

**ASSESSING THE PATTERN OF DRUG USE AMONG PREGNANT WOMEN AND
EVALUATING THE IMPACT OF COUNSELLING ON MEDICATION
ADHERENCE AMONG THEM**

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Article Received on: 10/06/11 Revised on: 12/07/11 Approved for publication: 09/08/11

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ABSTRACT

In the present study an attempt is made to assess the pattern of drug use among pregnant women and to evaluate the impact of counseling on medication adherence by providing patient education regarding pregnancy. During the study period pregnant women were enrolled in the study after obtaining consent from them. The prescriptions containing atleast one drug were analyzed and the drugs prescribed were classified according to their pharmacological class. Analysis of prescription patterns did not show the use of any drugs that should not be prescribed during pregnancy. Majority of the drugs prescribed belonged to vitamins, minerals and nutrients which play a very major role in foetal development. During the study, medication adherence of the pregnant women was assessed and the impact of counseling on adherence was seen. There is an increase in the rate of adherence in the pregnant women during their first and second follow-ups when compared with their baseline medication adherence. Pregnant women should be counseled and educated regarding the advantages and disadvantages of various drug used during pregnancy. The impact of self-medication and other alternative therapies should also be explained to them.

Key Words: Prescription pattern analysis, Medication adherence, Patient education.

INTRODUCTION

The study of prescribing pattern is a component of medical audit which seeks monitoring, evaluation and necessary modifications in the prescribing practices of the prescribers to achieve rational and cost effective medical care. Thus the monitoring of prescription and drug utilization studies can identify the problems and provide feedback to prescribers so as to create awareness about irrational use of drugs¹.

Rational drug prescribing is defined as the use of the least number of drugs to obtain the best possible effect in the shortest period and at a reasonable cost². Prescribing drugs during pregnancy presents a challenge to the physician to balance optimal treatment of the maternal symptoms and disease against possible harm to the foetus. For many drugs including those recently marketed, data are still inadequate to confirm their safety during pregnancy³.

A review of drug use during pregnancy has suggested that more than 80% of pregnant women take atleast one type of medication during pregnancy. Disregarding vitamin and iron supplementation, analgesics/antipyretics, anti-infectives and anti-histamines account for the majority of drugs consumed during pregnancy⁴.

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 pregnancy⁵. The safe use of drugs during pregnancy is essential to optimize the health of both pregnant women and their foetuses⁶. Careful consideration of the benefit to the mother and the risk to the foetus is required while prescribing drugs during pregnancy. The use of drugs during pregnancy calls for special attention because in this case in addition to the mother, the health and life of her unborn child is also at stake. The drugs given to pregnant mothers for therapeutic purposes may cause serious structural and functional adverse effects in the developing child. Since it is very difficult to determine the effects on the foetus before marketing new drugs due to obvious ethical reasons, most drugs are not recommended to be used during pregnancy. Since there are numerous gaps in knowledge about deleterious consequences for the foetus, prescription drug use by pregnant women should be viewed as a public health issue⁷. The use of drugs during pregnancy requires maintenance of a fine balance. Before prescribing a drug, consideration must be given to any potentially harmful effects on the foetus. Equally, no harm must come to the mother or baby because a disease is being inadequately treated. To minimize the foetal risks, the lowest possible effective dose should be used. In addition to the dangers associated with foetal exposure

to teratogenic drugs, there are risks associated with misinformation about the teratogenicity of drugs. This can lead to unnecessary abortions or the avoidance of essential treatment. The drug manufacturers and medical community should make every effort possible to protect women and their unborn babies from both risks. Implicit in this statement is the need to counsel pregnant women about the safety as well as the dangers of drug use in pregnancy⁸.

Adherence may be defined as the extent to which a patient's behavior (in terms of taking medication, following a diet, modifying habits, or attending clinics) coincides with medical or health advice⁹. Some investigators have further refined the definition of adherence to include data on dose taking (taking the prescribed number of pills each day) and the timing of doses (taking pills within a prescribed period). Adherence rates are typically higher among patients with acute conditions, as compared with those with chronic conditions; persistence among patients with chronic conditions is disappointingly low, dropping most dramatically after the first six months of therapy¹⁰. Lack of adherence may result from patient-related factors, such as a lack of motivation, or from effects from the medication, such as side effects, but it may also be related to the provider¹¹. If the goal of medication adherence is to improve the outcome for each patient through the correct use of prescribed medicines, then what is ultimately needed is a multidisciplinary approach to adherence management whereby the patient and all members of the health care team work together to cure the patient's illness, provide symptom relief, or arrest the disease process¹². Physicians counseling women who are pregnant or are planning a pregnancy should make sure that they understand clearly the nature and magnitude of a risk associated with a drug¹³.

