

SURVEILLANCE OF DRUG UTILIZATION PATTERN AND PRACTICES DURING PREGNANCY IN WOMEN ATTENDING ANTE-NATAL CLINIC: A PHARMACO-EPIDEMIOLOGICAL STUDY FROM A TERTIARY CARE TEACHING INSTITUTION

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ABSTRACT

To evaluate the drug utilization pattern and practices during pregnancy in women attending ante-natal clinic of a tertiary care teaching institution of western Uttar Pradesh. An additional objective was to find out relation of women's education with various parameters related to drug use during pregnancy. About 202 pregnant women were interviewed. Category A drugs constituted 54.57%, 86.99% and 41.11%, category B constituted 27.14%, 9.37% and 37.5% and category D constituted 6%, 0.19% and 14.14% of the drugs used during the first, second and third trimester of pregnancy respectively. Self-medication, homeopathic/ herbal drugs, women having knowledge about contraceptives, use of IFA and Calcium during pregnancy, women attending more than five antenatal visits were used more in literate, than in illiterate subjects ($p < 0.001$).

KEYWORDS : Medical audit, Pregnancy, Education, Prescription, Drug utilization, Pattern

Prescription order is an important document between the physician and the patient. Prescribing of drugs is an important skill, which needs to be continuously assessed and refined suitably and it reflects the physician's skill in diagnosis and attitude towards selecting the most appropriate cost effective treatment (Kanakambal, 2001). There is growing concern regarding the irrational production, prescription and the use of drugs in India.

Pregnancy is a special physiological condition, where drug treatment presents a special concern. In pregnancy, drug treatment presents a special concern due to the threat of potential teratogenic effects of the drug and physiologic adjustments in the mother, in response to pregnancy. About 8% of pregnant women need permanent drug treatment due to various chronic diseases and pregnancy-induced complications (Banhidy, 2005).

Drug utilization is the defined marketing, distribution, prescription and the use of drugs in society, with special emphasis on the resultant medical, social and economic consequences (WHO, 1997). Only a few studies have been conducted to analyze drug utilization pattern and practices during pregnancy hence this issue has not been explored by experts of the field. Not even a single study has

been conducted in western Uttar Pradesh till date. With this background the present study was undertaken to evaluate the drug utilization pattern and practices during pregnancy in women attending ante-natal clinic of a tertiary care teaching institution of western Uttar Pradesh. An additional objective was to find out relation of women's education with various parameters related to drug use during pregnancy.

MATERIALS AND METHODS

The current prospective study was planned and executed by the Department of Pharmacology & Microbiology in collaboration with Department of Obstetrics and Gynecology, MSDS Medical College, Fatehgarh during February 2013 to January 2014. The study population consisted of the pregnant women attending the ante-natal clinic of MSDS Medical College.

MSDS Medical College is a state of the art tertiary care teaching institution established in rural outskirts of Fatehgarh to provide super specialty care to underserved population. The first batch of students commenced its academic session in July 2011. Department of Obstetrics and Gynecology is serving primarily patients mainly from lower socio-economic strata of community not only from

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western Uttar Pradesh but also from neighboring states. On an average 70-120 patients seek care at Department of Obstetrics and Gynecology, MSDS Medical College on outpatient (OPD) basis per day. So this growing institution provided us a perfect base to plan and execute this study.

Pregnant women were interviewed in local language, after taking their well-informed written consent. The women's statements were also confirmed from the written record, if available with them. Data was collected one a week for a period of one year. The day of data collection was chosen randomly. A trained person conducted the interviews just after the parents came out of the ante-natal clinic. Data was captured on predesigned proforma. A total of 202 questionnaires were collected and analyzed for various study parameters like; educational status, duration of pregnancy, family income per capita per month, time of first antenatal visit, number of antenatal visits, self-medication practices, number of drugs used, number of herbal/homeopathic drugs used, knowledge about contraceptives and knowledge about drug use during pregnancy.

For the purpose of this study, first trimester was considered for first 12 weeks, second trimester for 13 to 24 weeks and third trimester for 24 weeks onwards. Drug use during pregnancy was classified according to US Food and Drug Administration (FDA) which is as follows (Wilkins, 1998). Category A = multivitamins, iron, folic acid, calcium, thyroxin. Category B = paracetamol, diclofenac sodium, ibuprofen, antacids, metaclopropamide, dicyclomine, rantidine, famotidine, omeprazole, pantoprazole, ampicillin, amoxicillin, cephalosporins, metronidazole, insulin, methyl DOPA. Category C = Nifedipine, Category D = phenobarbitone, carbamazepine, phenytoin. Category x = progesterone.

Permission of Institutional ethics committee (IEC) was sought before the commencement of the study. Informed consent was obtained from the study participants. All the questionnaires were manually checked and edited for completeness and consistency and were then coded for computer entry. After compilation of collected data, analysis was done using Statistical Package for Social Sciences (SPSS), version 20 (IBM, Chicago, USA). The

results were expressed using appropriate statistical methods. Chi-square test was applied to test for proportions wherever applicable. Two-tailed $P < 0.05$ was considered as statistically significant.

