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A COMPARISON OF DRUG UTILIZATION PATTERN DURING PREGNANCY IN URBAN AND RURAL WOMEN IN CENTRAL GUJARAT, INDIA

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ABSTRACT

Objectives- The present study was undertaken with the aim of evaluating the pattern of utilization of drugs prescribed during pregnancy and to compare their extent of utilization in urban and rural areas of Central Gujarat.

Methods- Data regarding drug utilization during pregnancy was collected from 1025 women over the period extending from February 2007 to May 2009 from Civil Hospital Petlad, S K Hospital Karamsad and various practicing gynaecologists in Anand district of Gujarat.

Results- Of the study population 53.2% women belonged to urban areas while 46.8% belonged to rural areas. A total of 5558 drugs were prescribed to the study population with an average of 5.42±3.89 drugs per pregnant woman. Routinely prescribed drugs were iron, calcium, folic acid, multivitamins and protein preparations which were utilized to the extent of 96.7%, 83.7%, 46.9%, 24.6%, and 24.5% respectively. Other drugs used were analgesics, antispasmodics, antacids, hormonal preparations, uterine relaxants etc. Comparing the utilization pattern of drugs among rural and urban study groups, statistically significant results were obtained.

Conclusion- Health care facilities in rural areas need to be improved. Also there is a need to educate and counsel women of child-bearing age especially in rural areas, regarding importance of antenatal checkup and utilization of routinely prescribed drugs during pregnancy.

INTRODUCTION

Prescribing drugs during pregnancy presents a challenge to the physician to balance optimal treatment of maternal symptoms and disease against possible harm to fetus. For many drugs including those recently marketed, data are still inadequate to confirm their safety during pregnancy. If adequate information on drug safety is lacking, essential drug treatment may be avoided and chronic illnesses requiring drug treatment may not be treated.[1]

Medication safety information in pregnancy is obtained through case reports, epidemiological studies and animal studies[2] which help to establish a profile of drug consumption by evaluating the existing health services and investigating the interventional measures.[3]

MATERIALS AND METHODS

The present retrospective, randomized, cross sectional study on the extent and pattern of drug utilization during pregnancy was conducted at various government hospitals and private nursing homes of qualified practicing gynecologists of Anand district. The study was carried out after obtaining clearance from Human Research Ethics Committee (HREC) of Shri Krishna Hospital Karamsad, district Anand.

Data of 1025 women who delivered babies over the period extending from February 2007 to May 2009 at above mentioned government and private hospitals of Anand district was collected. All aspects of the study were explained to them in the local language. Consent for participating in the study was obtained on Informed Consent Form in the language they understood. All women were interviewed only once after delivery, while they were still in the hospital. Their hospital case records were also referred to obtain detailed information about their demographic data and data about drug prescription and utilization during antenatal period only. Information about drugs given at the time of delivery and after delivery i.e. in the postnatal period was excluded.

Data collected was documented on a structured questionnaire and was analyzed for various study parameters like general demographic data, parity of women, time of first antenatal checkup (ANC) and number of antenatal visits, clinical findings like anemia, edema, hypertension etc., symptoms associated and not associated with pregnancy, the drugs prescribed and utilized for conditions associated and not associated with pregnancy and the outcome profile of pregnancy.

All drugs utilized during pregnancy were classified into Category A, B, C, D and X according to categorization of drugs for use in pregnancy introduced by US FDA in 1979[4] and the extent of utilization of different categories of drugs was determined. Also all women whose data was collected were categorized into two groups (urban and rural) based on residential background. Inter group comparison about extent and pattern of utilization of drugs during pregnancy was done.

Statistical analysis: All results were expressed in percentage and intergroup comparison was done by applying chi-square test using Statistical Package for Social Science (SPSS) software. *P* value <0.05 was considered to be statistically significant.