In the present study an attempt is made to assess the pattern of drug use among pregnant women and to evaluate the impact of counseling on medication adherence by providing patient education regarding pregnancy.

OBJECTIVES

- To study the prescribing patterns of drugs during pregnancy in the department of Obstetrics and Gynecology.
- To educate the pregnant women regarding drugs and diet during pregnancy.
- To evaluate the medication adherence of drug use during pregnancy.

MATERIALS AND METHODS

Study Site

The study was conducted in the outpatient department of Obstetrics and Gynaecology, at HKES Basaveshwar teaching and general hospital, Sedam road, Gulbarga, which is 750 bed tertiary care hospital.

Study duration Study has been carried out for a period of nine months from May 2010 to February 2011.

Study design It was a prospective study conducted on 100 pregnant women to know the prescribing patterns and impact of counselling on medication adherence during pregnancy.

Study criteria Pregnant women were enrolled into the study by considering the following criteria:

Inclusion Criteria

- Pregnant women attending to the OBG-OPD who are on at least one drug treatment were enrolled in the study including at least 2 follow ups.
- Pregnant women who are willing to participate in the study.
- Pregnant women of age above 18 years.

Exclusion Criteria

- Pregnant women below the age of 18 years.
- Pregnant women who are not willing to participate in the study.

Source of data

- Pregnant women visiting Obstetrics and Gynaecology Outpatient Department of HKES's Basaveshwar Teaching and General Hospital, Gulbarga.
- Data collection forms and outpatient cards of above pregnant women.

Study procedure

The data relevant to the study was collected from 115 pregnant women but only 100 were enrolled in the study as fifteen pregnant women did not turn up for follow ups for unknown reasons.

Prescribing pattern analysis

Prescriptions of the pregnant women containing at least one drug were analyzed and the drugs prescribed were classified according to their pharmacological class. The pregnant women were divided according to their trimester and the prescriptions were analyzed for different classes of drugs.

Assessment of Medication Adherence

The medication adherence of the pregnant women was assessed at baseline line by using the medication adherence questionnaires. Then the pregnant women were counseled regarding drug use and importance of medication adherence. During first and second follow-ups same medication adherence questionnaires were used to reassess their medication adherence.

Statistical analysis

Statistical analysis of the data was done by chi square method and Wilcoxon signed- ranked test.

RESULTS

During the 6 month study period, 115 pregnant women were enrolled. Total 100 pregnant women completed the study; the remaining fifteen pregnant women did not turn for the follow up due to unknown reasons. Those who have completed the study were included in the analysis.

Baseline demographic characteristics of enrolled pregnant women

Age

The age distribution of enrolled pregnant women is as follows 29(29%) of pregnant women were between the age group of 17-21 years of age, 51(51%) were between the age group of 22 - 26 years of age, 18 (18%) were between the age group of 27-31 and 2 (2%) were between the age group of 32-36.

Educational Background

Among the participants of the study, 41 (41%) of women were having formal education and were graduates, 59 (59%) were illiterate who have not received any education because most of the women belongs to rural area.

Socio-economic status

The socio-economic status of the pregnant women enrolled in the study was also considered. Among 100 women 41 (41%) were poor and the remaining 59 (59%) women were from middle class families.

Region

Among 100 pregnant women enrolled in the study, 69 (69%) were from urban area and 31 (31%) women were from rural areas.

Trimester wise classification

Among 100 women enrolled in the study, 35 (35%) women were from first trimester, 61 (61%) women were from second trimester and the remaining 4 (4%) are from third trimester.

Co-morbidities

Among 100 pregnant women enrolled in the study, 28 (28%) were known to have anaemia, 12 (12%) were having hypertension and 2 women were having both anaemia and hypertension.

Number of children

Among 100 pregnant women enrolled in the study 19 (19%) women were not having any children, 40 (40%) women had one child, 32 (32%) women were having two children and (9%) women were having three and more children.

Prescribing pattern analysis of pregnant women

Drug Use during First Trimester

The study was done by enrolling 100 pregnant women among whom 35 of them belonged to first trimester. Among the 35 women 26 (74%) of them were prescribed with folic acid, vitamins were prescribed for 5 (14.2%) women, proteins for 17 (48.5%) women, nutrients were prescribed for 5 (14.2%) women, iron, calcium were prescribed for 1 (2.8%) woman and 1 (2.8%) woman was prescribed with other (anti-cold) drug and none of them were prescribed with anti-hypertensives. The results are shown in Table 1

Drug use during second trimester

Among 100 pregnant women enrolled, 61 women belonged to second trimester out of which 20 (32.7%) were prescribed with folic acid, vitamins were prescribed to 35 (57.3%) pregnant women, proteins to 38 (62.2%), nutrients to 15 (24.5%) women, anti-hypertensives to 10 (16.3%) women, iron was prescribed to 24 (39.35%) women and calcium to 41 (67.2%) women. None of them were prescribed with other classes of drugs. The results are shown in Table 2.