RESULTS

A total of 202 (129 primigravida and 73 multigravida) pregnant women were interviewed. 51.9% (105), 39.6% (80) and 8.5% (17) women were in the first, second and third trimester of pregnancy respectively. 7.9% (16), 71.8% (145) and 20.3% (41) women were of less than 20 years, between 20 to 35 years and more than 35 years of age, respectively. The first antenatal checkup was conducted during the first, second and third trimester of pregnancy in 51.9% (105), 39.6% (80) and 8.5% (17) of women, respectively. However, less than three, three to five and more than five antenatal visits were attended by 25.2% (51), 33.7% (68) and 41.1% (83) women, respectively. (Table 1)

Category A drugs constituted 54.57%, 86.99% and 41.11% ($P < 0.001$), category B constituted 27.14%, 9.37% and 37.5% ($P = 0.002$) and category D constituted 6%, 0.19% and 14.14% ($P = 0.054$) of the drugs used during the first, second and third trimester of pregnancy, respectively. Herbal/homeopathic drugs included multivitamins and iron supplements, calcium, liver tonics, local analgesic ointments, drugs for acid-peptic disease, drugs for leucorrhoea and drugs for skin hyper-pigmentation. (Table 2)

Iron, folic acid, vitamins and calcium were the most frequently used drugs, during all the three trimesters of the pregnancy. During the first trimester-anti-emetics, phenobarbitone, isoxsuprine, progesterone and paracetamol, during the second trimester-antacids, protein supplements, antimicrobials and NSAIDs (nonsteroidal anti-inflammatory drugs) and during the third trimester-phenobarbitone, isoxsuprine, antibiotics, NSAIDs, anti-emetics, proton pump inhibitors/ H₂ blockers and antihypertensive drugs (nifedipine, methyl dopa) were the other commonly used drugs. (Table 3)

On evaluating the effect of education on various parameters, it was found that self-medication, homeopathic/ herbal drugs, women having knowledge

Table 1: Socio-Demographic Profile of Study Subjects

| Variables | | N (%) |
|--|--------------------|-------------|
| Age | <20 years | 16 (7.9%) |
| | 20-35 | 145 (71.8%) |
| | >35 years | 41 (20.3%) |
| Educational status | Literate | 90 (44.6) |
| | Illiterate | 112 (55.4) |
| Duration of pregnancy | First trimester | 16 (7.9%) |
| | Second trimester | 53 (26.2%) |
| | Third trimester | 133 (65.9%) |
| Gravida | Primigravida | 129 (63.9%) |
| | Multigravida | 73 (36.1%) |
| Time of first Antenatal Check-up (ANC) | First trimester | 105 (51.9%) |
| | Second trimester | 80 (39.6%) |
| | Third trimester | 17 (8.5%) |
| Total ANCs done | <3 | 51 (25.2) |
| | 3-5 | 68 (33.7) |
| | >5 | 83 (41.1) |
| Family income per month | Less than 5000 Rs | 105 (52.0) |
| | 5000 – 15000 Rs | 57 (28.2) |
| | More than 15000 Rs | 40 (19.8) |

Table 2 : Pattern of Different Categories of Drugs Used During Pregnancy

| Category | First trimester* | Second trimester** | Third trimester*** | P Value |
|--|------------------|--------------------|--------------------|---------|
| | N (Percentage) | N (Percentage) | N (Percentage) | |
| A | 191 (54.57) | 455 (86.99) | 125 (41.11) | <0.001 |
| B | 95 (27.14) | 49 (9.37) | 114 (37.5) | 0.002 |
| C | - | - | 18 (5.92) | NA |
| D | 21 (6.00) | 1 (0.191) | 43 (14.14) | 0.054 |
| X | 20 (5.71) | - | - | NA |
| Others# | 23 (6.57) | 18 (3.44) | 4 (1.32) | 0.877 |
| Total number of drugs 350*, 523**, 304***; herbal and homeopathic# | | | | |

about contraceptives, use of IFA and Calcium during pregnancy, women attending more than five antenatal visits were used more in literate, than in illiterate subjects. The difference was found to be statistically significant. (Table 4)

DISCUSSION

The current study assessed drug utilization pattern and practices during pregnancy in women attending antenatal clinic of a tertiary care teaching institution and found out relation of women's education with various parameters related to drug use during pregnancy. Valid conclusions were drawn on the basis of data collected by interviewing 202 pregnant women.

Our study revealed that folic-acid was taken by only 52% of women (23%, 16% and 13% women in the first, second and third trimester, respectively). It is well known fact that folic-acid supplementation in pregnancy is associated with the decreased incidence of habitual spontaneous abortion and pregnancy complications (e.g., placental abruption and preeclampsia) (Hernandez, 2002). It is a noteworthy observation which need to be addressed.

