

A CROSS-SECTIONAL, OBSERVATIONAL, PROSPECTIVE STUDY FOR EVALUATION OF RATIONAL DRUGS USED DURING PREGNANCY

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ABSTRACT

Background and Objective: Rational use of drugs is well recognized as an important part of health policy. Pregnancy is a special physiological condition, where rational drug treatment presents a special concern because the physiology of pregnancy affects the pharmacokinetics of medications used and certain medications can reach the fetus and cause harm. Total avoidance of pharmacological treatment in pregnancy is not possible and may be dangerous because some women enter pregnancy with medical conditions that require ongoing and episodic treatment (e.g. asthma, epilepsy, and hypertension). So objective of this study was to identify use of rational, irrational and essential drugs from the prescriptions given during pregnancy.

Materials and methods: This was cross-sectional, observational, prospective study in which total 200 prescriptions from three antenatal clinics were collected. The collected data were analyzed for various study parameters.

Results: In 200 prescriptions total 609 drugs were prescribed. Out of 609 drugs 566 (i.e. 92.93%) drugs were rational, 43 (i.e. 7.09%) were irrationally used and 423 (i.e. 69.45%) drugs used were from WHO Essential drug list.

Conclusion: Rational drug use in pregnancy is desirably high. The occurrence of irrational medicines is low but the use of such medicines may be considered in cases where benefits outweigh the risk. There are no definitive and complete answers for the safe use of drugs so there is need to develop the separate Rational & Essential Drug List for drug used in pregnancy.

Keywords: Rational uses of drugs, Pregnancy, Drug use problems, Cross sectional study.

INTRODUCTION

In both the developed and the developing world, medically inappropriate, ineffective and economically inefficient use of pharmaceuticals commonly occurs in health care facilities. Such irrational drug uses are enormous in terms of both scarce resources and the adverse clinical consequences of therapies that may have real risks but no objective benefits [1]. Various studies conducted in developed as well as in developing countries during past few years regarding safe and effective use of drugs shows that irrational drug use is a global phenomena and only few prescription justify rational use of drug [2].

The World Health Organization in Nairobi in 1985 defined that, "Rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and the lowest cost to them and their community"[3]. The definition implies that rational use of drugs, especially rational prescribing should meet certain criteria as follows, appropriate indication, appropriate drug, appropriate patient, appropriate information and appropriate monitoring [1].

Unfortunately, in the real world, prescribing patterns do not always conform to these criteria and can be classified as inappropriate or irrational prescribing. Irrational prescribing may be regarded as "pathological" prescribing, where the above-mentioned criteria are not fulfilled [1]. It has been estimated that fifty percent of medicine being used in this country, either on prescription or over the counter sales, are inappropriately or irrationally used. This can result in three undesirable effects. First the medicine may induce resistance to microorganisms. Secondly irrational use leads to side effects and lastly it is unethical and inequitable to prescribe expensive medicine when an equally effective cheaper medicine is available. Rational use of drug research increases our understanding of how drugs are being used in number of patients within the selected time period. On the basis of epidemiological data of a disease we can estimate to what extent the drugs are properly used, over used or under used. Rational use of drug (RUD) in any disease will give us clue on improving the proper information about use of drugs, its indications,

contraindications and appropriate dosages to assure a safer use so that we can avoid ADRs [1].

Drugs play an important role in improving human health and promoting well being. However, to produce the desired effect they have to be safe, efficacious and have to be used rationally. 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. However, it has been documented that congenital abnormalities caused by human teratogenic drugs accounts for less than 1% of total congenital abnormalities. About 8% of pregnant women need permanent drug treatment due to various chronic diseases and pregnancy induced complications [6].

During pregnancy mother and fetus form a non separable functional unit. In India, 2.5% of newborn have birth defect. Congenital malformation ranked as third most frequent cause for prenatal mortality [4]. Medication during pregnancy is very important and it calls for special attention because in this case in addition to mother, the health and life of her unborn child is also at stake. The drugs given to pregnant mothers for therapeutic purpose may cause serious structural and functional adverse effects in the developing child. So caution should be maintained while prescribing them to pregnant woman [5].

Many studies have been done to document drug use patterns, and indicate that overprescribing, multi-drug prescribing, misuse of drugs, use of unnecessary expensive drugs and overuse of antibiotics and injections are the most common problems of irrational drug use by prescribers as well as consumers. Prevention of potentially harmful drug-drug interactions is an important element in helping patients avoids medication related problems and improving medication safety in inpatients and outpatients settings [8]. Improving drug use would have important financial and public health benefits. Therefore present study is planned to analyze the appropriate and Rational Use of Drugs in Pregnancy based on rule of right i.e. right drug given to right patient, in right dosage at the right cost. The goal of this paper is to examine the available treatment of pregnancy.

