.67, RR=2.889, AR=0.4359, snout=0.07273, spin=0.9884), HELLP syndrome (OR=infinity, RR=4.185, AR=0.7611, snout=0.01818, spin=1), DVT (OR=0, RR=0, AR=0.25,snout=0, spin=0.9826), cardiac issues (OR=infinity, RR=4.44, AR=0.77, snout=0.0909, spin=1).From the results obtained from the odds ratio, relative risk, attributable risk, sensitivity, specificity we conclude that there is a strong relationship between the birth defects developed and the complications experienced by the mother.

Key words: Birth defects, risk assessment.

INTRODUCTION:

Pregnancy is also called as the gestation. It is the time in a woman's life whenan offspring develop in the uterus. The sperm fertilizes an egg that is released from the ovary during ovulation. This fertilized egg then travels down into the uterus and gets implanted in the uterus. On average, a full-term pregnancy lasts 40 weeks. There are many factors that can affecta pregnancy. Women who receive an early diagnosis and prenatal care are more likely to experience a healthy pregnancy and give birth to a healthy baby.

THE STAGES OF DEVELOPMENT OF EMBRYO:

During the 9 months gestation period of the pregnant woman, thedevelopment of the organs occurs in the following manner.

BIRTH DEFECTS:

Birth defects are the abnormalities that occur in infants either functionally or structurally. The incidence of these birth defects was found to be 7.7per 1000 births (National center for health statistics, 2016). These birth defects in infants may be caused due to drugs, physiological conditions, genetic abnormalities, diet (poor iodine intake, poor folic acid intake, excess vitamin A intake etc.,), age, BMI of the mother etc., The major complications experienced by the mother during her pregnancy are as follows

PREECLAMPSIA

Pre-eclampsia is one of the most serious conditions and major cause of maternal mortality of about 15–20% in well developed countries and acute and long-term morbidities, perinatal deaths,preterm birth, and intrauterine growth restriction (Sibai et al., 2005). It is characterized by the high blood pressure and a significant amount of protein in your urine or liver or kidney abnormalities after 20 weeks of pregnancy. Risk factors for the preeclampsia include history of preeclampsia, nulliparity, multifetal pregnancy, diabetes mellitus, vascular and connective tissue disorders like SLE and antiphospholipid antibodies, overweight, age greater than 35 years at firstpregnancy, smoking, and African American race (Elosha Eiland et al., 2012). According to a number of theories on the etiology of the preeclampsia, the disease is a cascade that is activated by the combination of abnormal maternal inflammatory response, endothelial cell activation/damage with deranged hemodynamic milieu, and the deranged immunity (Elosha Eiland et al., 2012).

If a pregnant lady develops high blood pressure after 20 weeks of pregnancy but doesn't have protein in her urine sample or other key symptoms of preeclampsia, then she will be diagnosed with gestational hypertension, sometimes called pregnancy-induced hypertension (PIH). Mortality and morbidity from preeclampsia increased with increasing in the maternal age. The highest risk of death was at gestational age 20–28 weeks and after the first live birth.

GESTATIONAL DIABETES MELLITUS:

Gestational diabetes is a state in which a woman develops higher levels of blood sugar during her pregnancy. In other words, it may be defined as glucose intolerance with onset or initial recognition during pregnancy (Reece et al., 2009). About 7% of all the pregnancies are complicated by gestational diabetes mellitus, resulting in more than 200,000 cases annually. The prevalence may range from 1 to 14% of all the pregnancies, depending onthe population studied and the diagnostic tests.Risk assessment for gestational diabetes mellitus should be commenced at the first prenatal visit. Women with clinical features reliable with a high risk of gestational diabetes mellitus (marked obesity, previous history of gestational diabetes mellitus, glycosuria, family history of diabetes) should undertake glucose testing as soon as possible. If they do not experience the gestational diabetes mellitus at that initial screening, they should be retested between 24 and 28 weeks of gestation. Gestational diabetes mellitus upsurges the risk of adverse consequences during pregnancy and has significant long-term adverse health effects on both mothers and their offspring, including a tendency to obesity, metabolic syndrome and type 2 diabetes mellitus (T2DM) in future (American Diabetes Association, 2004; Bellamy et al., 2009; Reece et al., 2009).

