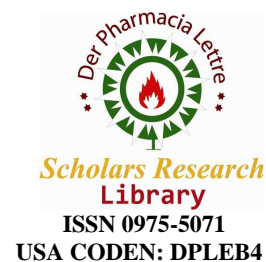




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A study on over the counter drugs in retail pharmacies in Indore city

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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. The purpose of this study was to determine the prevalence of over the counter medications and to assess patients' perceived safety of these medications in Indore city. A cross sectional study was conducted to determine the extent and pattern of use of over the counter medications. Data were collected from a random sample of 127 pharmacists from various pharmacies in city following WHO methods. A questionnaire was developed and administered to collect information on the demographic profile and use of over the counter medication among the consumers or patients. The principal pharmacists were asked about the prevalence of use of over the counter drugs, categories of medications preferred, safety priority of using the drugs and knowledge of use of over the counter drugs. The prevalence of over the counter drug use was estimated and found substantial use of over the counter medications in our study. We recommend a strong patient education program and government legislative control over the sale of medications in the country.

Keywords: OTC drugs, Indore city, Survey, Pharmacist.

INTRODUCTION

'OTC Drugs' means drugs legally allowed to be sold 'Over The Counter', i.e. without the prescription of a Registered Medical Practitioner. In India, though the phrase has no legal recognition, all the drugs that are not included in the list of 'prescription drugs' are considered as non-prescription drugs (or OTC drugs). Prescription Drugs are those that fall under two schedules of the Drug and Cosmetics Rules, 1945: Schedule H and Schedule X. Drugs falling under Schedule G require the following mandatory text on the label: "Caution: It is dangerous to take this preparation except under medical supervision" and hence are not advertised to the public voluntarily by the industry. In India, the import, manufacture, distribution and sale of

drugs and cosmetics are regulated by the Drugs and Cosmetics Act (DCA) and its subordinate legislation, the Drugs and Cosmetics Rules (DCR) [1].

Intentional drug abuse of prescribed and OTC medicines has climbed steadily. Data from the 2005 National Survey on Drug Use and Health demonstrated that 6.4 million (2.6%) people aged 12 or older had used prescription drugs for nonmedical reasons during the past month. Of these, 4.7 million used pain relievers, 1.8 million used tranquilizers, and 1.1 million used stimulants. The nonmedical use of prescription drugs in the past month among young adults aged 18 to 25 increased from 5.4% in 2002 to 6.3% in 2005, primarily because of an increase in the abusive use of pain relievers [2]. It is also alarming that the prevalence rates are on the rise despite efforts to limit this problem.

Internationally, the use of OTC medications has been reported as being on the rise [3-5]. Various studies have shown that the use of OTC drugs is twice as common as that of prescribed medication [6-9] and that self-medication is often used together with prescribed medication.

In India, pharmacists and pharmacy attendants play an important role in fostering self-medication among the public [10]. Combination preparations containing 'hidden' classes of drugs and food supplements or tonics of doubtful value were commonly used in India [11]. In India, it is possible to buy prescribed and non-prescribed drugs with or without prescriptions from a wide variety of sources. These drugs, if not fully used, may be kept for future use by the parents. In order to have a better understanding of the use of over the counter drugs among patients, a study was carried out. The aims of our study were to obtain baseline data on the use of over the counter drugs in Indore city in accordance with the pharmacist's prospective and information obtained from the pharmacies regarding general practice of use of OTC medications among people in Indore city.

METHODS

The study design and sample size followed World Health Organization guidelines for investigation of therapeutic practice [12] Accordingly a sample of 180 pharmacies was selected randomly from Indore city, using simple random sampling technique and the response were obtained from 127 pharmacies only. Indore is prime city located in the western region of Madhya Pradesh, and is close to the centre of India with a population about 35 million. A self-administered questionnaire was distributed amongst the principal pharmacist or shopkeeper of each pharmacy after explaining the purpose of the study and taking informed consent. The study questionnaire was adapted from various similar studies conducted previously [13-14] and pre tested on a sample of 10 participants. Any ambiguities in the questions or responses were removed before its implementation. The questionnaire was administered in English used to collect the information. The study consisted of a survey of the use of over the counter medication to ascertain:

1. Prevalence of use of OTC drugs
2. Categories of medications preferred
3. Safety priority of using the drugs
4. Knowledge of use of OTC drugs

The prevalence of use of OTC drugs was determined as percentage of all users out of the total sample.

RESULTS

Amongst the visited pharmacies that is 180, only 127 pharmacists or shopkeepers took part in the study (n=127). The demographic profile of pharmacists and consumers according to the information obtained from pharmacies has been tabulated in table 1.

Among 127 shopkeepers of retail pharmacies only 48% are having their education in pharmacy field (i.e. diploma, graduation or post-graduation) other were having B.Com, B.sc and other education level.

Table 1. Demographic profile of pharmacists or shopkeepers and patients asking for OTC (n=127)

Parameter		Percent (number)
Principal pharmacists or shopkeepers		
Sex	Male	92.9 (118)
	Female	7.1 (9)
Mean age	Years	32.7
	Diploma (pharmacy)	29.9 (38)
	Graduate (pharmacy)	14.2 (18)
	Post-graduate (pharmacy)	3.9 (5)
	Diploma (others)	8.6 (11)
	Graduate (others)	36.2 (46)
	Postgraduate (others)	7.1 (9)
Number of persons working in pharmacy	One	32.2 (41)
	Two	49.6 (63)
	Three or more	18.1 (23)
Years of service	Mean	11.4
Patients asking for OTC drugs every day		
Sex	Male	43.7 (7)
	Female	56.3 (9)
Mean age	Years	37.4

Because of increasing trends of using OTC drugs, people ask for the various medications. During the study surprising results were obtained that majority of drugs that comes under antipyretic, analgesic and anti-inflammatory, antihistaminic and anti-allergic categories are asked by patients and such drugs are dispensed by pharmacist without the proper prescription. The use of vitamins and complementary herbal drugs is also found out to be prevalent. The various categories of drugs which are sold over the counter by pharmacists, if requested by patients are shown in table 2.

