Organia Article

Prescription Audit and the Compliance of Medicines Prescribed in Pregnant Women

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Abstract

Proper use of medicines can be ensured in the society through various ways. Scientific and rational prescription is one of them, but at the same time judicious use of medicines by the patients is also equally important. Compliance of therapy can determine fate of any medicine. This study was planned to explore some important aspects of use of medicines in pregnant women in remote villages of India. This was an observational, cross sectional study using face to face interview of the pregnant ladies and also auditing the prescriptions available from them. Present study revealed that the average age of the study population was 23.6 years and primi-gravida (51.4%) constituted slight majority over multi-gravida. Most commonly prescribed medicine during pregnancy was iron, folic acid (79%) and injection tetanus toxoid (91%). A large number of pregnant women (37.5%) were non compliant with the medicine prescribed for them. In modern therapeutics, drugs or

medicines play an important role in the health of any individual. But at the same time its proper use should be ensured. This study showed the importance of use of medicines by the patient. Judicious use of scarce resources on medicines not only improves the quality of therapy but also the quality of life.

Keywords

medicine use, drug compliance, pregnant women, rural india

Introduction

Pregnancy is a physiological process. This period is important for both mother and child ^{19, 12}. Medicines are used during pregnancy for preventive, promotive and curative purposes ²⁰. Medicines ²² are chemical substances capable of producing desirable effects as well as adverse effects anytime ¹⁶. It was established after the thalidomide

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tragedy ¹⁸, that judicious and cautious use of medicines during pregnancy possesses an important place in therapy. It is essential to use safe and rational medicine during pregnancy ¹¹. Though medication during pregnancy is wide spread, there is still lack of comprehensive and valid data worldwide about the use of medicine during pregnancy ⁸.

Successful action of any drug depends not only on efficacy of the drug, but also on rational and judicious prescribing, proper use by the consumers as far as dose, frequency and duration is concerned ¹⁰ and also on some other factors. For medicine use in any society, a chain of four factors are important. They are: the pharmaceutical industries, wholesaler-retailer-pharmacist chains, the physician and the patients. Any defect at any point of this chain can lead to irrational use of medicine in the society. Studies evaluating the medicine use are useful to explore the actual situation about it in any society¹.

The assumption that the doctor tells the patient what to do and the patient meticulously follows orders is unrealistic. It must be recognized that the patient is the final and most important determinant of how successful a therapeutic regimen will be. Compliance with a medication regimen is generally defined as the extent to which patients take medications as prescribed by their health care providers ¹⁷. For successful therapy, especially if it is of long term duration, adherence of the patient with the therapy is a prerequisite. Even the most carefully prepared prescription for the ideal therapy will be useless if the patient's level of compliance is not adequate ¹³.

Lots of studies have been conducted throughout the world on medicine use by pregnant women ^{7,6}. But in India, there are very few studies on this important issue ^{21, 23, 14} especially in rural areas. Therefore, the present study was justified and timely one.

Materials and Methods

It is a cross sectional study using questionnaires and face-to-face interview. Pregnant women attending the antenatal clinics from 1st January 2005 to 31st August 2006 were informed about this study. Randomly selected six hundred and fifty six pregnant women were included in the study. The study was carried out in different villages of Anji, Bhidi & Talegaon areas of Wardha district of Maharashtra state of India. Only those women agreed to participate in this study were interviewed with a

questionnaire. Informed consent was taken from all pregnant women. The questionnaire was validated by pre-testing. A pilot study was done with fifty pregnant women from a nearby village, which was not included in the study. Prescriptions available from the pregnant women were copied and evaluated later. The study was planned according to the WHO guidelines ²⁴. The study was conducted after taking prior permission from Institutional Ethical Committee. Results in this study were expressed in terms of percentage.