METHODOLOGY

STUDY DESIGN:
This was a Prospective observational study in which information is obtained on usage ofvarious category drugs and their complications in pregnant women.

STUDY SITE:
The study was conducted in few tertiary care hospitals in Coastal Andhra region.

STUDY PROCEDURE:
- Informed consent was obtained from the patients both orally and by written forms. Thedemographic details were collected from the patient.

STUDY DURATION: The study was carried out for a period of 6 months.

STUDY ELIGIBILITY:

a) INCLUSIONCRITERIA:
- All pregnant females and those with complications that arise before or during pregnancyare included in our study.
- Research participants who are willing to join the study and signing the informed consentby her are included in the study.

b) EXCLUSIONCRITERIA:
- Patients having psychiatric diseases which include incorporation of questionnaireinvestigation were excluded.
- Research participants having certain problems with signing informed consents wereexcluded from the study.
- Accidental cases of pregnancy

c) WITHDRAWAL CRITERIA:
- Unwilling to keep on participating in the study

STUDY TOOLS:
A Self administered questionnaire was prepared using information and thorough review from the literature survey and factors used in previous studies and it was validated byfaculties in department of pharmacy practice and physicians.

QUESTIONNAIRE VALIDATION:
Two physicians with experience in tertiary care hospitals as gynecologists were asked to evaluate the clarity, relevance and conciseness of items included in the questionnaire (limitations on questionnaire was a feedback which was rectified by eliminating).

INTERVIEWERS:

The interviews were carried out by the students of the project members. The interviewers were familiarized with the questionnaire and trained in the proper manner of questioning as well as being familiarized with the operational definitions in order to maintain the uniformity of interpretation and explanation for the benefit of the illiterate and non-English speaking respondents. It was stressed that the interviewers write the responses as stated by the respondents and not their own interpretation of what was stated. A brief introduction about the purpose and nature of the study and assurance about confidentiality were explained to the respondents prior to the interview.

DATA COLLECTION:

- The relevant data required for the study will be collected using self designed patientprofile forms questionnaires which will be validated by the doctor.
- The data regarding the complication reported is collected by using patient record forms inthe hospital and during patients follow up to the hospital.
- The questionnaire form takes into the consideration both the past and the present data ofthe patient.
- Data will be collected directly by asking patients or by referring patient medication records, physician and patient care takers followed by the written consent of the patient after describing about the study.
- Assessment of mortality rate in newborns is done by using APGAR score.
- Assessment of complication is done manually and reported in statistical format.

The data will be collected from pregnant women during their regular check up's and follow up's.

FOLLOW-UP:

Follow up is done in order to collect data from the pregnant woman's during their totalgestational period.

DATA MANAGEMENT:

After data is collected, it was documented in excel sheet for monitoring and verification.
Strict privacy and confidentiality was maintained during data collection and processing.

ETHICAL ISSUES:

The following ethical issues were considered in the design of the study:

1. The participants were briefed regarding the nature, objectives and method of study and theirvoluntary participation acquired.
2. Total confidentiality with regard to the identification of the participants and informationvolunteered was assured at all times during and after survey.

RESULTS AND DISCUSSION

1. Complications in pregnancy:

During the study period of 6 months a total number of 304 pregnant woman and their new born babies were observed. From the data collected the following results were obtainedas shown in Fig.1.