Table 2. Groups of over the counter medications given by pharmacists or shopkeepers (n=127)

Group of medication	Percent (number)
Analgesics	56.7 (72)
Antibiotics	15.8 (20)
Tranquilizers	5.6 (7)
Antihistamines	8.6 (11)
Antipyretics	4.7 (6)
Vitamins	2.3 (3)
Herbal medicines	3.9 (5)
Others	2.3 (3)

The safety profile as per the prospective of the pharmacists or shopkeepers using OTC medication has been shown in table 3. On an average according to pharmacists, the use of OTC

drugs, vitamins and herbal medicines is safe but need the consultation of registered medical practitioner.

Table 3. Data on perceived safety of over the counter medications, vitamins and herbal medications (n=127)

Safety in using the drugs	Very safe	Safe, but one should consult the physician first	Unsafe
	Percentage (number)		
Over the counter medications	3.9 (5)	75.5 (96)	20.4 (26)
Vitamins	16.5 (21)	77.9 (99)	5.5 (7)
Herbal medicines	63.8 (81)	28.3 (36)	7.8 (10)

Every day nearly 16 over the counter prescriptions are sold by shopkeepers of retail pharmacy. Choice of over the counter drug made by consumer is 73.2% cases and 26.7% in case of pharmacist. Sometime consumers reveal their problems to the pharmacists or shopkeepers and the drugs are decided by pharmacist. Clinical history of consumers is taken by 81.1% of pharmacists or shopkeepers before giving OTC drugs, while only 18.9% do not. The pharmacists or shopkeepers selling the over counter drugs are much aware (68.5%) about the adverse effect or side effect of drug then the consumers. Consumer generally purchases drug by brand name of drug and its hard to predict whether they know about their ingredient. The pharmacists (42.5%) change the brand written by physician. Forty seven percent of the pharmacists believe that such medications need prescription while others do not. Some basic information revealed as an outcome of the study has been shown in table-4.

Table 4. Some basic information regarding over the counter medications (n=127)

Questions	Answers	Percentage (number)
Choice of OTC medications dispensed is made by....?	Consumer Pharmacist or shopkeeper	73.2 (93) 26.7 (34)
If the OTC medication is given by pharmacist or shopkeeper, the clinical history of patient is taken?	Yes No	81.1 (103) 18.9 (24)
Are the pharmacists or shopkeeper aware of the side effects/ADR of the given OTC drugs?	Yes No	68.5 (87) 31.5 (40)
Are the consumers aware of the side effects/ADR of the taken OTC drugs?	Yes No Can not say	13.3 (17) 25.1 (32) 61.4 (78)
Consumer generally purchases drug by brand name or know the ingredients?	By brand name only Know ingredients Can not say	37.0 (47) 7.8 (10) 55.2 (70)
Does the pharmacist change the brand written by physician?	Yes No	42.5 (54) 57.5 (73)
Is the use of OTC drugs safe?	Yes No Can not say	47.2 (60) 18.2 (23) 34.6 (44)

DISCUSSION

The nonmedical use of prescription or over the counter medications implies that the user is using them for reasons other than those indicated in the prescribing literature or on the box label. The abuse of these medications is a national issue. The need to avoid unnecessary medication exposure is common knowledge in the healthcare community and among most consumers. Interestingly, this has led to a decrease in prescription drug use, but an increase in the use of over the counter medications, herbals, and dietary supplements [15].

In this study we have documented the use of OTC medications among people as per the pharmacists prospective. Analgesics were the most commonly used class of drugs, which is similar to findings in the literature [16, 17].

The assumption that increased access leads to irrational use of OTC medicines has not been substantiated. This shows that the availability of medicines over the counter but with proper safeguards and regulations is required. Physicians need to watch for prescription and OTC medication abuse. Treatment strategies include (1) inquiring about prescription, OTC, and herbal drug use at the initial examination (even though many individuals are drug-abuse savvy, some are nave and do not realize that OTC medications can be problematic); (2) inquiring about drug use during office visits; (3) providing disposal containers that patients can use to dispose of their unused or unneeded prescription or OTC medications; (4) treating pain aggressively and appropriately; (5) practicing careful record keeping of prescription refills and controls over prescription blanks; (6) referring patients who are addicted to medications to 12-step programs such as Alcoholic Anonymous, Narcotics Anonymous, and Pills Anonymous; and (7) considering detoxification.

It is expected that patients will continue to place an increasing emphasis on “selfcare”, and we have to remain up-to-date in our knowledge, in order to make such practice is safe and useful.

CONCLUSION

The prevalence of use of OTC drugs is alarmingly high in Indore city. NSAIDs were the drugs most commonly used over the counter. Few people consult pharmacists on drug information. 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. It is recommended that the dispensing procedure in India needs improvement through educational, regulatory and managerial strategies. There is need for authorities to be proactive regarding over the counter, prescribed and non-prescribed drugs so as to ensure rational sale.

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