RESULTS

1- General demographic data of study population-

All women whose data was collected were in the age range of 16-40 years. Of the 1025 women whose data was collected, 88.7% i.e. majority of women belonged to age group 20-30 years, 2.9% women were aged less than 20 years while 8.4% women were above 30 years of age. 40.9% were primiparous, 35.5% were 2nd para, while 23.6% were multipara. Of the study population 53.2% belonged to urban areas while 46.8% belonged to rural areas.It was observed that 47.75% of women were illiterate, while 52.3% women were literate. 56% of the study population belonged to low income group, 21% belonged to middle income group while 23% was in high income group. (Table 1)

2- Antenatal checkup-

The study population was categorized into 4 categories based on the number of ANC. Comparing the data of number of ANC in urban and rural population; it was observed that higher percentage of rural women reported not taking any ANC. On the other hand more number of women who took regular ANC belonged to urban areas. (Table 2)

Our observation shows that only 35% women took first ANC in first trimester of which more number of women were from urban areas .Similarly comparing the number of urban and rural women who underwent first ANC in third trimester,statistically significant results were obtained with more number of women from rural areas reporting for ANC in third trimester. (Table 3)

3- Clinical findings during ANC-

Clinical findings like recording of blood pressure (BP), pulse rate, respiratory rate, pallor, edema etc. and investigations like hemoglobin, blood group, urine examination, testing for HIV and HBsAg etc. were recorded from case records of women enrolled in the study. Anemia was found to be the most predominant finding with 68.7% of the study population being anemic. On comparing the incidence of anemia among women living in urban and rural areas it was observed that the incidence of severe anemia was higher among rural pregnant women. (Table 4)

4- Drug utilization during pregnancy-

Drug utilization during pregnancy was found to be extensive with only 2.14% women reporting no drug use. A total of 5558 drugs were prescribed to the study population with an average of 5.42±0.121 drugs per pregnant woman. Drugs prescribed during pregnancy can be categorized into 3 groups-

a- Drugs routinely prescribed during pregnancy- Drugs like folic acid, iron, calcium, multivitamins and dietary supplements are routinely prescribed during pregnancy. Overall

utilization rate of these drugs and comparison of their utilization among urban and rural pregnant women revealed significant differences in utilization of folic acid, calcium, multivitamins and dietary supplements. (Figure 1).

b- Drugs prescribed for conditions associated with pregnancy- Various conditions associated with pregnancy like nausea and vomiting, dyspepsia, aches and pains, urinary tract infection, preeclampsia/eclampsia, threatened abortion etc. need treatment and therefore extent of utilization of drugs for conditions associated with pregnancy was analyzed and found to be 81.34%. A total of 4521 drugs were prescribed for conditions associated with pregnany which also include routinely prescribed drugs, with a mean of 4.41±0.096 drugs per pregnant woman. Significant differences were observed in their utilization among urban and rural women. (Figure 2)

c- Drugs prescribed for conditions not associated with pregnancy- Drugs were also prescribed for various other ailments like infections, chronic conditions like asthma, thyroid disorders, heart disease etc. Total number of drugs prescribed for these conditions were 1049. Overall utilization rate of such drugs was 18.87% with a mean of 1.02±0.054 drugs per pregnant women. (Figure 3)

5- US FDA Fetal Risk Classification-

In our study we observed that category A and B drugs were prescribed the most followed by category C drugs while category D and category X drugs which are not considered safe for the fetus were also utilized in some of the women.(Table5)

Table 1- General demographic data of study population

Parameters	**Number of women (Percentage of women)**		
Age range	<20years: 30(2.9)	20-30years: 909 (88.7)	>30 years: 86(8.4)
Gravida	Primi: 419(40.9)	Second: 364(35.5)	Multi: 242(23.6)
Background of women	Urban: 545 (53.2)	Rural:480 (46.8)	
Literacy status	Literate: 536(52.3)	Illiterate: 489(47.7)	
Family income range	<Rs. 5000: 574(56)	Rs.5000-10000: 215(21)	>Rs. 10000: 236 (23)
Time of first ANC	I trimester: 359(35)	II trimester: 225 (22)	III trimester: 441 (43)
Number of ANCs	No ANC: 226(22)	1-3: 236(23)	≥4: 563(55)

ANC- Antenatal check up

Table 2- Percentage distribution and comparison of number of ANC of study population based on background of women