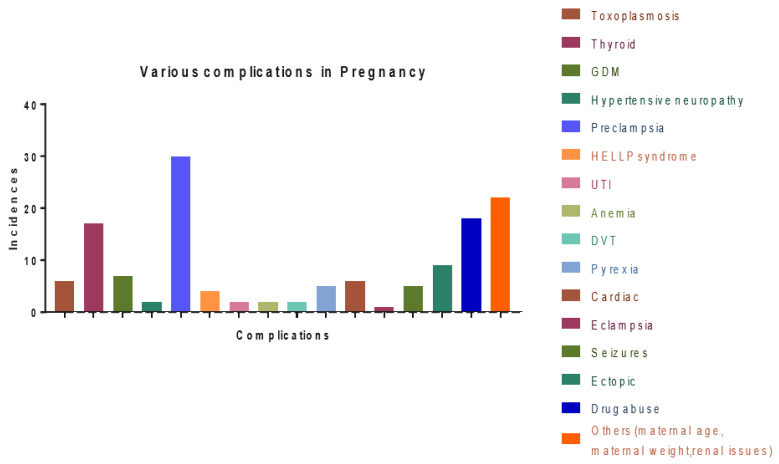

Figure 1: Various complications in pregnancy

Various types of complications arise before or during pregnancy. The major complications reported during our study period include preeclampsia(which means onset of high blood pressure and proteinuria condition) maternal weight related, age related complications(miscarriage placental abruption, hyper emesis gravidarum), thyroid disorders anddrug abusers either knowingly or unknowingly by the pregnant woman had led to complications. Other complications such as toxoplasmosis (rubella infection), gestational diabetes and ectopic pregnancies are reported in some pregnant woman. From the data collected,we observed complications with

high rate included preeclampsia, drug abuse, thyroid and maternal weight related. A total of 30 cases for preeclampsia, 18 cases for drug abuse, 17 cases for thyroid, 13 cases for maternal weight related complication were reported. Age related complications, gestational diabetes, toxoplasmosis cardiac diseases and chickenpox cases reported were 9, 7, 6,6 and 4 respectively. A total of 4 cases were reported for HELLP syndrome. DVT, UTI and eclampsia together accounted for 5 cases while other complications including pyrexia, depression, PCOD and anemia are reported for 10 cases. Large number of cases of preeclampsia followed by drug abuse, and thyroid cases were observed. Other cases such as HELLP syndrome, UTI, eclampsia, toxoplasmosis etc., have occurred less in number. These complications experienced by the mother during the pregnancy may affect the health of the mother or the fetus or both.

2. Age based comparison of complications:

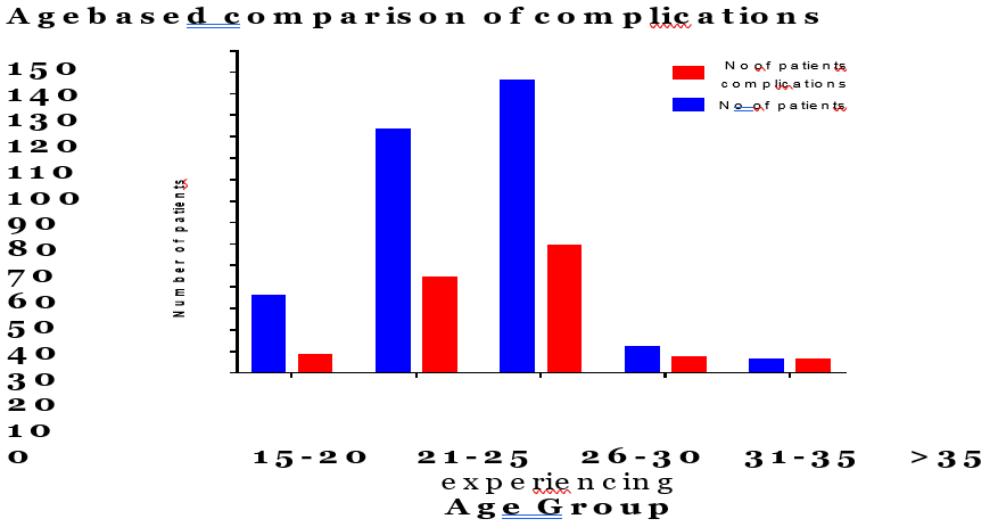

Figure 2: Age based comparison of complications

Fig.2 compares maternal age with the complications experienced by the pregnant woman within a specific maternal age.During our study by taking age range of 5 years we observed the number of pregnancies occurring and complications experienced by the mother in that particular age range . By comparing the plottedresults we reported that 22.2% of the patients of age group 15-20 years have experienced complications whereas 38.9% of patients of age group 21-25years have experienced complications. About 43.38% of the patients of age group 26-30 years have experienced complications and 58.3% of the patients of age group 31-35 years have experienced complications. All the patients belonging to the age group of >35 years have experienced complications.As the age of the patients increases the risk of experiencing the complications also increase. Hence the age groups above 35 years of age are exposed to higher risk of developing complications in both the mother and the fetus.

