Research Article

Drug use pattern of over-the-counter and alternative medications in pregnancy: A cross sectional descriptive study

Ganti Shruti, Podila Karuna Sree, Yadala Venkata Rao

Department of Pharmacology, Kamineni Institute of Medical Sciences, Narketpally, Nalgonda, Telangana, India.

Correspondence to: Podila Karuna Sree, E-mail: drpkarunasri@gmail.com

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Abstract

Background: Drug treatment in pregnancy presents a special concern because of the physiological changes in the mother besides the drug effects on fetus. In addition, usage of drug available over-the-counter (OTC) medication adversely affects the mother and fetus. Hence, this study was planned to observe the OTC usage during pregnancy in India. **Aims and Objective:** To assess and compare the pattern and extent of OTC drug usage in pregnant women of rural and urban areas. **Materials and Methods:** It was a cross-sectional descriptive study done at a tertiary-care hospital. Pregnant women aged 18–38 years attending the obstetrics outpatient department at KIMS and urban clinics were enrolled randomly. Written informed consent was taken and questionnaire filled consisting of sociodemographic data and OTC usage, mode, source, and type of request. Statistical analysis was done using percentages and χ^2 test. **Results:** Among 483 (rural, 248; urban, 235) antenatal women enrolled, 12.83% consumed OTC drugs (urban areas, 16.5%; rural, 9.27%). Higher OTC usage was observed in first (rural, 39.13%; urban, 53.84%) and second trimesters (rural, 43.47%; urban, 33.3%) and women with higher income levels (rural, 52.17%; urban, 58.97%) and education (rural, 60.86%; urban, 56.41%). The main reason for OTC usage was emergency situation (for immediate relief). Source of request was pharmacist's advice/previous prescriptions. Type of request for acquiring OTC was by telling symptoms in both urban and rural areas. **Conclusions:** Although OTC usage was less, most of the women were not aware of the teratogenic effects of drugs. Hence, an alarming need is necessary to educate the women and pharmacists and to frame and follow the strict regulatory guidelines for the OTC drugs sale, thereby to prevent the irrational use of drugs.

KEY WORDS: Drug utilization pattern; OTC drugs; teratogenic drugs

Introduction

Self-medication is the treatment of common health problems with medicines specially designed and labeled for use without medical supervision and approved as safe and effective for such use. Medicines for self-medication are often called "nonprescription" or "over-the-counter" (OTC) drugs. OTC drugs are available without a doctor's prescription from the pharmacies.[1] With the increase in health-care cost, self-medication is on rise, and the use is no longer adhered to OTC drugs but has extended to many other medications that are available OTC. The source of information or advice about which drugs to be taken may differ to procure the drugs. Although OTC drugs are cheaper and give relief from the symptoms, they have potential harmful effects too. In the developing countries, owing to inadequate medical services and lack of regulatory control on pharmaceutical products, practice of self-medication

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is high. OTC market in India is expanding, which was ranking 11th position in 2009 and expected to move to 9th position by next 5 years.[2] In India, OTC drugs sale is accepted under law and specifies the list of OTC drugs for sale; however, lack of monitoring made all the drugs accessible on OTC. In this scenario, where huge number of drugs available as OTC drugs and lack of control on their sale, the usage of self-medication in pregnancy has increased. Pregnancy is a specialized condition accompanied by physiological changes[3] and often has symptoms such as nausea, heartburn, backache, constipation, and so on and requires medications. Drug usage in pregnancy needs special attention because of the threat of potential teratogenic effects of the drug and needs dose adjustment because of physiological changes. One such example is the thalidomide[4] tragedy that occurred in 1960s. Hence, an owl's eye should be kept on the usage of OTCs in pregnancy. Although the OTC market is fast flourishing in India, there is a scarcity of data about the practice and impact of self-medication, and studies on OTC in Andhra Pradesh, India, were limited. Hence, this study was planned. The objectives of the study were to assess and compare the extent and usage pattern of OTC and alternative medications among the pregnant women attending the obstetrics outpatient department in the rural and urban areas.

Materials and Methods

The study was conducted after the approval of the Institutional Ethics Committee, Kamineni Institute of Medical Sciences, Narketpally, Telangana, India.

