

SHORT COMMUNICATION

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Over the Counter Medications: An Assessment of their Safety and Use

Ravi Shankar¹, Monika Joshi², Manish Kumar³¹Sheat College of Pharmacy, Varanasi, Uttar Pradesh, India²Ashoka Institute of Technology and Management, Varanasi, Uttar Pradesh, India³M. M. College of Pharmacy, Maharishi Markandeshwar (Deemed to be University), Mullana, Ambala, Haryana, India

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*Correspondence to:

Dr. Manish Kumar, PhD

Email:

manish_singh17@rediffmail.com

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**Abstract**

Over the counter drug means a drug that is sold without a prescription. The use of over the counter drugs is growing rapidly in India. Therefore, a study was conducted with aim to determine the prevalence of over the counter medications in students of pharmacy colleges in eastern Uttar Pradesh and to assess patients' perceived safety of these medications. A cross-sectional study was designed; using a self-administered questionnaire for the students' convenience and easy response disclosure. Data were statistically analyzed. A total of $N = 800$ students participated in this survey. Ease in access to OTC medicine, availability of pharmacist consultation and advertisement in print and electronic media were the main factors disclosed by the respondents that may result in an increase in the use of OTC products. The study revealed that the use of OTC medications was high in the students. Gender, age and educational institution were found significantly affecting the use of OTC medicines. Use of OTC medicines was generally higher among female students ($p = 0.001$). It was also found that the knowledge about adverse effects and contraindications is very limited.

Keywords: OTC drugs, RMP, analgesic, antipyretic, ADR.

INTRODUCTION

The promotion of consumer involvement in their healthcare is the core principal of health promotion and wellbeing of the society. The best way which is in use in the present scenario is the increased use of OTC drugs rather than prescription drugs. Over the counter (OTC) drugs is one of the self-care activities undertaken by individual, family and community intended to promote health and minimize illness [1]. 'OTC Drugs' means drugs legally allowed to be sold 'Over the Counter', i.e. without the prescription of a Registered Medical Practitioner [2]. OTC drugs plays vital role in healthcare system. A huge part of population relies on OTC for the treatment of common ailments like headache, cold, fever, and cough, indigestion, flu and dermatitis. Therefore, wide safety margin must be established for the OTC drugs. OTC product benefits must outweigh the risk and the chances of misuse of it should be low [3]. Individuals can directly be involved in their healthcare by increasing purchase of OTC rather than prescribed drugs [4]. The switching of drugs from prescription to OTC has increased worldwide. Popularity of OTC drugs in India had risen promptly. As per OTC market size, India ranks 11th as result of high growth rate of OTC market over past eight years.

Current data indicates Indian OTC market to represent \$1,773 million with a share of 23% as demonstrated by figure 1.9 In India manufacture, purchase, sale of drug is regulated by Drug and cosmetic act 1940 and rules 1945. In India there is no

judicial recognition for OTC drugs. The drug included in the schedule H and X of drug and cosmetic act are termed as prescription drugs. For the drug listed in schedule G of drug and cosmetic act (1940) no prescription is required but the following mandatory text must be mentioned in the label: "caution: It is dangerous to take this medicine except under medical supervision [5]. In India and most of the underdeveloped countries all the drugs which are non-prescription are easily available for over the counter sale.

Moving trend from prescription to non-prescription medications saves the time and also reduces cost as it is cheaper for patients to purchase OTC rather than file a prescription [5]. However, there are certain other reasons due to which the patients can choose self-medication including previous experience of the acute disease, knowledge of drugs and their uses, unavailability of health care professionals for treatment of patients [6]. OTC drugs are easily accessible and are used for the treatment of minor illness. Although OTC medicines are supposed to be relatively safe, readily available and consumed by patients without physicians' consent, it is very important that the patients have the access to clear and broad information to make an informed choice of proper selection of medicine and their fruitful use. It is very important to recognize that even OTC medicines can cause unwanted side effects if not properly used and there are certain OTC drugs which have been used by the patients for drug abuse [9]

There are various research reports all over the world claiming that the graduates and post graduates in professional colleges are more vulnerable and prone to practice self-medication due to their perception of low toxicity of OTC drugs, knowledge of drugs, and easy access to internet, wider media advertisements and involvement, unregulated practice of pharmacy profession and level of education. The study was conducted to ascertain: Prevalence of use of OTC drugs, categories of medications preferred, safety priority of using the drugs and knowledge of use of OTC drugs.

METHODOLOGY

This cross-sectional study was conducted during July 2017 to Oct 2017 at different university colleges in eastern region of Uttar Pradesh. A total of 800 students randomly selected from different pharmacy colleges consented to participate in the study. The objective of the study was explained to the students and their verbal consent was obtained. The data were collected through self-administered closed ended questionnaire. The questionnaire was divided mainly in two sections first dealing with the demographic parameters and second section dealing with the factors related to attitude, practice and safety parameters for effective use of OTC drugs.

RESULT AND DISCUSSION

The Cross-sectional studies over 800 students in different colleges of eastern Uttar Pradesh revealed the fact that the practice of self-medication is quite common in the students without consulting the physicians. Self-medication with OTC drugs can be used in treating minor ailments as it saves time and money especially in areas where health resources are very limited. The use of analgesics and antipyretics in students was found to be most common followed by cough preparations as can be seen in Fig 1. The major reason for self-medication was to save money and have minimum expenses signifying the need in developing countries of the world as shown by table 2.