3. Type of delivery procedure:

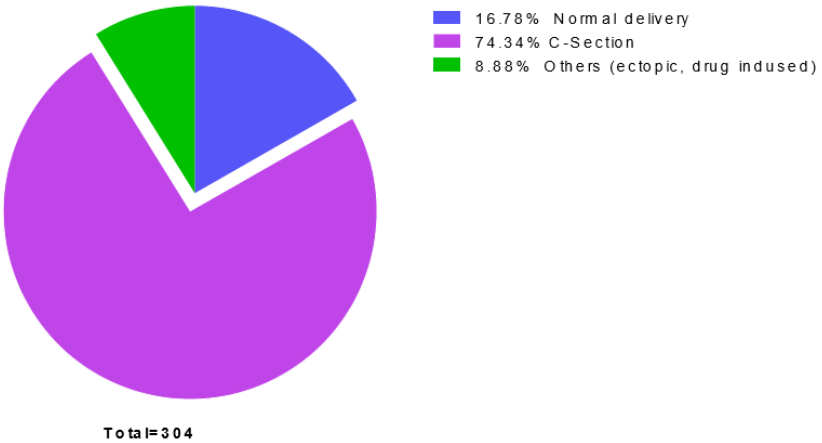

Figure 3: Type of delivery procedure

In Fig.3 we have plotted the information regarding the type of the delivery procedure i.e., number of C-sections (caesareans) performed, number of normal deliveries and the number of ectopic or drug induced aborted conditions.From the data collected in our study period, we observed that 226 women had undergone c-section and 51 cases had normal delivery and 27 cases are ectopic and drug induced aborted ones.A C-section is

performed in complicated cases considering the safety of the mother or the fetus or both. It is mainly preferred if the mother has any health conditions such as cardiac problems, high blood pressure or any infection that could affect the baby during vaginal delivery. It is also preferred in case of absence of fetal movements or any other complications related to the baby.Another major reason include reduction in baby's oxygen supply and changes in baby's heartbeat or if baby is in abnormal position which is difficult for a normal delivery or if mother is carrying multiples C-section is recommended. Ectopic pregnancy is a condition in which the fetus gets attached in the fallopian tube i.e. other than the uterus and starts development in the fallopian tube. Hence, in such cases the fallopian tube is removed by surgical procedure.

4. Condition of the baby:

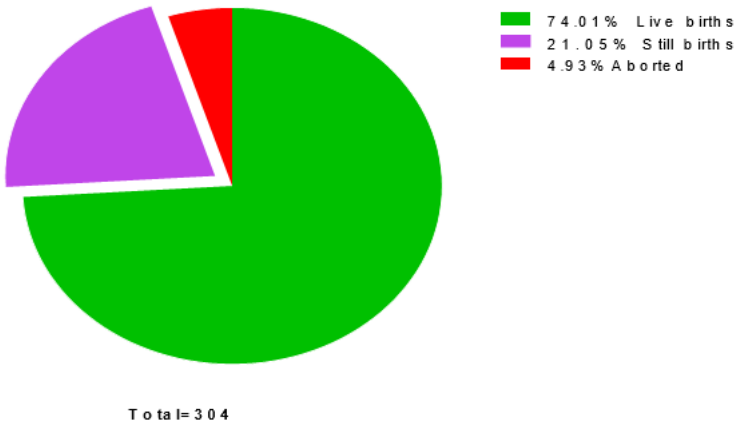

Figure 4: Condition of the baby after delivery

Fig.4 shows the outcomes that are reported during our study period. The outcomes include live births or still births or abortions.Out of 304 cases we have collected 74.01% of live births were reported, whereas about 21.05% of still births were observed. 4.93% of abortions were observed. Reasons for still births include placental problems or pregnancy related form of high blood pressure i.e., preeclampsia, birth defects due to chromosomal disorders, bacterial infections during gestation period, lack of oxygen supply to the fetus, inadequate prenatal care, drug abuse, mal nutrition, maternal age and weight.
In our study period we observed still births occurred mostly in preeclampsia, drug abuse, thyroid disorders, maternal weight related complications and HELLP Syndrome cases.