Place and Duration of Study

The study was conducted in the Outpatient Department of Obstetrics, Kamineni Institute of Medical Sciences, situated at Narketpally Mandal, Nalgonda District, Telangana, India, covering the rural population, and in the antenatal clinics at Hyderabad, Telangana, India, covering the urban population after the permission from the consulting doctor. The duration of the study period was 4 months (May–August 2013).

Subjects

Subjects were enrolled by systematic random sampling method, and every third pregnant women attending the antenatal outpatient department aged between 18 and 38 years were included in the study. The number of patients enrolled in this study was 483, of which 248 were from the rural area 235 from urban area.

Study Procedure

After taking the written informed consent from the subject, the importance of medication during pregnancy was explained and a questionnaire was filled. The questionnaire consisted of the information under general category, patient history, and drug history. General information consisted of age, parity, educational level, occupation, and economic status. In the patient history, information about the family, history of chronic diseases, and personal history for addictions were noted. In the drug history, information about illness in the present pregnancy, drug intake, and if taken whether prescribed or OTC were noted. In addition, the information regarding the reason for taking OTC, type of OTC, source of information, procurement of OTC, and knowledge and awareness of safety issues concerning the OTC were noted. Similar information regarding the usage of any supplementations and alternative medications during pregnancy was noted.

Statistical Analysis

After filling up of questionnaires, data were entered in Microsoft excel sheet, version 2010. Percentage of patients on OTC/prescribed medications was calculated in both urban and rural subjects. The urban and rural data were compared by χ^2 test using IBM SPSS statistics, v19 software.

Results

In this study, the mean ± SD of age in rural area was 22.79 ± 3.46 years and, in urban area, 24.10 ± 3.67 years. The mean ± SD of the marital life in months for this pregnancy in rural areas was 42.5 ± 35.40 and, in urban areas, 45.50 ± 44.81.

All the pregnant women were on at least one drug/nutritional supplement, which was either prescribed or OTC.

Table 1: Usage pattern of drugs in rural and urban areas during pregnancy

	Rural	Urban
Prescription drugs, *N* (%)	148 (59.67)	143 (60.85)
OTC, *N* (%)	23 (9.27)*	39 (16.59)*
No drugs except supplements, *N* (%)	77 (31.04)	53 (22.5)

*χ^2 = 5.781, p = 0.02.

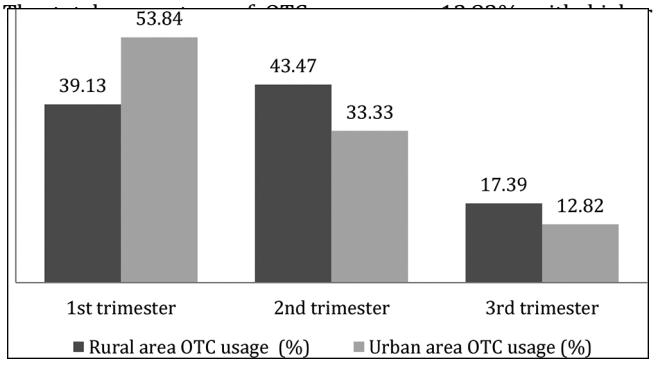

Figure 1: Percentage of OTC usage in each trimester in rural and urban areas.

Table 2: OTC usage in rural and urban areas as categorized by education

Educational level	Rural area OTC usage (%)	Urban area OTC usage (%)
Group 1	21.73	15.38
Group 2	60.86	56.41
Group 3	17.39	28.20
χ^2 value	9.399*	6.138**

*Rural (p =0.009), **urban (p =0.046).

usage in urban (16.5%) than the rural area (9.27%) and significant difference noted in OTC usage between the areas (χ^2 = 5.781, p = 0.02) (Table 1).

In this study, most of the pregnant women were in their third trimester (rural, 54.83%; urban, 57.44%). The pregnant women were categorized according to their trimester as first, second, and third trimesters, and the percentage of OTC usage in these trimesters was calculated. We observed high OTC usage in the second trimester in case of rural area and first trimester in the urban area (Figure 1).

The pregnant women were categorized based on education: group 1, below 10th standard (std); group 2, 10th std to graduation; and group 3, postgraduation and above. The percentage of OTC usage in these groups was assessed, and higher OTC usage was observed in group 2 (Table 2). We also observed significant difference in OTC usage and education levels in both rural (χ^2 = 9.399, p =0.009) and urban (χ^2 = 6.138, p =0.046) areas.