Observations

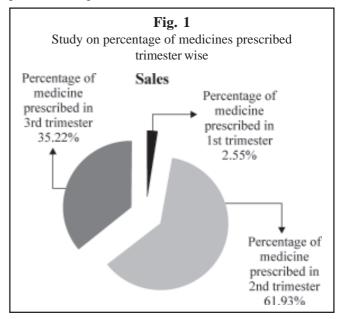
Present study showed 63.9% pregnant women were in the age group of 20-24 years, with a range of 18 to 35 with most common age 20 years. Religion-wise distribution showed that most of the women i.e., 84% belonged to Hinduism, followed by Buddhism (13.9%), Islam 1.8% and Christianity 0.3%. Majority (59.8%) of pregnant women were from low socio-economic sector of the society. 51.4% pregnant women were primi-gravida and 48.6% multigravida. Among the multi-gravida, maximum was 2nd gravida, 35.2%. Trimester wise distribution showed 62% and 26% women were of 2nd and 3rd trimesters respectively, with minimum in first trimester. 63.3% women were housewives, 20.1% were unskilled labour mainly engaged in farming, skilled labour 4.3% mainly engaged in sewing. 71.3% pregnant women have monthly family income of Rs. 1000/- to Rs. 5000/-(INR=Indian National Rupees), with average family income per month of Rs. 2679/-(INR). 66.16% pregnant women belonged to joint family whereas 33.84% from nuclear family.

When pregnant ladies were enquired about the occurrence of illness during this present pregnancy, 61.6% pregnant women informed that they did not suffer from any illness. But 38.4% pregnant women suffered from different types of illness, like abdomen pain, urinary tract infection, gastroenteritis and dermatitis. Out of those who suffered from different illness, 47.2% did not consult any physician for their illness. Out those who consulted for their illness during this pregnancy, 50.4% consulted with private allopathic doctors, 29.3% consulted with medical college doctors, 9.8% pregnant women consulted with the doctors of Govt. district hospital, 6.8% with doctors of primary health centre, 3% with the practitioners of other system of medicine, mainly Homeopathy and Ayurveda. Only 0.8% (1) pregnant women consulted with unqualified medical practitioners.

Pregnant women when enquired about the informant who provide them information on proper use of medicines as per as dose, frequency and duration are concerned, informed that mainly doctors (64.5%) provided them necessary information; whereas 25% got information from village health workers and 10.5% from the persons of chemist shops.

Present study audited 565 prescriptions and observed that 1508 number of number of medicines were prescribed, so, number of medicines prescribed per prescription was 2.66. On the contrary, 7.61% prescriptions were without any medicine and only with advice and direction for investigation. Percentage of drugs prescribed in pregnant women of different trimester were 2.55% (1st trimester), 61.93% (2nd trimester) and 35.52% (3rd trimester) respectively (**Fig. 1**). 21% medicines were prescribed by generic names and 18% from essential drug list. Injection tetanus toxoid (91%) was the most commonly prescribed injection. Other than tetanus toxoid injection, a total of 62 injections belonged to antibiotic, hormones and antiemetic group were prescribed. Percentage of encounters with an injection prescribed (other than tetanus toxoid) was 10.97.

commonly prescribed medicines for pregnant women were of iron, folic acid or their combinations, 79% prescriptions contain one or more of such drugs. Vitamins and Calcium preparations were prescribed in about 58% and 39% prescriptions respectively. Nutrients mainly in the form of powder were prescribed in 7.5% cases. Anti-abortive and



Prescription audit showed (Table 1) that most

Table 1 Study on the medicines prescribed for pregnant women $(n = 565)$		
Drugs Prescribed for Pregnant women	Percentage of prescriptions containing medicine	
Iron & Folic acid preparations (Both individual & combined)	79	
Vitamins	58	
Calcium	39	
Nutrients	7.5	
Anti abortive & Hormonal preparation	11	
Antimicrobials	9.6	
Cephalosporins	27	
Amoxycillin	22	
Clotrimazole	21	
Erythromycin	21	
Ampicillin	9	
NSAID (Aspirin mainly)	7.6	
Antiemetic	5	
Antiallergic	5.6	
Antacids,H2 blockers & PPI	8	
Sedative & hypnotics	1.5	

hormonal preparation, anti-emetic, anti-allergic and antacids (including H2 blocker, Proton Pump Inhibitors-PPI) were prescribed in 11%, 5%, 5.6% and 8% prescriptions respectively. Antimicrobials including antifungal were also prescribed in 9.6% cases. NSAID (Non Steroidal Anti Inflammatory drugs) was one of the commonly prescribed drugs (7.6%) and aspirin was prescribed more frequently by the private practitioners. Sedative and hypnotic were prescribed in 1.5% cases.