5. Condition of the baby associated with the complication experienced by mother:

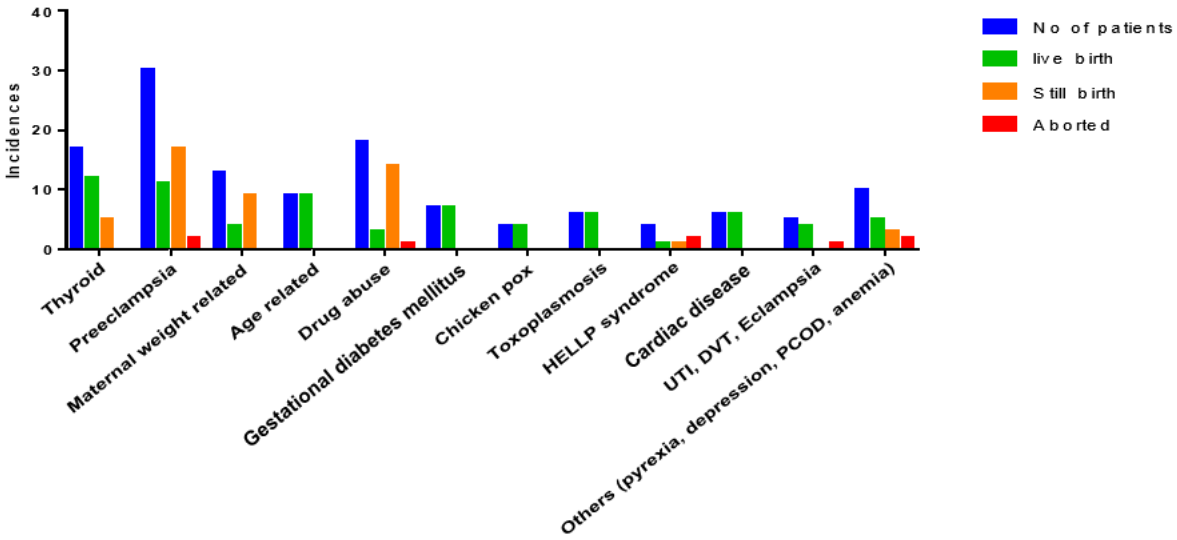

Figure 5: Condition of the baby associated with the complication experienced by mother

Fig.5 indicates the number of the patients experiencing complications and the number of live births, still births and aborted cases reported in relation to that specific complication. From the data collected, the following results have obtained.

Percentage of live births in exposed group:

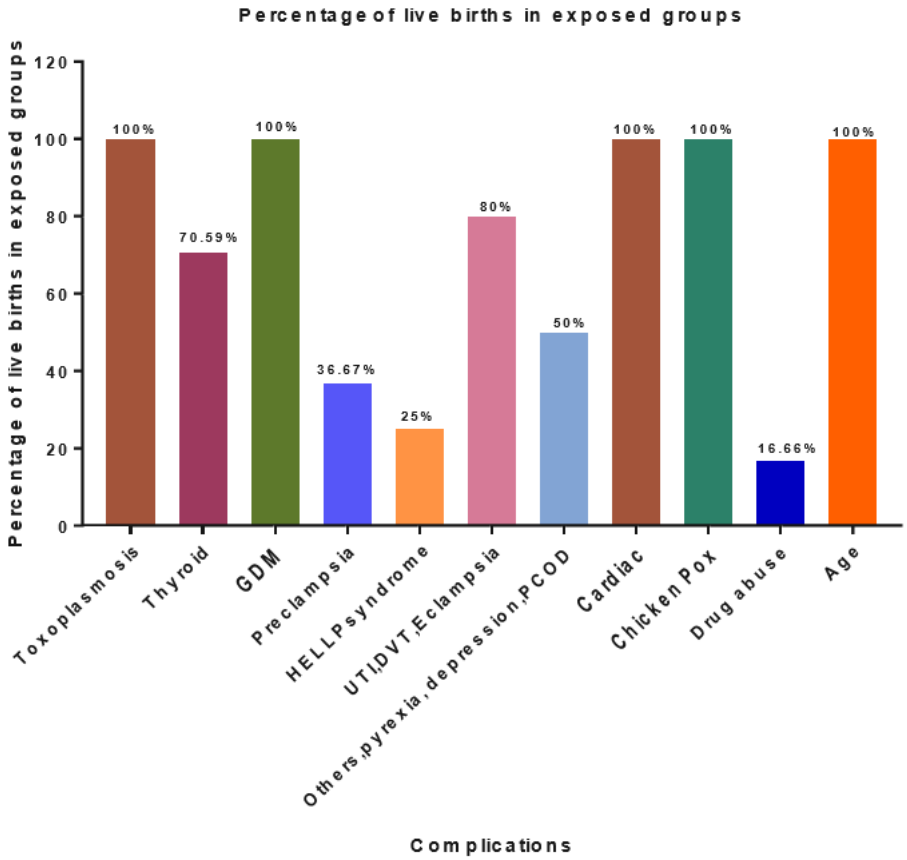

Figure 6: Percentage of live births in exposed group

100% of live birth infants were observed in the patients with the complications chicken pox, toxoplasmosis, cardiac diseases, gestational diabetes mellitus and age related. The live births in the infants born to the patients with drug exposure, HELLP syndrome, maternal age related are very less
This indicate that there is high risk in the infants born to the mothersexposed to different OTC medications, larger maternal weight, HELLP syndrome etc.,

Percentage of still births in exposed group:

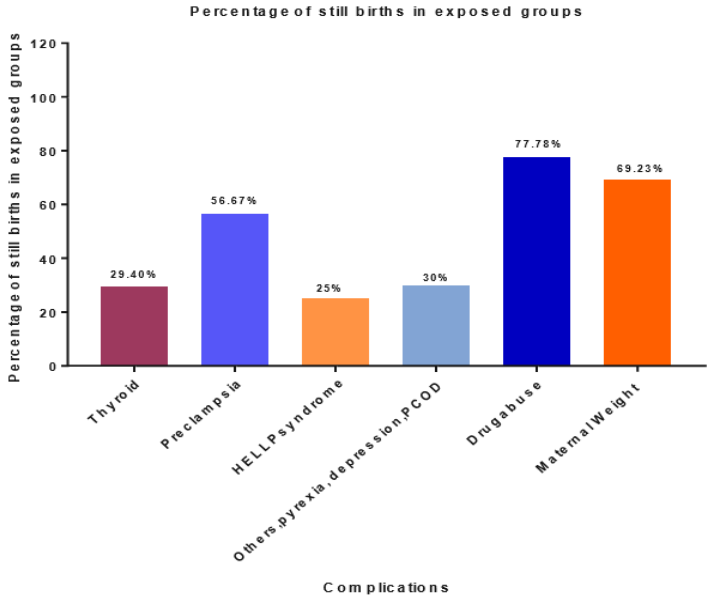

Figure 7: Percentage of still births in exposed group

In 5.6% of the patients exposed to thyroid 29.40% of the still birth infants were observed. 9.87% of the patients were exposed to preeclampsia of which 55.67% of still birth infants were observed (see Fig.7). A total of 1.31% of patients were exposedto HELLP syndrome of which 25% of still birth infants were observed, 5.92% of

patients were exposed to OTC medications of which 77.78% of still birth infants were observed and 4.28% of larger maternal weight patients were observed of which 69.23% of still birth infants were observed. From 3.29% of cases exposed to other factors such as pyrexia, PCOD, anemia etc., 30% of still birth infants were observed.

Large numbers of still births were observed in the patients exposed to complications such as maternal weight related, preeclampsia, and drug abusers. Hence the patients exposed to these complications are at higher risk of experiencing fetal death exposed to these complications.

