HEALTH PRACTITIONERS’ VIEW ON CONCOMITANT USE OF OTC AND PRESCRIPTION DRUGS: A SURVEY REPORT

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ABSTRACT

STUDY BACKGROUND: With the tremendous increase in the use of over the counter (OTC) medicines worldwide as a concomitant therapy to prescription medicines, the safety and efficacy of these medicines has become an important concern. There is poor communication between the physicians and patients regarding the concomitant use of OTC products with prescribed conventional allopathic drugs; which can result in various drug interactions at pharmacokinetic and/or pharmacodynamic levels. OBJECTIVE: To assess the awareness of doctors regarding consumption of OTC drugs concomitantly with prescription drugs by patients. DESIGN: A close-ended questionnaire based survey was conducted. SUBJECTS: Doctors from Mumbai, Maharashtra. METHOD: Respondents were asked questions regarding the consumption of OTC products by their patients, reasons behind self-medication, most common form of OTC drugs (conventional/alternative system) the patients preferred and other related questions pertaining to the same subject. RESULT: The study found that most of the doctors believe that up to 40%-80% of patients self-medicate. Most common form of OTC medicine was found to be ayurvedic herbal medicines (44%), followed by allopathic OTC products (37%), homeopathic medicines (18%) and others including unani, siddha etc. (1%). It was also found that very few doctors (5%) report drug interactions to a pharmacovigilance centre. CONCLUSION: A collective effort of a healthcare team consisting of doctors, nurses and pharmacists towards creating awareness about the hazardous effects of consumption of OTC drugs along with prescription drugs and documentation of the same for future references is the need of the hour.
INTRODUCTION:
Self-medication has become an alarming practice all over the world for treating numerous diseases \(^1\). The legal meaning of OTC drugs is to be sold ‘over the counter’ \(i.e\). they are sold directly to the customer without the prescription of a healthcare professional \(^2\). People consume these OTC drugs either by their own wish or by pharmacist’s advice \(^3\). Most of the times, patients do not inform the medical practitioners about the consumption of OTC products since they have an interim belief that as these products do not require a prescription for their usage, they are safe for consumption. Patients also consume ayurvedic products/ health supplements on their own since they have a strong perception that drugs of natural origin are safe and effective \(^4\). Changing a drug from prescription-only to over the counter availability may risk patient’s life. There may be different interactions taking place in an individual at pharmacokinetic and/or pharmacodynamic levels which may prove fatal \(^5\). At pharmacodynamic level, a drug might give response which is additive, synergistic or antagonistic along with other drug \(^6\). Pharmacokinetic interaction occur when one herb/drug interferes with the absorption, distribution, protein binding, metabolism and elimination of other drugs \(^7\). The possibility of interaction due to self-medication has been reported since ages. However, there is very less data available about the reporting of such interactions \(^8\). The use of dietary health supplements is also increasing day by day to address specific health concerns, optimize health conditions and increase quality of life \(^9\). There is a lot of influence of herbal medicines, diet, nutrient supplementation, environment on the health of an individual. Drug–drug, drug–herb, and drug–nutrient interactions have garnered importance in the pharmacovigilance system \(^10\).

The survey was undertaken to assess the awareness of doctors regarding the consumption of OTC drugs concomitantly with prescription drugs by their patients.

METHODS:
The study was a questionnaire-based survey, undertaken in October 2014. The survey population comprised of doctors from various hospitals and dispensaries in Mumbai, India.

For this survey, a self-developed and a structured questionnaire was prepared. The results are based upon the data obtained from 50 respondents. The data was summarized as counts and percentages and some of the questions were categorised with multiple options for the physicians to select with space for other answers. The questions asked to the doctors pertained to:

- Whether patients consume OTC drugs along with prescription drugs
Main reasons behind self-medication
Most common source of information for self-medication
Most common form of OTC medicines (Allopathic/ Ayurvedic/ Unani/ Homeopathic)
Whether practitioner asked their patients about consumption of OTC drugs
Percentage of patients consuming OTC drugs according to the practitioners
Most common clinical conditions for which patients self-medicated
Whether patients consumed OTC products for fatal disorders
Whether practitioners witnessed any interactions between OTC products and prescription drugs among their patients
Whether the interactions were reported to pharmacovigilance centre.
Whether the practitioners advised their patients to avoid the consumption of OTC drugs with prescription drugs.

RESULTS AND DISCUSSION:
There were 50 doctors in total who responded to the questionnaire. Out of which, most of them were M.B.B.S. (general practitioners) and few of them were post graduates doctors (MS/MD in various specialities).

