Prescription Pattern in Pregnant Women in a Tertiary Care Hospital of West Bengal

Amit Kumar Ghosh¹, Mausumi De², Ajanta Sarkar³

¹Associate Professor, Department of Pharmacology, RG Kar Medical College, Kolkata, West Bengal. ²Associate Professor, Department of Pharmacology, RG Kar Medical College, Kolkata, West Bengal. ³Postgradute Trainee, Department of Pharmacology, RG Kar Medical College, Kolkata, West Bengal.

ABSTRACT

BACKGROUND
The World Health Organization (WHO) addressed drug utilization as the marketing, distribution, prescription and use of drugs in a society, considering its consequences, either medical, social and economic. There are several limitations on the use of drugs during pregnancy as there is a potential risk of malformations of foetuses. So, drugs have been classified into several categories (A, B, C, D, X and N) according to their safety profile during pregnancy. It is found that a pregnant woman received on an average 2 to 3 prescription drugs throughout her pregnancy period due to different medical problems. Overall dispensed drug use (excluding vitamins) decreased during pregnancy. However, there is still substantial exposure to drugs including drugs that are contraindicated during pregnancy. We wanted to determine, the use of different pregnancy categories of drugs in 1st, 2nd and 3rd trimesters for preventive and therapeutic purposes, commonly prescribed medicines in each trimesters, adverse drug reactions, congenital malformations, low birth weights abortions, premature deliveries and prolongation of hospital stay of mother and baby.

METHODS
It is a retrospective study with cross sectional design among the pregnant women admitted in the Department of Obstetrics and Gynaecology, R. G. Kar Medical College and Hospital. After taking written informed consent from the pregnant women or their relatives, few relevant questions were asked to the mothers attending postnatal clinic and/or admitted in the gynaecology and obstetrics department of R. G. Kar Medical College. The antenatal card of the mother was examined, and the list of drugs were documented which they had received during antenatal period for different problems. Information like name, age, address, parity, contact number etc. were registered accordingly. Drugs prescribed to them were noted along with indications.

RESULTS
107 prescriptions were studied and outcome were noted. From the study it is found that category A is the safest category and most commonly used category of drugs. The next commonly used drug is category N.

CONCLUSIONS
Few drugs in the unsafe category may be useful to tackle the emergency situations in pregnant women with minimum adverse outcome. So, for Indian subcontinent, a new categorisation of drugs is essential in antenatal use of drugs.

KEYWORDS
Categorization of Drugs, Antenatal, Prescription
BACKGROUND

The World Health Organization (WHO) addressed drug utilization as the marketing, distribution, prescription and use of drugs in a society, considering its consequences, either medical, social and economic. There are several limitations on the use of drugs during pregnancy as there is a potential risk of malformations of Fetuses. So, drugs have been classified into several categories (A, B, C, D, X and N) according to their safety profile during pregnancy. It is found that a pregnant woman received on an average 2 to 3 prescription drugs throughout her pregnancy period due to different medical problems. Overall dispensed drug use (excluding vitamins) decreased during pregnancy. However, there is still substantial exposure to drugs including drugs that are contraindicated during pregnancy. In another study it is found that during the gestational period, study mothers received on an average 3.1 prescriptions for nonvitamin drugs. However, the general patterns of use were similar, with higher use in early pregnancy compared to late trimester.

In India there is no established data regarding the safe use of drugs during pregnancy and lactational period in Indian Pharmacopoeia. We have to use the USA (FDA) or Australian categorisation of drug lists to measure the safety profile during pregnancy. There are few reports published all over the world on the drug usage pattern in pregnancy but the current trend in our society is not clear. Moreover, in our country where prevalence of infectious diseases are very high, pregnant women also suffer from several infections throughout their pregnancy periods from 1st to 3rd trimester and physicians are compelled to prescribe drugs of high-risk categories to treat these infections to save the life of the patients. It is seen that in united states about one third of prescription drugs are of high-risk category i.e. C, D X categories. In different studies it is seen that use of some specific medications are markedly decreased or increased. Prescription medication use increased with maternal age and education.