Number of ANC	Background of women				Total number of women (n=1025)	Percentage of total women
	Urban (n = 545)		Rural (n = 480)			
	Number of women	Percentage of women	Number of women	Percentage of women		
No ANC	41	18.1	185	81.9	226	22
1-3	109	46.2	127	53.8	236	23
≥4	395	70.15	168	29.84	563	55
Total	545	53.17	480	48.83	1025	100

(P<0.001)

Table 3: Percentage distribution and comparison of time of first ANC of study population based on background of women

Time of first ANC	Background of women				Total number of women (n=1025)	Percentage of total women
	Urban (n = 545)		Rural (n = 480)			
	Number of women	Percentage of women	Number of women	Percentage of women		
I Trimester	260	47.7	99	20.6	359	35
II Trimester	142	26.1	83	17.3	225	22
III Trimester	143	26.2	298	62.1	441	43

(P<0.001)

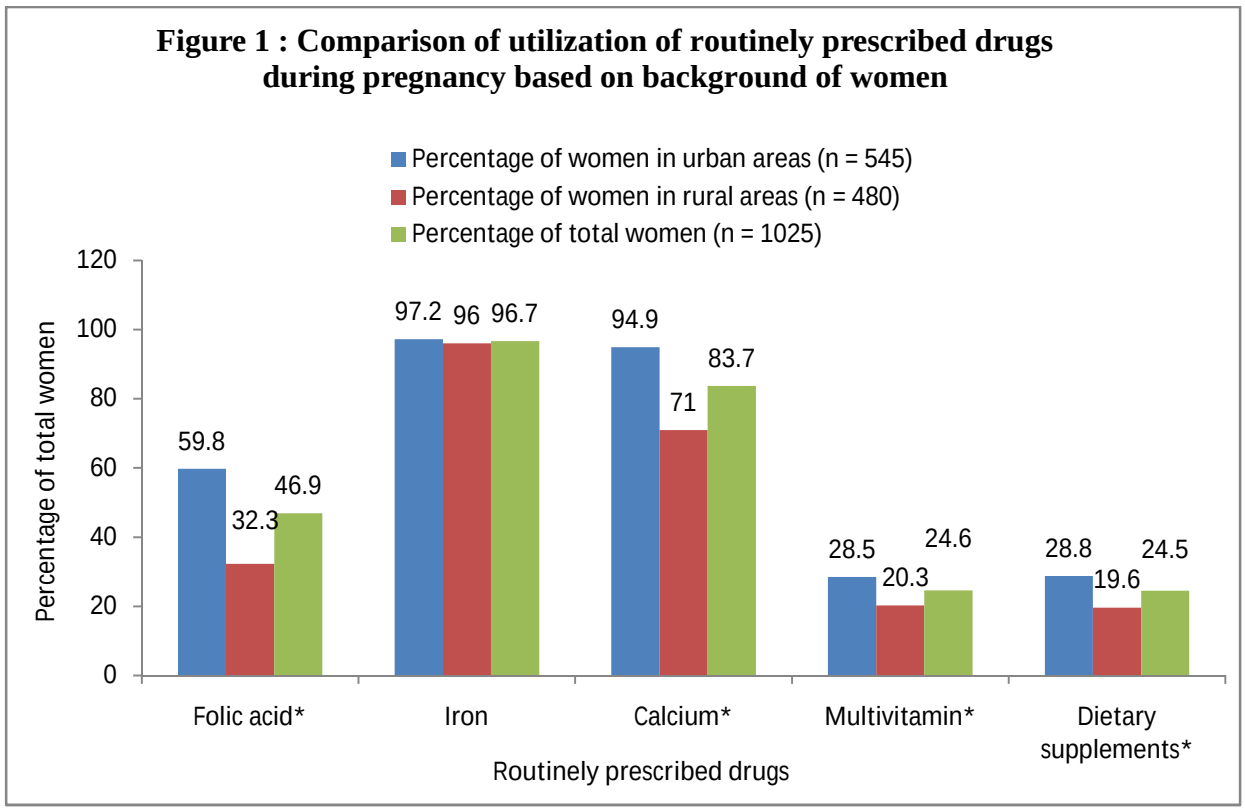
Table 4- Percentage distribution and comparison of anemic status of study population based on background of women