Drug use during third trimester

Among the 100 pregnant women in whom the study was conducted, 4 of them belonged to third trimester of which 2 (50%) women were prescribed with folic acid, proteins were prescribed to 3 (75%) women, 2 (50%) of them were prescribed with anti-hypertensives and iron supplements, all the 4 (100%) women were prescribed with calcium and none of them were prescribed with vitamins, nutrients and any other classes of drugs. The results are shown in Table 3.

Assessment of medication adherence in pregnant women

Morisky Medication Adherence Scale (MAS) Score

All the 100 participants of the study were initially provided MAS questionnaires at the time of enrollment and subsequent follow up and medication adherence score was evaluated at baseline, first and second follow up.

Baseline to first follow up showed a mean increase in medication adherence level of 1.340 ± 0.2184 and ($P < 0.0001$) which is statistically significant.

Baseline to second follow up showed a mean increase of 2.490 ± 0.1930 and ($P < 0.0001$) which is statistically significant. The results are shown in Table 4.1 and 4.2.

Improvement of medication adherence by comparing literacy rate of pregnant women:

Overall medication adherence of pregnant women based on the literacy rate was compared by using Wilcoxon signed-ranks test and Paired t-test.

Medication Adherence Scores in literate pregnant women.

Baseline score to first follow up score in literate pregnant women revealed a mean increase in medication adherence level of 1.271 ± 0.2914 with $P < 0.0001$ which is statistically significant.

Baseline to second follow up showed a mean increase of 2.542 ± 0.2314 with $P < 0.0001$ which is significant. The results are explained in Table 5.1 and 5.2.

Medication Adherence Scores in illiterate pregnant women.

Baseline score to first follow up score in illiterate pregnant women revealed a mean increase in medication adherence level of 1.512 ± 0.3096 with $P < 0.0001$ which is statistically significant.

Baseline to second follow up show a mean increase of 2.439 ± 0.3056 with $P < 0.0001$ which is significant. The results are shown in Table 6.1 and 6.2

DISCUSSION

Prescriptions of the pregnant women were analyzed for different classes of drugs prescribed during pregnancy. Folic acid was prescribed to 26 (74.2%) women in their first trimester, 20 (32.7%) in second trimester, to 2 (2%) women in their third trimester. Vitamins were prescribed to 5 (14.2%) pregnant women in first trimester and to 35 (37.3%) women in second trimester and none of them were prescribed with vitamins in third trimester. Proteins were prescribed to 17 (48.5%), 38 (62.2%) and 3 (75%) pregnant women in their first, second and third trimesters respectively. Nutrients were prescribed to 5 (14.2%) in first trimester and to 15 (15%) in second trimester. Anti-hypertensive drugs were not prescribed to any pregnant women belonging to first trimester and to 10 (16.3%) during second trimester and to 2 (50%) women in their third trimester. Iron was prescribed to 1 (2.8%) woman in first trimester, 24 (39.3%) during second trimester and to 2 (50%) women during third trimester. Calcium was prescribed to 1 (2.8%) woman in first trimester, to 41 (67.2%) women during their second trimester and to 4 (100%) women in third trimester. Other classes of drugs were prescribed in 1 (2.8%) woman.

A similar study was conducted by Dileep K Rohra in which anti-anemic drugs including iron preparations and vitamin and mineral supplements (79.4%) were the most frequently prescribed drugs followed by analgesics (6.2%) and anti-bacterials (2.2%). Seven thirty nine women (19.6%) received prescriptions containing drugs other than vitamin or mineral supplements⁷.

During the study medication adherence of the pregnant women was assessed and the impact of counseling on adherence was seen. There is an increase in the rate of adherence in the pregnant women during their first and

second follow-ups when compared with their baseline medication adherence scores. The study showed significant difference in medication adherence at baseline to first and second follow ups ($P < 0.0001$). The medication adherence scores during first, second and third trimesters were also significant at baseline level to first and second follow ups.

During the time of baseline assessment we asked the reasons to stop/miss the medications to the patients. Following were the reasons: (Results are shown in table 7).

Fifty nine (59%) pregnant women reported that high cost of the medication was one of the reasons for medication non-adherence. As majority of the pregnant women enrolled were from poor and middle class families and from low economic group they couldn't afford the cost of medications.

Another frequently reported reason for non-adherence was forgetfulness **64(64%)**. This problem was resolved by using the tools like medication reminder or diary keeping.