It was observed in this study that the majority of the drugs used during pregnancy were from category-A, followed by category-B and category-D. Category A drugs constituted 54.57%, 86.99% and 41.11%, category B constituted 27.14%, 9.37% and 37.5% and category D

Table 3: Pattern of Various Drugs Used During Pregnancy

| Description of drugs | Category# | First trimester* | Second trimester** | Third trimester*** |
|------------------------|-----------|------------------|--------------------|--------------------|
| | | Number (%age) | Number (%age) | Number (%age) |
| Vitamins | | 43 (12.28) | 57 (10.89) | - |
| Iron | A | 41 (11.71) | 170 (32.5) | 62 (20.39) |
| Folic acid | | 80 (22.86) | 81 (15.49) | 39 (12.83) |
| Calcium | | 27 (7.71) | 145 (27.72) | 22 (7.24) |
| Thyroxin | | - | 2 (0.38) | 2 (0.66) |
| Paracetamol | B | 16 (4.57) | - | 10 (3.29) |
| NSAIDs | | - | 12 (2.29) | 29 (9.54) |
| Isoxsuprine | | 14 (4.00) | - | 20 (6.58) |
| Insulin | | 3 (0.86) | 2 (0.38) | 2 (0.66) |
| Ant acids | | 9 (2.57) | 26 (4.97) | 5 (1.64) |
| Anti-emetics | | 41 (11.71) | - | 13 (4.28) |
| PPIs/H2 blockers | | - | 4 (0.76) | 12 (3.95) |
| Antibiotics | | 12 (3.43) | 3 (0.57) | 18 (5.92) |
| Antiprotozoals | | - | 2 (0.38) | - |
| Methyldopa | | - | - | 5 (1.64) |
| Nifedipine | C | - | - | 18 (5.83) |
| Phenobarbitone | D | 18 (5.14) | | 41 (13.49) |
| Anti-epileptics | | 3 (0.86) | 1 (0.19) | 2 (0.66) |
| Progesterone | X | 20 (5.71) | - | - |
| Ayurvedic preparations | O | 23 (6.57) | 18 (3.44) | 4 (1.32) |

#Total number of drugs 350*, 523**, 304***

Table 4: Relation of Education With Various Parameters Related to Drug Use During Pregnancy

| Parameters | Educational status | | P-value* | |
|---|--------------------|-------------------|------------|--------|
| | Literate (n=112) | Illiterate (n=90) | | |
| | Number (%age) | Number (%age) | | |
| Self-medication Practices | 85 (75.89) | 32 (35.55) | <0.001 | |
| Use of homeopathic/ herbal drugs | 37 (33.03) | 14 (15.55) | 0.004 | |
| ANCs done | <3 | 5 (4.46) | 46 (51.11) | <0.001 |
| | 3-5 | 41 (45.56) | 27 (24.10) | 0.27 |
| | >5 | 65 (58.04) | 18 (20.0) | <0.001 |
| Knowledge about contraceptives | 98 (87.5) | 22 (24.44) | <0.001 | |
| Use of IFA and Calcium during pregnancy | 90 (80.36) | 29 (32.22) | <0.001 | |

*P-value <0.001, Highly Significant

constituted 6%, 0.19% and 14.14% of the drugs used during the first, second and third trimester of pregnancy, respectively. Studies have reported use of potentially harmful drugs (category D drugs-1.5% to 4.8% and category X drugs-2.3 to 4.6%) during pregnancy from other countries of the world also (Carmo, 2004; Bakker, 2006; Riley, 2005).

Regarding self-medication the present study observed that self-medication was significantly higher in literates as compared to illiterates. Another study on similar study subjects revealed that over the counter medication including contraindicated medications like ibuprofen were used at unexpectedly high rates during pregnancy (Glover, 2003). In an epidemiological study, NSAID use during

conception or during pregnancy in 5% women, was associated with an 80% increased risk of miscarriage (Li, 2003).

This study has several strengths. We have identified scope of improvement in rational drug use among pregnant women attending ante-natal clinic in a growing medical college. In-depth analysis of this aspect has not been closely investigated by many experts in the field. This study becomes very important as long lasting impact can be achieved if rectifications of deficiencies are identified well in time and corrected at the earliest. We interviewed the subjects before the pregnancy outcome is known thus minimized the recall bias till great extent. All the investigations were conducted by authors of the study only, which creates a sense of uniformity.

The study has some limitations as well. Some may argue that the results obtained may not be applicable to general population. I agree because these findings are based on a single centre and hospital based study. Hospital based data never reflects true picture. Hence community based studies are warranted. Second, we have not considered certain factors which may have bearing on outcome of this study such as history of chronic diseases, bad obstetric history and multi parity or nulli-parity on the pattern of the drug use.

CONCLUSION

The findings of this study highlight role of education for better outcomes of pregnancy. There is a need to educate women of child-bearing age regarding importance of ante-natal checkups, drug use during pregnancies etc. This data can be utilized in strategic planning to ensure better patient care services in the institution and to improve rational drug use in our facility.

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