Anemic status of women	Background of women				Total number of women (n=1025)	Percentage of total women
	Urban (n = 545)		Rural (n = 480)			
	Number of Women	Percentage of women	Number of women	Percentage of women		
No Anemia	210	38.5	111	23.1	321	31.3
Moderate Anemia	284	52.1	264	55	548	53.5
Severe Anemia	51	9.4	105	21.9	156	15.2

(P<0.001)

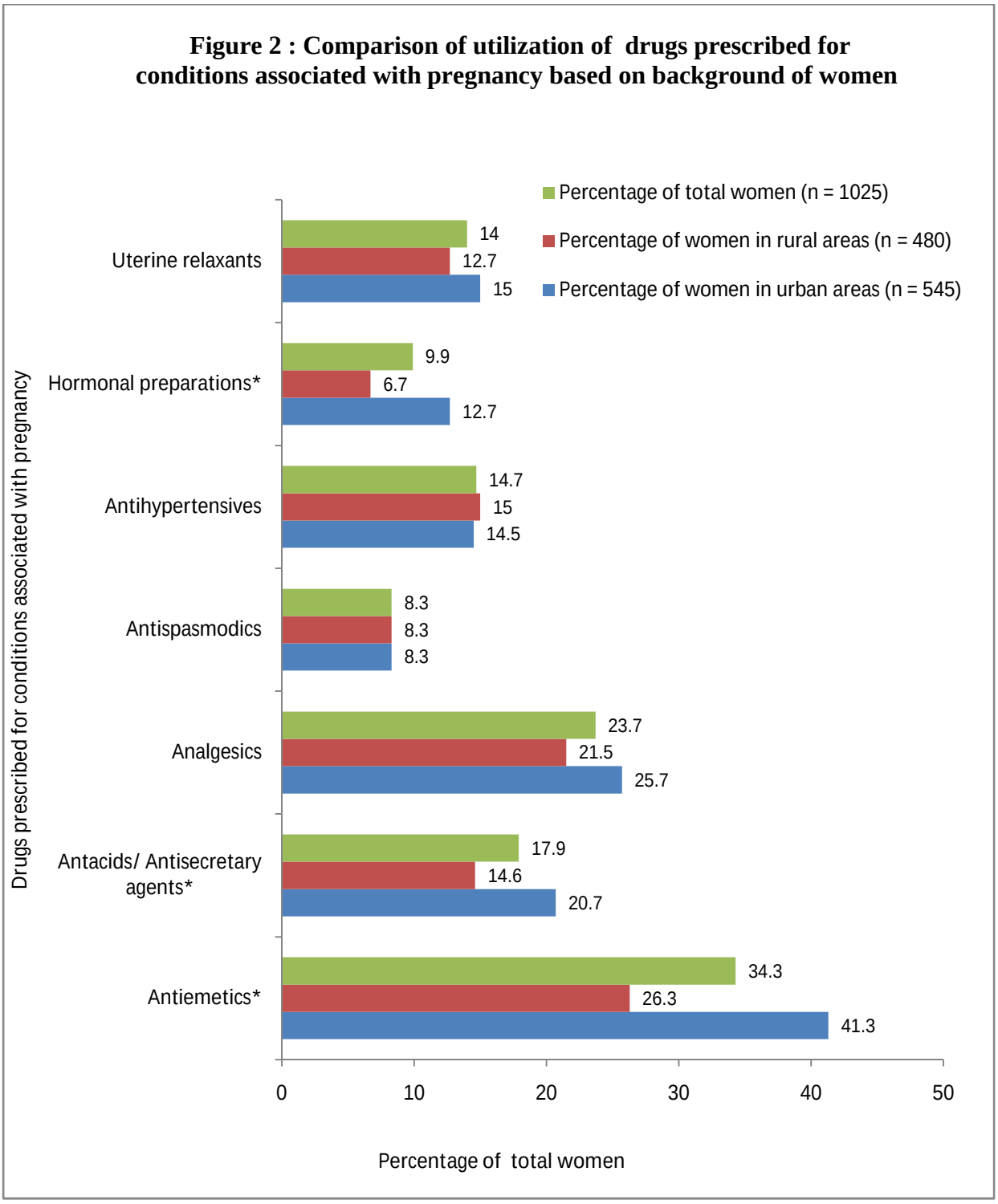
Table 5- Percentage distribution of drugs prescribed based on US FDA fetal risk classification