Table III. Risk assessment (Odds ratio, relative risk, attributable risk, sensitivity,specificity):

Birth defects observed in the new born due to various conditions experienced by the mother during her pregnancy								
	Birth defects		**Odds ratio**	**Relative risk**	**Attributable risk**	**Sensitivity**	**Specificity**	**P value**
	Present	**Absent**						
ThyroidPresent Absent	6 49	6 166	3.39	2.194	0.2721	0.1091	0.9651	0.05
Preeclampsia Present Absent	1 54	10 162	0.3	0.3636	0.1591	0.01818	0.9419	0.05
GDM PresentAbsent	3 52	4 168	2.42	1.813	0.1922	0.0545	0.9767	0.05
Anemia PresentAbsent	1 54	2 170	1.57	1.383	0.0922	0.01818	0.9884	0.05
Maternal weight related Present Absent	13 42	0 172	infinity	5.095	0.8037	0.2364	1	0.05
Maternal age related Present Absent	9 44	0 172	infinity	4.909	0.7963	0.1698	1	0.05
Drug abuse Present Absent	3 52	3 169	3.25	2.125	0.26	0.05455	0.9826	0.05
Chicken pox Present Absent	1 54	0 172	infinity	4.185	0.76	0.01818	1	0.05
Toxoplasmosis Present Absent	4 51	2 170	6.67	2.889	0.4359	0.07273	0.9884	0.05
HELLP syndromePresent Absent	1 54	0 172	infinity	4.185	0.7611	0.01818	1	0.05
DVT Present Absent	0 55	3 169	0	0	0.25	0	0.9826	0.05
Cardiac Present Absent	5 50	0 172	infin ity	4.44	0.77	0.0909	1	0.05

The above data suggests that there is an association of the occurrence of birth defects in the newborn to the complications experienced by the mother during her pregnancy.There are infinite chances of developing birth defects due to the exposure groups such as larger maternal weight, older maternal age, chicken pox, HELLP syndrome and cardiac issues (OR=infinite). The chanceof developing birth defects due to the exposure group is higher in case of toxoplasmosis (OR=6.67) followed of drug abuse (OR=3.25), gestational diabetes mellitus (OR=2.42) and anemia (OR=1.57).. In comparison to these results the chances of developing birth defects are less in case of preeclampsia (OR=0.3) condition. The mortality rate is more in case of preeclampsia due to its exposure in early gestational age in the mother.

CONCLUSION

Based on the findings obtained from our study several complications were observed in the pregnancy condition. We studied the birth defects associated with different complications experienced by the mother such as thyroid causing cerebral palsy, cleft lip, larger maternal weight causing heart defects, limb deficiencies, spina bifida, older maternal age causing down syndrome, drug abusers such as isotretinoin causing septal heart defects, diclofenac causing limb deficiencies, gestational diabetes mellitus causing cleft lip, chicken pox, toxoplasmosis, jaundice causing cerebral palsy, anemia causing spina bifida, cardiac diseases in mother may cause cardiac defects in the infants.The maximum birth defects were observed in the infants born to themothers with cardiac issues, HELLP syndrome, chicken pox, older maternal age and larger maternal weight (OR=infinity). Preeclampsia associated birth defects were observed to be less significant (OR=0.3).In our study maternal weight also posed maximum risk of developing birth defects (RR=5.09) followed by older maternal age (RR=4.909), cardiac diseases (RR=4.44), chickenpox (RR=4.185), HELLPsyndrome (RR=4.185). The risk of developing birth defect is low in case of preeclampsia (RR=0.3636).In our study incidence of birth defects are more due to maternal weight (AR=0.8037) followed by older maternal age (AR=0.7963), cardiac issues (AR=0.77), HELLP syndrome (AR=0.7611), chicken pox (AR=0.76), the incidence of birth defects due to DVT (AR=0.1591) and preeclampsia (AR=0.25) are less.

Overall our study reports that the birth defects due to older maternal age, increased maternal weight, cardiac issues and HELLP syndrome are more whereas the birth defects due to preeclampsia and DVT were found to be less.

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