It was evident from the data that the students were well known with the drugs and the major source of information being the pharmacist on the pharmacy followed by doctors and then by the parents and relatives. The major concern was that there were a large percentage (42%) of them were not having the knowledge about side effects or adverse effects of drugs and their storage and other requirements which can be detrimental

Table 3. Knowledge of the respondents regarding drug used for self-medication

Participants	Name of the drug	Indication	Knowledge of ADR, precautions and storage specifications
Males	74.5%	83.7%	58.8%
Females	76%	79.3%	50%

to drugs and finally to the patient himself as evident from the table 3.

Table 1: Demographic profile of pharmacists or shopkeepers and patients asking for OTC (n=800)

Variable	N (800)	Percentage	
Gender	Male	520	65%
	Female	280	35%
Age (in years)	18-22	295	36.87%
	22-24	242	30.25%
	25-28	235	29.37%
	Above 28	28	3.5%
Marital Status	Single	785	98.12%
	Married	15	1.87%

Figure 1: Pie diagram comparing the use of different category of OTC drugs

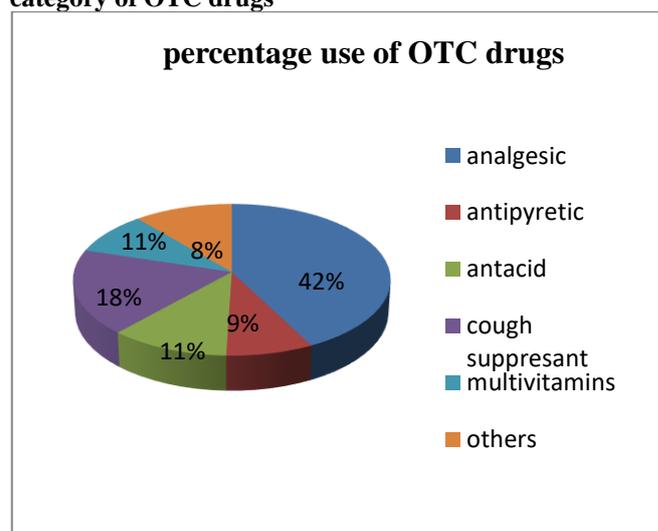
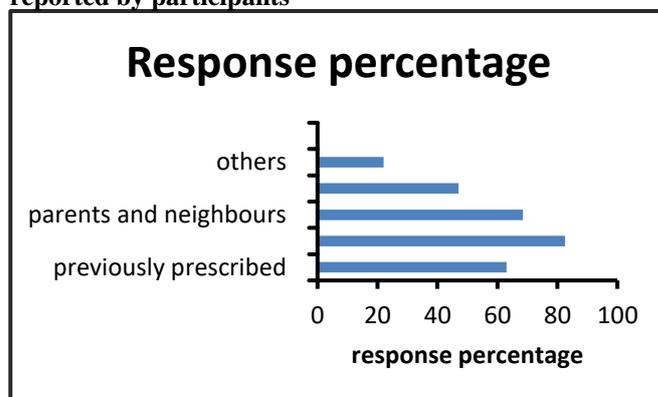


Table 2: Reasons for using self-medication

Reason for self-medication	Percentage
Knowledge about the drugs & disease	28.9%
Prevention of disease	33%
To prevent the Expenses	85%

Figure 2: Source of Information for self-medication as reported by participants



CONCLUSION

The prevalence of use of OTC drugs is alarmingly high in students. NSAIDs were the drugs most commonly used over the counter. Maximum students consult pharmacists on drug

information but have very less information over the knowledge of side effects and adverse effects and proper storage conditions. This issue needs to be addressed by the responsible authorities in India. The need for promoting the appropriate use of drugs in the Indian health care system is important. There is need for authorities to be proactive regarding over the counter, prescribed and non-prescribed drugs to ensure rational sale.

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Conflict of interest: None declare

Abbreviation used: None

REFERENCES:

1. S Betsy, H RRichard, C William, G Lisa, C Trina. Physician–patient communication about over-the-counter medications. *Social Sci Med.* 2001;53(3):357-69.
2. Drug Applications for Over-the-Counter (OTC) Drugs, Available from:<http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm>
3. O Erin. An overview of the US regulatory system for OTC products. *Regulatory Rap Porteur.* 2013;10(3):4-9.
4. B. Dianne, R Theo , K Peter , B Elisabetta . Over the counter medicines and the need for immediate action: a further evaluation of European Commission recommended wordings for communicating risk. *Patient Educ. Couns.* 2004;53(2): 129-34.
5. The drugs and cosmetics act, 1940, Ministry of Health and Family Welfare, GOI. Available from: <http://www.cdscsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf>
6. Now Available Without a Prescription, USFDA, Available from: <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143547.htm>
7. Prescription to Over-the-Counter (OTC) Switch List, Available from: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm106378.htm>.
8. Elizabeth A, Sujit SS, Caroline N, Rosa FY. Use/misuse of over-the-counter medications and associated adverse drug events among HIV-infected patients. *Research in Soc Admin Pharm.* 2008; 4(3):292-301.
9. Ahmad A, Patel I, Mohanta GP, Balkrishnan R. Evaluation of self-medication practices in rural area of town Sahaswan at Northern India. *Annals Med Health Sci Res.* 2014;4(8):73-8.

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