FDA category of drugs	Number of drugs Prescribed	Percentage of drugs prescribed
A	2889	51.98
B	1887	33.95
C	596	10.72
D	117	2.11
X	6	0.11
No category	63	1.13
Total	5558	100



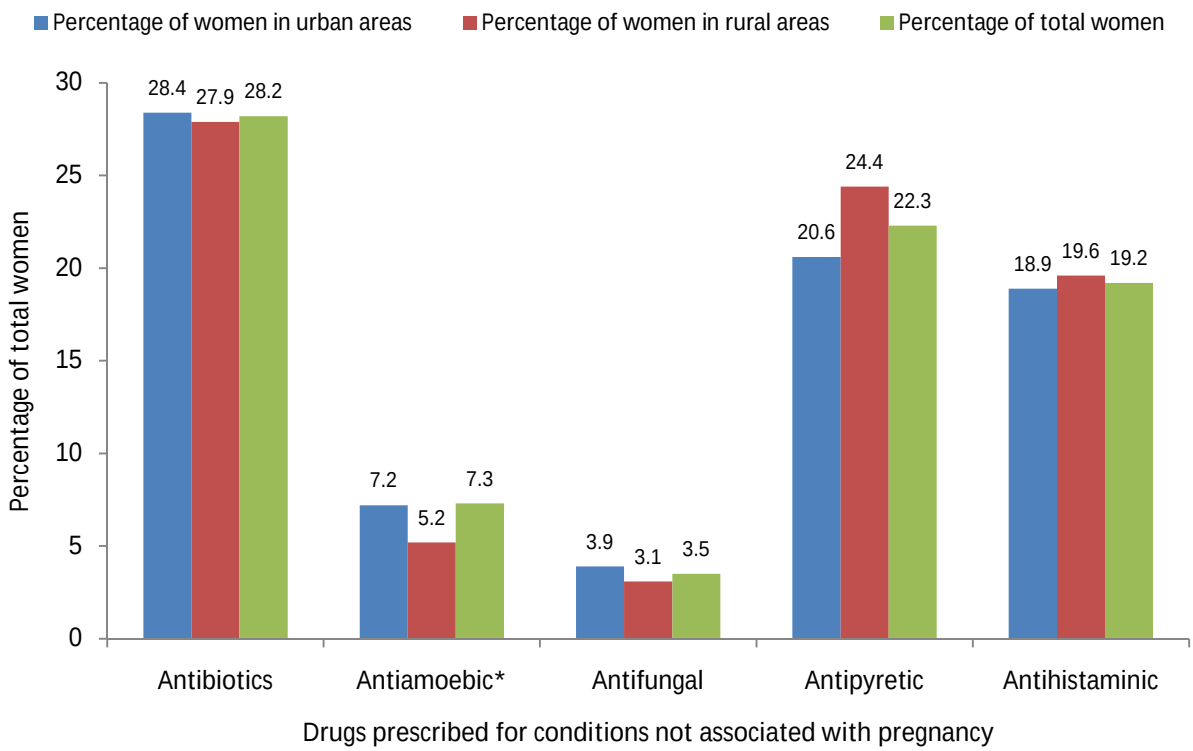
*Statistically significant (P<0.05)

Figure 2 : Comparison of utilization of drugs prescribed for conditions associated with pregnancy based on background of women



*Statistically significant (P<0.05)

Figure 3: Comparison of utilization of drugs prescribed for conditions not-associated with pregnancy based on background of women



*Statistically significant (P<0.05)

DISCUSSION

Drug utilization during pregnancy is an increasing trend; meanwhile medical practice incorporates risk as a concept.[5] The unique nature of physiology of pregnancy presents challenges for pharmaceutical treatment of chronic and acute disorders and for symptom management of many complaints associated with pregnancy.[4]

Antenatal care is the care of the woman during pregnancy. It is recommended that a minimum of 4 visits covering the entire period of pregnancy should be the target.[6] Higher percentage of rural women reported not taking any ANC throughout pregnancy or took ANC late in pregnancy i.e. in third trimester. Results obtained from our study are consistent with the results reported by a study carried out in India, which states that 86% urban pregnant women and only 60% rural pregnant women received ANC.[7]

Overall incidence of anemia was more or less similar in urban and rural pregnant women. The Indian Council of Medical Research (ICMR) Bulletin 2000 reports that in India 87% of pregnant

women suffer from anemia and about 10% of them have severe form of the disease.[8] This is in correlation with our observation of 15.6% incidence of severe anemia with more number of rural women suffering from severe anemia.