Also, there are several drugs which are cheap and may be safe during pregnancy. But there are no clear data regarding their safety profile in our country, though they are occasionally used by our physicians at the time of crisis. For example, the drug paracetamol has been placed in category N, i.e. unknown by USA (FDA), as few reports of hyperactive children occurred in UK. But in our country paracetamol is prescribed by our physicians for control of raised body temperature in pregnant mothers in all the three trimesters. There is no report of adverse pregnancy outcome or congenital malformation with the use of paracetamol. But, the records regarding safety profile of paracetamol are lacking in our country. There are some chronic diseases like epilepsy, diabetes, hypertension, asthma, psychosis, depression, insomnia etc., where different drugs that are used may be of high-risk category (C, D, X) and we have to use these drugs to control these diseases during pregnancy also. But the pregnancy outcome in these cases are under reported. Medications like benzodiazepine receptor agonists, antidepressants, and antihistamines have showed no correlation of increased risk of congenital malformations. However, benzodiazepines and hypnotic benzodiazepine receptor agonists may increase rates of preterm birth, low birthweight, and/or small-for-gestational-age-infants.

Today’s Physicians are very much worried regarding these special cases and unwilling to treat pregnant mothers even in emergency situations. Physicians are totally blind to choose the safe drug during pregnancy to manage the various common health problems like fever, diarrhoea, urinary tract infection, vomiting, hyperacidity, insomnia, trauma etc.

So, in this situation, we are going to study the different prescriptions written by the physicians for prevention and treatment of various problems during antenatal periods in women attending gynaecology and obstetrics department of R.G. Kar Medical College & Hospital. We wanted to determine, the use of different pregnancy categories of drugs in 1st, 2nd and 3rd trimesters for preventive and therapeutic purposes, commonly prescribed medicines in each three trimesters, adverse drug reactions, congenital malformations, low birth weights abortions, premature deliveries and prolongation of hospital stay of mother and baby.

METHODS

Study Design
It is a propagative study with cross sectional design among the pregnant women admitted in indoor of Obstetrics and Gynaecology department of R. G. Kar Medical College and Hospital. The time periods of this study is 03 (three) months starting from 1st October to 31st December 2017.

Sample Size
Any pregnant lady admitted in the hospital during the study period and willing to give consent may be recruited to this study. So, no definite sample size can be calculated.

Procedures
After taking written informed consent from the pregnant women or their relatives few relevant questions would be asked to the mothers attending postnatal clinic and/or admitted in the gynaecology and obstetrics department of R. G. Kar Medical College. The antenatal card of the mother would be examined, and list of drugs is to be documented which they have received during antenatal period for different problems. Information like name, age, address, parity, contact number etc. will be registered accordingly. The drugs prescribed to them is to be noted along with indications of prescribing these medicines will also be noted. The outcome of these pregnancy i.e. any congenital malformation, foetal death, asphyxia or any adverse effect on mother and baby should be registered. APGAR score at birth would be registered accordingly. Any complications during delivery like post-partum haemorrhage, retained placenta, obstructed labour etc. should be noted. Duration
of hospital stay of mother and baby must be noted and causes of overstaying should be monitored.

**RESULTS**

107 prescriptions were studied and pregnancy outcome were noted. From the study it is found that category A is the safest category and most commonly used category of drugs. The next commonly used drug is category N. In this study it is found that total 524 drugs were used in all the three trimesters. These drugs prescription distribution have been given in table 1.

<table>
<thead>
<tr>
<th>Category</th>
<th>1st Trimester</th>
<th>2nd Trimester</th>
<th>3rd Trimester</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>43 (46.7%)</td>
<td>91 (51.1%)</td>
<td>88 (34.6%)</td>
</tr>
<tr>
<td>B</td>
<td>15 (16.3%)</td>
<td>10 (5%)</td>
<td>55 (21.6%)</td>
</tr>
<tr>
<td>C</td>
<td>12 (13%)</td>
<td>9 (5%)</td>
<td>36 (14.1)</td>
</tr>
<tr>
<td>D</td>
<td>82 (9.1%)</td>
<td>01 (0.6%)</td>
<td>59 (21.5%)</td>
</tr>
<tr>
<td>X</td>
<td>20 (21.7%)</td>
<td>68 (38.2%)</td>
<td>66 (25.98%)</td>
</tr>
<tr>
<td>Total</td>
<td>92</td>
<td>178</td>
<td>254</td>
</tr>
</tbody>
</table>