On the basis of the income level, pregnant women were classified into 3 categories: category 1, <Rs. 10,000/month; category 2, Rs. 10,000–Rs. 25,000/month; and category 3, >Rs. 25,000/month. When the OTC usage was assessed in different income categories, we observed usage was high in category 3 (higher income group), in both rural and urban areas (Table 3). Significant difference in OTC usage was noted in both rural (χ^2 =27.667, p = 0.001) and urban (χ^2 =20.43, p = 0.001) areas.

The other important aspect of our study was why and what for the OTC was taken, from where they have obtained the information, and effects of OTC drugs.

The common indication for OTC usage was nausea/vomiting with 42.64% (rural, 39.13%; urban, 46.15%), followed by cough and cold with 26.76% (rural, 30.43%; urban, 23.08%). In addition, the overall OTC usage for more than two or three ailments such as fever and nausea, or at times for fever and cold, or pain abdomen and vomiting was 30.6% (rural, 30.43%; urban, 30.76%).

Table 3: Comparison of the income levels and OTC usage

Income level	Rural area OTC usage (%)	Urban area OTC usage (%)
Category 1	13.04	7.69
Category 2	34.78	33.33
Category 3	52.17	58.97
χ^2 value	27.667*	20.43**

*Rural (p = 0.001), **urban (p = 0.001).

When the pregnant women were enquired about their reason for self-medication rather than consulting a doctor, majority of them said it was emergency for immediate relief of symptoms in both rural (34.78%) and urban (38.46%) areas. Other reasons were considering the complaint was not serious (rural, 26.08%; urban, 30.76%) and prior knowledge of the drug and less expensive (rural, 39.12%; urban, 30.8%).

In this study, we observed that, in the rural areas, main source of information about the OTC drug was pharmacist (47.82%), followed by the previous prescription of doctors (34.78%) and advice from family/friends (17.39%). However, in the urban areas, the source was from both previous prescription of doctors and pharmacists advice (35.89% each), followed by advice from family/friends (28.2%).

The type of request for urging OTC drugs was by telling symptoms in both rural (52.17%) and urban (46.15%) areas. Other requests are by telling the name or category of drug (rural, 26.08%; urban, 30.76%) and by presenting the piece of paper/old prescription (rural, 21.73%; urban, 23.07%).

When the pregnant women who had not taken OTC drugs were questioned for the reasons, most of them said it was a precautionary measure and scared of medicines in both rural (65.77%) and urban (42.54%) areas. Some of them said because of uneventful pregnancy and regular antenatal check-ups (rural, 17.55%; urban, 36.03%) and few of them told they were aware of adverse effects of drugs and used only with doctors advice (rural, 4.44%; urban, 9.53%).

The knowledge about the effect of drugs on pregnancy to the mother, fetus, or both was assessed: 68.45% in rural and 58.29% in urban area were unaware of it.

Nutritional supplements were taken by all the pregnant women in both urban and rural areas. Usage of alternative medication was observed in 12.09% of rural and 7.23% of urban pregnant women, and the reason for using herbal or home remedies was for the purpose of fair children (saffron) or for simple ailments such as constipation.

Finally, when the usage of OTC in nonpregnant period was assessed, 43.14% in rural and 51.48% in urban areas took OTC drugs.

Discussion

Medications are important for promoting human health and maintaining well-being. However, it is crucial to outweigh the risks and benefits for rational use of drugs. In the developing countries such as India, owing to the easy availability of the drugs, inadequate health services, and lack of regulatory control on drugs, self-medication is increasing. In India, there is no legal recognition of phrase OTC, and the drugs under Schedule G and Schedule K are called as nonprescription drugs and/or as household remedies. They are sold OTC by the pharmacist without registered medical practitioner's prescription. Commonly used OTC drugs are

analgesics, antipyretics, cough syrups, and anti-emetics, besides herbal medications and nutritional supplements. In this scenario, drug usage in pregnancy need a very special attention as it effects both the mother and fetus. Very limited studies were done in India on the usage of OTC in pregnancy, and hence, adequate data on knowledge, attitude, and usage pattern of OTC during pregnancy are lacking. This study was aimed to fulfil this gap. In this study, we observed that most of the pregnant women visited the doctor in their third trimester (56.1%) in both rural and urban areas. OTC usage was high in first trimester (53.84%) in urban areas, followed by second and third trimesters, and high in second trimester (43.43) in rural areas followed by first and third trimesters. First trimester is the crucial part of pregnancy where utmost care to be taken as it is the period of organogenesis and drug intake during this period has profound effect on the fetus. Not all the drugs are teratogenic; but, if the pregnant women are not aware of the drug usage and importance of consulting a doctor, it may lead to hazardous effect on fetus/mother. For example, use of high-dose aspirin results in increased perinatal mortality, neonatal hemorrhage, low birth weight, prolongs gestation/labour, and possible birth defects, whereas the use of folic acid in the first trimester prevents the neural tube defects.