Adherence to or compliance with a medication regimen is generally defined as the extent to which patients take medications as prescribed by their health care providers. Compliance of the pregnant women was evaluated in this study by questionnaire and by collecting the used medicine foils. When the women were enquired about their compliance for iron-folic acid preparation, it was observed that a large number of women (37.5 %) were noncompliant for iron-folic acid preparation as far as dose, frequency and duration was concerned. Association between age groups of study population and their compliance for iron and folic acid preparations was evaluated. There is no significant correlation between age and compliance (**Table 2**) for iron and folic acid preparations.

Discussion

The present study showed that the age distribution of study population was same with studies of Uppal *et al.*, 1988²³ and Sharma *et al.*, 2006²¹, India and religion wise with Chandra *et al.*, 1980¹⁹. Educational status of pregnant women in the present study was similar with the results of Bhalerao *et al.*, 1988² in India, but differ from other

international studies like Rubin *et al.* 1993¹⁴. As far income was concerned, Rubin *et al.*, 1993¹⁴ showed in their study at USA, 40% of the pregnant women belonged to middle income group followed by 35.3% belonged to higher income group, which differs from the present study due to socio-economic difference of the two countries.

Analysis of prescriptions revealed that 2.66 medicines was prescribed per prescription in the present study, whereas international studies⁴ observed this parameter as 2.9, but studies for neighbour countries like Nepal, Das *et al.*, 2003⁵ reported this as 2, which is more or less same with the present study. Medicines prescribed in different trimester of the study showed similar results with Sharma *et al.*, 2006²¹.

Iron and folic acid preparations accounts about 79% of the prescription in present study, whereas an international study (CGDUP-Collaborative Group on Drug Use in Pregnancy) 1992⁴ evaluated iron and vitamins alone or in combination accounts 50.5% of all prescription. In Finland, Heikkila *et al.*, 1994⁹ investigated and found that iron and vitamin supplementation was used by all the pregnant women during the third trimester of pregnancy and by 35% and 88% during 1st & 2nd trimester respectively. Present study is in agreement with other studies from Nepal and India like Das *et al.*, 2003⁵, Uppal *et al.*, 1998²³ and Sharma *et al.*, 2006²¹.

Most commonly prescribed injection in this study was tetanus toxoid (91%). Study from Finland (CGDUP), 1992⁴ commented that out of the total prescriptions only 5.8% contained injections. The majority of these were injection

Table 2 Study on association between age and the compliance of the pregnant women (n=656) for iron folic acid preparation		
Age in years	Number of pregnant women complied for the iron-folic acid preparation as far dose, frequency & duration (%)	Number of pregnant women not complied for the iron-folic acid preparation as far dose, frequency & duration (%)
< 20	35 (5.33)	37 (5.62)
20-24	268 (40.85)	151 (23.01)
25-29	85 (12.9)	46 (07)
30-34	21 (3.20)	12 (1.82)
? 35	1 (0.15)	0
Total	410 (62.5%)	246 (37.5)

tetanus toxoid. This result was contradictory with the study mainly because of the better coverage and virtual elimination of tetanus from these developed countries.

21% of prescribed medicines in this study were in generic name and 18% from essential drug list. In a study conducted at Pune, India, Kshirsagar *et al.*, 1998¹⁵ evaluated the pattern of prescription in terms of generic name and from essential drug list, which is in agreement with the present study.

Summary

This study investigated different parameters related to use of medicines by pregnant women. Regular study on medicine use is a prerequisite to evaluate the exact status of medicine use knowledge among general people. Continuous evaluation system among majority of people should be done and data collected from these researches should also be evaluated for planning and implementation of rational therapy. On the other hand doctors and health care providers should be encouraged for rational cost effective prescribing through generic prescription and implementing essential drug concept. These will strengthen the overall health policy and use of medicines in the society in terms of rationality.