MATERIALS AND METHODS

The study was conducted in compliance with the protocol, ICH GCP guidelines, ICMR, Schedule 'Y' and Indian Regulatory requirements. This cross-sectional observational prospective study for Evaluation of Rational Use of Drug during Pregnancy was carried out at three different gynecology hospitals in Nashik city. Total 200 prescriptions were collected from women attending antenatal clinics during 4 months of study duration. Informed consent was taken before enrolling patient in the study. The prescriptions were recorded according to the case record form. The prescriptions were analyzed on the following basis of Percentage of rational drugs in the prescriptions, Percentage of irrational drug use, in terms of Choice of

drug, dose of drug, route of administration, frequency of the drug, duration of treatment. And lastly for percent of essential drug used. Data collected was used for further representation in percentages, charts and diagrams.

RESULTS

Total 200 prescriptions of pregnant women attending three different ante natal clinics at Nasik were analyzed to assess the percent of essential drugs, rational drugs and irrational drugs in prescription. In 200 prescriptions total 609 drugs were prescribed. Out of 609 drugs 566 (i.e. 92.93%) drugs were rational and 43 (i.e. 7.09%) were irrationally used. 423 (i.e. 69.45%) drugs were from WHO Essential drug list.

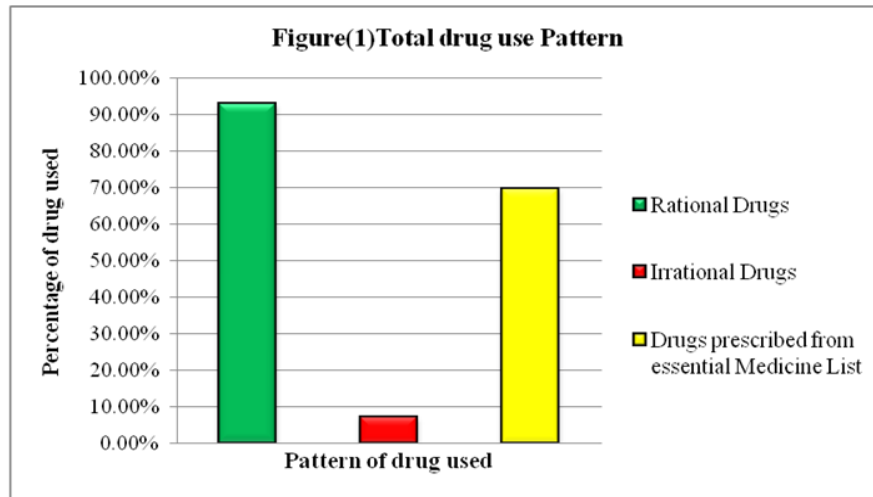


Fig. 1: Total drug use pattern

Each of 161 prescriptions which contain 90-100% of drugs which were used rationally, 5 prescriptions had 80-90%, 3 prescriptions had 70-80%, 22 had 60-70% and 9 prescriptions had 50-60% Rational Drugs.

Table 1: Percentage of Rational drugs per prescription

S. No.	Percentage of Rational Drugs	No. of Prescription
1	90 – 100 %	161
2	80 – 90 %	05
3	70 – 80 %	03
4	60 – 70 %	22
5	50 – 60 %	9
Total		200

Each of 11 prescription contain 50-60% of irrational drugs, 1 prescription contain 40-50%, 18 prescription contain 30-40%, 7 prescriptions contain 20-30%, 1 prescription contain 10-20% and 162 prescription contain only up to 10% of irrational drugs.

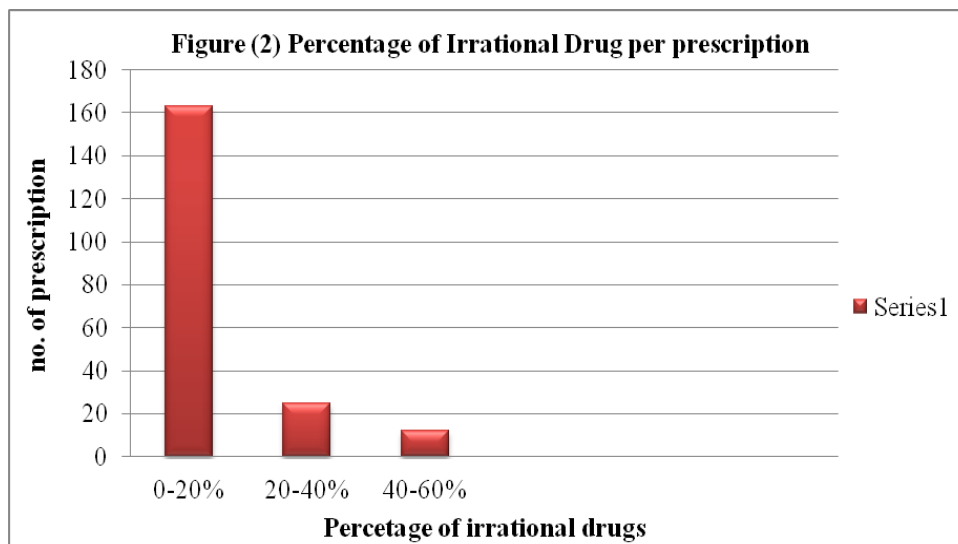


Fig. 2: Percentage of irrational drug per prescription

Each of 88 prescriptions contain 80-100% of essential drugs, 56 prescription contain 60-80%, 35 prescription contain 40-60%, 12 prescription contain 20-40% and 9 prescription contain upto 20% of drugs from essential drug list