Twenty six (26%) pregnant women reported that lack of access to hospital or drug store was another main reason for prescription non-adherence. Many of the pregnant women were from rural areas where they don't have access to health care services, or medications.

Twenty three (23%) women reported that fear of side effects caused by the medications was the problem to continue their therapy. This problem was solved by counseling them regarding side effects caused by each drug and rescue action to be taken when it happens.

Thirteen (13%) pregnant women believed that the medications were not very effective, 9 (9%) of them were having occupational problems and 6 (6%) women were non-adherent due to lack of motivation and family support. All the reasons for medication non-adherence were solved by providing counseling by clinical pharmacist in specific areas so as to improve their adherence rates.

CONCLUSION

Analysis of prescription patterns did not show the use of any drugs that should not be prescribed during pregnancy. Majority of the drugs prescribed belonged to vitamins, minerals and nutrients which play a very major role in foetal development. Other drugs mostly prescribed were anti-hypertensives which were prescribed in pre-eclampsia patients. Anti-hypertensives which are contraindicated in pregnancy were not prescribed to any patients.

In the study the major reasons for non-adherence were forgetfulness, cost of medications, lack of hospital/drug store, fear of side effects and lack of motivation. Patient

education and counselling may be effective in solving some of the problems, except lack of hospital/drug store and high cost of medications which need further strategies to improve them. By providing counseling and patient education, the rate of medication adherence was improved during first and second follow-ups when compared with the baseline assessment.

Pregnant women should be counseled and educated regarding the advantages and disadvantages of various drug used during pregnancy. The impact of self-medication and other alternative therapies should also be explained to them.

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Table 1: Pattern of drug use in first trimester

PHARMACOLOGICAL CLASS	NO.OF PREGNANT WOMEN
FOLIC ACID	26 (74.2%)
VITAMINS	5 (14.2%)
PROTEINS	17 (48.5%)
NUTRIENTS	5 (14.2%)
ANTI-HYPERTENSIVES	0
IRON	1 (2.8%)
CALCIUM	1 (2.8%)
OTHERS	1 (2.8%)

Table 2: Pattern of drug use in second trimester

PHARMACOLOGICAL CLASS	NO.OF PREGNANT WOMEN
FOLIC ACID	20 (32.7%)
VITAMINS	35 (57.3%)
PROTEINS	38 (62.2%)
NUTRIENTS	15 (24.5%)
ANTI-HYPERTENSIVES	10 (16.3%)
IRON	24 (39.3%)
CALCIUM	41 (67.2%)
OTHERS	00

Table 3: Pattern of drug use in third trimester

PHARMACOLOGICAL CLASS	NO.OF PREGNANT WOMEN
FOLIC ACID	02 (50%)
VITAMINS	00
PROTEINS	03 (75%)
NUTRIENTS	00
ANTI-HYPERTENSIVES	02 (50%)
IRON	02 (50%)
CALCIUM	04 (100%)
OTHERS	00

Morisky Medication Adherence Score (MAS) (n=100): Score (0-6)

Table 4.1: Baseline adherence score to first follow up score

Average of Baseline	Average of Follow up I	Mean ± SD	P-Value
2.47	3.81	1.340 ± 0.2184	P<0.0001

Table 4.2: Baseline adherence score to second follow up score

Average of Baseline	Average of Follow up II	Mean ± SD	P-Value
2.47	4.96	2.490 ± 0.1930	P<0.0001

Medication Adherence Score in literate pregnant women (n=59): Score(0-6)

Table 5.1: Baseline adherence score to first follow up score

Average of Baseline	Average of Follow up I	Mean ± SD	P-Value
2.76	4.03	1.271 ± 0.2914	P<0.0001

Table 5.2: Baseline adherence score to second follow up score

Average of Baseline	Average of Follow up II	Mean ± SD	P-Value
2.76	5.30	2.542 ± 0.2314	P<0.0001

Medication Adherence Score in illiterate pregnant women(n=41):Score(0-6)

Table 6.1: Baseline adherence score to first follow up score

Average of Baseline	Average of Follow up I	Mean ± SD	P-Value
2.02	3.53	1.512 ± 0.3096	P<0.0001

Table 6.2: Baseline adherence score to second follow up score

Average of Baseline	Average of Follow up II	Mean \pm SD	P-Value
2.02	4.46	2.439 \pm 0.3056	P<0.0001

Table 7: Factors for medication non-adherence:

Reasons	No. Of Patients (n=100)	Percentage (%)
Forgetfulness	64	64
High cost of medications	59	59
Lack of access to hospital/drug store	26	26
Fear of side effects	23	23
Believed medication was not effective and decided not to take dose	13	13
Absorbed in daily work and forget to take/Occupation related problems	09	09
Lack of family support/Motivation	06	06

Source of support: Nil, Conflict of interest: None Declared