References

- Bergman U., Grimsson A., Wahba A.H.W., Westerholm B. — Studies in Drug Utilization, Methods and Applications, World Health organization. WHO Regional Publication. European Series No. 8:1. 1979.
- Bhalerao Ashwini, Purandare Mandakini, Mehta Ajit.
 — Awareness of Family Planning Methods among Pregnant Women. Journal of Obstetrics and Gynaecology of India. 38: 451-455, 1988.
- 3. Chandra R., Saxena S.C, Bagga S.L, Srivastava V.K, Srivastava B.C. Utilization of services of community health workers by rural population. *Indian J Med Res.* **71**: 975-984, 1980.
- 5. Collaborative group on drug use in pregnancy (C.G.D.U.P). Medication during pregnancy: an international cooperative study. *Int J Gynaecol obstet*. **39**: 185-196, 1992.
- 6. Das B., Sarkar C., Dutta A., Bhora S. A study of

- drug use during pregnancy in a teaching hospital in western Nepal. *Pharmacoepidemiol Drug Saf.* **12**(3):221-225, 2003.
- 7. Donati S., Baglio G., Spinelli A., Grandolfo M.E. Drug use in pregnancy among Italian women. *Eur J Clin Pharmacol.* **56**(4): 323-328, 2000.
- 8. Egen-Lappe V., Hasford J. Drug prescription in pregnancy: analysis of a large statutory sickness found population. *Eur J Clin Pharmacol.* **60**(9): 659-666, 2004.
- 9. Hasford J., Irl, C. Drug Utilization during Pregnancy and its Effects on Fetal Outcome The PEGASUS project., EURO DURG first meeting. Rational drug use in Europe: challenges for the 21st century, Balaton, Ungarn 27-30., July 1996.
- Heikkila A.M., Erkkola R.U., Nummi S.E. Use of medication during pregnancy-a prospective cohort study on use and policy of prescribing. *Ann Chir Gynaecol.* 208: 80-83, 1994.
- 11. Hogerzeil V. Hans. Trends in drug utilization research in developing countries. *WHO Drug Information.* **16**(3): 236, 2002.
- 12. Irl C, Hasford J. The PEGASUS project-a prospective cohort study for the investigation of drug use in pregnancy. *Int J Clin Pharmacol Ther.* **35**(12): 572-576, 1997.
- 13. Jejeebhoy Dr. Shireen. J. Maternal mortality and morbidity in India: Profiles for social science research. *Journal of Family welfare*. **43**: 1, 2001.
- Joel G. Hardman, Lee E., Limbird, Alfred Goodman Gillman. *The Pharmacological Basis of Therapeutics*. 10th Edition. McGraw Hill companies Inc.: 1911-1914, 2003.
- Judith D. Rubin, Charlotte Ferencz, Christopher Loffredo and The Baltimore-Washington Infant Study group. — Use of Prescription and Non-prescription Drugs in Pregnancy. *J Clin Epidemiol.* 46: 581-589, 1993.
- 16. Kshirsagar M.J, Langade D., Patil S., Patki P.S. Prescribing patterns among medical practitioners in

- Pune, India. Bulletin of the World Health Organization. **76**(3): 271-275, 1998.
- 17. Lande Anne Kari. Drug utilization statistics and health policy. *WHO Drug Information*. **16**(3): 235, 2002.
- 18. Lars Osterberg, Terrence Blaschke. Adherence to Medication. *N ENGLJ MED*, **353**(5): 487-497, 2005.
- 19. Lenz W. Malformations caused by drugs in pregnancy. *Am. J. Dis. Child.* **112**: 99-106, 1964.
- 20. Park K. Park's Text book of Preventive and Social Medicine., 17th Edition, M/s Banarasidas Bhanot, Jabalpur,: 359-367, 2002.
- 21. Paul W. Lofholm., Bertram G. Katzung. Rational

- Prescribing and Prescription writing. *Basic & Clinical Pharmacology*, Eight Edition, 1091: 2000.
- 22. Sharma R., Kapoor B., Verma U. Drug utilization pattern during pregnancy in North India. *Indian J Med Sci.* **60**: 277-287, 2006.
- 23. Tripathi K.D. *Essentials of Medical Pharmacology.*, Fifth edition, Jaypee Brothers, New Delhi, **4**: 2003.
- Uppal R., Ahmed E., Gupta A.N., Dhall K., Sharma P.L. — Perinatal Prescribing Trends at PGI, Chandigarh. *Journal of Obstetrics and Gynaecology* of India. 586-589, 1988.
- 25. World Health Organization. How to investigate drug use in health facilities, Selected drug use indicators, Geneva, WHO/DAP/93. 1: 25 30, 1993.