The PEGASUS study carried out in Germany states that 3.8% women reported no drug use during pregnancy,[9] and Women's Health Issues of Merck Manual also reports that more than 90% of pregnant women take drugs at some time during pregnancy.[10]Both the reports correlate with observation of our study. In our study drug utilization was 5.42 drugs per pregnant woman, which is close to 4.6[11] and 4.7[9] drugs but higher as compared to 2.3,[12] 2.6,[13] 2.9[14] and 3.8[15] drugs per pregnant woman reported by other studies.

As per our study utilization of folic acid was significantly higher in urban women and correlates well with 35%[11] and 40%[16] utilization reported by other studies. Iron was found to be the highest utilized drug with wide variation observed in its utilization as reported by other studies 46%,[15] 48%,[11] 54%[17] and 64%.[16] Calcium was found to be second highest utilized drug with significantly higher utilization in urban women. A study from Australia reports use of multivitamins to the extent of 27%,[18] which is close to our observations. Other studies have reported utilization of multivitamins to the extent of 33.5%[19] and 12%.[16]

We observed higher utilization of antiemetics as compared to other studies which reported 17%[20] and 8%[17] utilization rate of antiemetics. Our observation of utilization of antacids is close to the report of 20.98% utilization of antacids[21] though another study reports utilization of antacids to the extent of 11%.[17] The PEGASUS study reports 15%,[11] while a Brazilian study reports 22.2% utilization of analgesics[19] which is quite close to our observation.

The incidence of preeclampsia varies widely from 5-15%.[4] We also observed preeclampsia in 14.7% of the study population. In India the incidence of preeclampsia is reported to be 8-10% of the pregnancies.[22] 9.9% of our study population utilized hormones, which is high as compared to 5.71% reported by another study.[21] Isoxuprine is most commonly used uterine relaxant with utilization to the extent of 14% which is high as compared to 7.86% reported by another study.[21]

Various studies have reported utilization of antibiotics to the extent of 11.1%,[19] 15%,[11] 24.1%[1] and 28.7%[13] some of which are quite close to our observation. Our observation of utilization of antiamoebics is quite high as compared to 0.46% reported by a study from Jammu India.[21] Utilization rate of antihistaminics is in correlation with the report of PEGASUS study, mentioning utilization of antihistaminics to the extent of 17%.[11] Another study reported utilization of antihistaminics to the extent of 11.11%.[21]

CONCLUSION

Drug utilization during pregnancy is influenced by factors such as urban or rural background of women, access to health care facilities, literacy and socio-economic status of pregnant women. Most of the rural women have poor access to health care facilities, are illiterate and are from low socio-economic background. This results in inadequate or no ANC, poor utilization of drugs during pregnancy, higher incidence of anemia, complications during pregnancy and poor or bad pregnancy outcomes among rural pregnant women. On the other hand higher percentage of urban pregnant women is literate, belong to middle or high income group and have good access to health care facilities. They are also aware of importance of regular ANC and utilization of drugs essential for the wellbeing of mother and fetus. This results in adequate drug utilization, a good pregnancy outcomes with fewer complications among urban pregnant women.

Improvement in health care facilities and emergency obstetric care services especially in rural areas are necessary for regular ANC, early detection, treatment and management of obstetric conditions associated with pregnancy and promotion of good health. Interventions to improve maternal health and nutrition and to reduce incidence of adverse pregnancy outcomes through information, education and counseling of women of child bearing age should be implemented. Regular analysis of prescription data through pharmacoepidemiological studies can identify harmful therapies and offer sound hypothesis generating information essential to clinical practice.

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