In this study, we also observed significant difference in OTC usage with education and income. There was an increase in usage of OTC in subjects with higher education in both rural (56.41% of graduates) and urban areas (60.86% of graduates) and significant difference noted in OTC usage in different groups (rural, $p = 0.009$; urban, $p = 0.046$). Our study findings were similar to the study findings of Sharma et al.,[5] where they found higher usage of OTC in graduates and observed significant difference ($p = 0.001$) in the OTC usage between graduates and undergraduates.

When OTC usage in different categories of income was assessed, usage was more in higher income group in both urban (58.99%) and rural areas (52.17%). The findings of our study are comparable with the studies of Sharma et al. and Abasiubong et al.,[6] where they found higher OTC usage in high-income groups.

When the indication of OTC usage was assessed, we observed gastrointestinal symptoms, that is, nausea and vomiting, are the primary indications followed by cough/cold, fever, and pain in abdomen. The indications of OTC usage were commonly related to the pregnancy-associated symptoms, and our findings are comparable with the study findings of Inamdar et al.[7] and Sharma et al.[5]

When the reason for OTC intake was analyzed, most of the patients responded the usage for emergency purpose such as to get relief from vomiting/pain, and many responded saying that the disease was not that serious and, hence, OTC usage saves time and money. This indicates the less availability of health-care services, which made the subject to wait for longer time during consultation and higher cost.

In our study, when the source of information about OTC and type of request was assessed, most of the patients get the OTC drugs by telling symptoms or by the pharmacist advice. This indicates the need to educate the pregnant women and to restrict the pharmacists in selling the OTCs to pregnant women.

When the subjects were enquired about the effect of the drug usage in pregnancy, 68.45% in rural and 58.29% in urban areas were not aware the harmful effects of the drugs, indicating the alarming need to educate the pregnant women regarding the drug usage.

In this study, intake of nutritional supplements was taken by all the subjects as the subjects included in the study were from the outpatient department of the hospital/clinic. We would have noted a difference in taking the nutritional supplements if the subjects were included from the community by household survey. But, we observed some of the patients in the rural area were not aware why these supplements were given.

Use of herbal/alternative medications during pregnancy was more in the rural (12.09%) compared with urban area (7.23%). Our study findings, that is, high usage in subjects with low education (53.19%), are similar to those of the studies by Inamdar et al.,[7] where they found the high usage in low education group. In the study by Refuerzo et al.,[8] done in 418 patients at Detroit, USA, 4.1% used herbal and/or alternative remedies and 96.9% used at least one medication that was prescribed, OTC, or nutritional supplements, similar to our study.

In this study, we also observed high OTC usage during normal times compared with pregnancy. The most common reason for not taking the OTC during pregnancy was precautionary and scared about taking medicines.

In India, The Drugs and Cosmetics Act, 1940, regulate the import, manufacture, distribution, and sale of drugs in India; but, there are no standard regulatory guidelines for the sale of OTC drugs. This is more important in case of special populations such as pregnancy. Self-medication not only contributes to polypharmacy but also increases the risk of adverse drug reactions. Hence, OTC drug list along with their FDA risk category during pregnancy should be prepared and made available at all the pharmacies. In addition, it is essential to educate the pregnant women and pharmacists about the pros and cons of drug use in pregnancy.

Conclusion

The percentage of OTC usage (12.83%) although minimal, many of the pregnant women were not aware of the drug effects on pregnancy. Hence, there is an alarming need to educate and counsel women of child-bearing age regarding the drug usage in pregnancy, with a special attention toward the self-medication/alternative therapies. It is the combined responsibility of the clinicians, pharmacists, and community health-care workers to counsel patients with complete, accurate, and current information on the risks and benefits of using medications during pregnancy for the better pregnancy outcome.

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