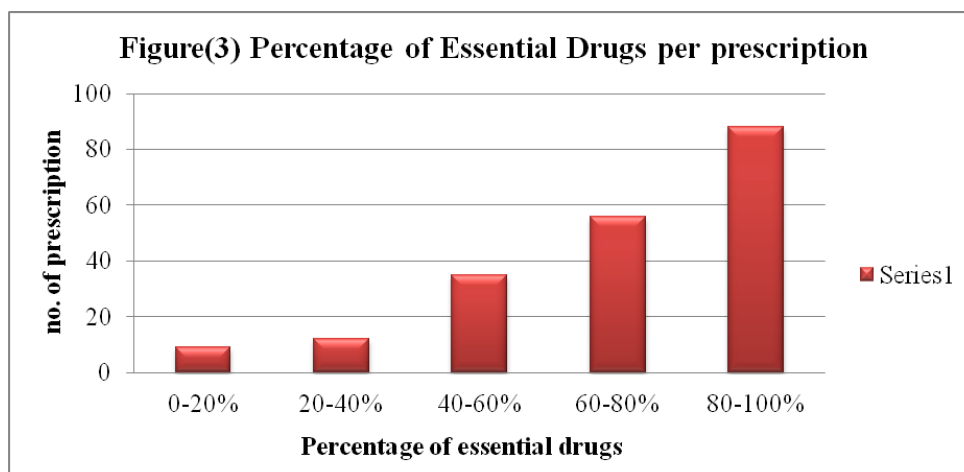


Fig. 3: Percentage of essential drugs per prescription

DISCUSSION

The use of drug during pregnancy is a question of fine balance; no harm should be allowed to the baby due to any drug, and no harm should be allowed to the mother or baby due to a disease is being inadequately treated [7]. Rational drug use in pregnancy is desirably high. It requires the balancing of benefits and potential risks associated with the use of the drug. The prescription of drugs during pregnancy must be evaluated carefully, weighing the risks versus benefits for both fetus and mother.

The occurrence of irrational medicines was low but the use of such medicines may be considered in cases where benefits outweigh the risk. However, the available information provides the physician with a choice of various therapeutic and prophylactic options within relatively safe limits. To attain the ideal healthcare service doctor, pharmacist, nurse and other healthcare professionals must work together [9].

There are no definitive and complete answers for the safe use drugs so there is need to develop the separate Rational & Essential Drug List for pregnancy.

CONCLUSION

Our study supports the concept of rational drug use during pregnancy. We found that around 93% (566) drugs used were rational and almost 81% (161 out of 200) prescriptions following rule of rationality. Most of the prescriptions in our study contain the nutritional supplements. So in conclusion, it is believed that the

exposure to drug use during pregnancy can be reduced except for the chronic diseases like epilepsy, asthma, hypertension etc.

REFERENCES

1. WHO booklet "Assessing the problems of irrational use of drugs" 2003, ISBN 92 4 156234X
2. Ambwani S & Mathur, A, Rational drug use, health administrator, vol 19, 2006 p.5-7.
3. Sharma HL, Sharma KK. Concept of essential medicine & rational use of drugs in Principle of Pharmacology, Pras publication 2001:9, 106-107.
4. Park K, Preventive and social medicine, 18thed., Banarsidas Bhanot publishers 2005.
5. Kulkarni P 2007, Drugs in pregnancy, viewed 6 March 2010, <<http://www.pharmainfo.net/reviews/drug-pregnancy>>.
6. Sharma R, Kapoor B, Verma U Drug utilization pattern during pregnancy in North India. Indian J Med Sci. 2006 Jul; 60(7):277-87.
7. E. Bhavya, T. Sankaravadiyu, K.Vivekanandan, An Epidemiological Study on Drug Use in Pregnancy Current Pharma Research Vol. 1, Issue 1, October-December 20
8. Bhaskar HV, Sathish A Physicians expectations to prevent the drug interactions in clinical practice Int j pharmacy and pharm sci, vol 2, issue 3, 172-173, 2010
9. Manik CS, Das AK, Medication Practices in Bangladesh-Roles of Pharmacists at Current Circumstances Int j pharmacy and pharm sci, Vol 3, Suppl 4, 2011