**Table 1**

<table>
<thead>
<tr>
<th>Pregnancy Outcome</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital anomalies</td>
<td>3(2.8%)</td>
</tr>
<tr>
<td>IUFD</td>
<td>2(1.8%)</td>
</tr>
<tr>
<td>IUGR</td>
<td>10(9.3%)</td>
</tr>
<tr>
<td>Preterm delivery</td>
<td>24(24.29%)</td>
</tr>
<tr>
<td>Low birth weight</td>
<td>46(42.99%)</td>
</tr>
<tr>
<td>Normal baby</td>
<td>20(21.7%)</td>
</tr>
</tbody>
</table>

**Table 2**

**DISCUSSION**

After studying these prescription very minutely is found that out of these congenital anomalies 1 case is bilateral hydronephrosis, 1 case is cleft lip, and 1 case is bilateral renal pelvis dilatation. The causes of IUFD probably that one mother was suffering from PIH and eclampsia with poor general condition, and other was hypothyroidism and was on L-thyroxine. The cause of IUGR was due to uteroaplacental insufficiency and antenatal drug history were tab Promethazine 25 mg (Phenergan), usrosedoxorhylic acid (UDILIV) 300 mg, syrup lactulose, intravaginal clotrimazole and clindamycin (Cansoft CL). It is seen that most of the cases pregnancy outcome was uneventful. In 103 cases baby were normal and duration of hospital stay of mothers and baby were not more than 07 days.

It is also found that most of the drugs were prescribed in 3rd trimester (254) where chances of teratogenicity is least followed by 178 drugs in 2nd trimester and 92 drugs in 3rd trimester. So, it is the rule that in 1st trimester all kinds drugs must be avoided except folic acid to prevent open neural tube defect. In our study it is seen that more drugs were prescribed in late pregnancy which is contradictory to the previous study made by Andrade SE and others in USA. In another study it is found that during the gestational period, the study mothers received on an average 3.1 prescriptions for non-vitamin drugs. In our study also the average medication was 4.8 per prescription including vitamins and 1.73 drugs for non-vitamin drugs. So, pregnant mothers offered a minimum amount of medications during her carrying periods though this region is prevalent for infectious diseases. The cause of this reduced medication may be due to fear of teratogenicity of both doctors and patients. It is seen that in United States, about one third i.e. (33%) of prescription drugs are of high risk category i.e. C, D, X categories. In our study it is found that only 13% drugs are of C and D category but no X category drugs are present.

In one research study in United kingdom it is seen that in 1st trimester 4% were FDA category A, 34% B, and 49% C and D combined. By 2nd trimester, prescription of category A medications increased (folic acid, iron) while other categories declined. Category X medications, with potential teratogenic risk that outweighs the maternal benefit, were prescribed to 5714 (7%) women in 1st trimester, and 501 (0.6%) women in 2nd trimester. In our study it is seen that 46.7% drugs are category A, 16.3% category B, 13% category C, D category 2.1% and 21.7% category N but no X category. This discrepancy is mainly due to increased use of folic acid from early pregnancy which is an A category drug. In 2nd trimester category A (51.1%), category B (5%), category C (5%), category D (0.56%), category X (0%) category N (38.2%). In 3rd trimester category A (34.6%), category B (21.6%), category C (14.1%), category D (3.54%), category X (0%), category N (25.98%).

So, from our study it is found that few pregnant women did not receive folic acid supplement as prophylactic treatment to prevent open neural tube defect of foetus because they have not got any antenatal healthcare support.

**CONCLUSION**

Safe use of drug during pregnancy is the rule, so pregnancy categorization of drug is an essential guideline in choosing drugs during pregnancy to treat multiple ailments during pregnancy. Sometimes, physician may be compelled to prescribe unsafe category of drugs titrating risk-benefit ratio. In this study, the average number of drugs prescribed during pregnancy is far less than western countries and high-risk category drugs are very few. Teratogenicity is also very rare compared to western population. This is mainly due to over consciousness and worries of the treating physician. These worries are also harmful especially in emergency situations when general physicians are blind to manage any emergency condition during pregnancy and refer them to specialists for minor ailments. Further, a large-scale study is required to establish the safety profile of different drugs at least of commonly prescribed medicines to manage different emergency situations and also to identify the unsafe drugs.
REFERENCES