Doctor’s awareness of their patients consuming OTC drugs along with prescription drugs:

87% of the total surveyed number of doctors believed that their patients consumed OTC drugs along with prescription drugs as seldom do the patients have a good knowledge about the drug mechanism, their side effect profiles and the interactions of the consumed drugs. This statistics represents a shocking scenario of the patients consuming OTC drugs along with prescription drugs.
Main reasons behind patients’ self-medication:

The most common reason for self-medication was to obtain quick relief (45%) followed by consultation fees (30%) and lack of time (25%) respectively. The statistic represents that most of the patients consume OTC drugs for faster relief; unaware of the ill effects caused by the concomitant usage of medicines. Doctors also believed that, their patients do not visit them because of their consultation fees and also due to the hectic schedule of the patients.

Most common source of information for self-medication:

It was found that according to the doctors, the most common source of information for self-medication is the Chemist/Pharmacist. Other sources of information include advertisements,
internet, friends and family. It is a prime duty of a pharmacist to give medications only on
doctor’s prescription. Pharmacists must obey regulations put forth by the government and favour
the sale of prescription drugs only \(^{11}\). Healthcare system must put up stringent regulations
regarding the advertisements displayed for the people regarding OTC usage. Governments in the
Western countries have started taking legal actions against complementary and dietary
supplement promoters and websites that promote and make deceptive statement about the OTC
products \(^{12}\). Enforcing stringent federal regulations is the need of the hour in developing countries
like India, where practising OTC complementary therapy is most prevalent. It is important to look
out for reliable source of information about drugs rather than believing friends and family.
Though the internet information gives a whole insight of the drug from its therapeutic benefit,
mechanism of action to its reported interaction with other drugs, the interaction information is
generally overlooked by the patients resulting in practising concomitant therapy. Special
healthcare unit need to be set up throughout the country to educate people about the ill effects of
consumption of many drugs at a time.

**Most common form of OTC medicines (Allopathic/ Ayurvedic/ Unani/ Homeopathic)
consumed by the patients:**

![Figure 4: Most common form of OTC medicines consumed by the patients]

Most common form of OTC medicines (Allopathic/ Ayurvedic/ Unani/ Homeopathic) the patients
consume concomitantly according to the doctors was found to be ayurvedic herbal medicine
(44%), followed by allopathic OTC products (37%), homeopathic medicine (18%) and others like
siddha and unani (1%). The survey found that majority of the patients opted for ayurvedic OTC
over other forms of OTC medications. This observation can be attributed to the fact that majority
of the people have a strong belief that ayurvedic medicines are effective as well as completely
free of side effects\textsuperscript{4, 14}. Now that ayurvedic industry has seen a new boom in the existing medicinal market\textsuperscript{15}, proper standards and regulations need to be set up on the efficacy and safety of these herbs\textsuperscript{16}. In depth studies are required to prove the safety of these herbal medicines. Proper documentation is to be done for the usage of these medicines. Generally patients consuming both allopathic prescription drugs and ayurvedic/homeopathic medicines interpret that it is the allopathic medicine which lead to adverse drug reactions, unaware of the fact that these complementary medicines might also contribute to these interactions and decrease the effect of allopathic drug.

\textbf{Whether the practitioner ask the patients about consumption of OTC drugs:}

\begin{figure}[h]
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\includegraphics[width=0.5\textwidth]{figure5.png}
\caption{Whether the practitioner ask the patients about consumption of OTC drugs}
\end{figure}

This analysis gives a pleasant picture with regards to the concern of the practitioners towards their patient’s health, but 16\% cannot be ignored as this survey was conducted taking a small number of representative respondents. If such a survey were to be done taking a larger number of representative population the number of doctors who enquire about their patients consuming OTC would significantly decrease.
Percentage of patients consuming OTC drugs:
From the interpreted statistics we came to a conclusion that 9/10 doctors believe that up to 40% of the patients self-medicate and 1/10 believe that 40-80% of the patients self-medicate. Patients usually abstain from informing their doctors about they practising concomitant therapy; as a general mind set is set up amongst them, that allopathic practitioners have a somewhat flippant approach towards traditional medicine. The reason for the increase in number of complementary OTC consumption is that they are cheap as well as safe to use. Also, many patients have experienced dissatisfaction about the conventional allopathic treatment because it might have been less or ineffective or might be too costly.

Most common clinical conditions for which patients self-medicate:

The statistics reveal that most of the patients consume OTC drugs for cough, cold, fever and headache. Most of the fatal disorders have primary symptoms like cold, fever, headache etc. For example, common cold and influenza accompanied with fever and body ache are the most common syndromes of infection in human beings.
clinical conditions irrespective of the fact that these primary symptoms may cause major illness if not diagnosed and treated properly.

*Whether patients consumed OTC products for fatal disorders:*

64% of doctors believed that their patients consume OTC drugs even for fatal conditions like neurological, neuropsychological disorders as well as metabolic syndrome. This statistics represents that people rely on OTC medications even in the midst of a fatal disorder. They do not think of the ill effects the concomitant therapy might cause. Many herbals are used as OTC medicines to treat various heart diseases, diabetes, liver disorders, depression, pain, cancer to name a few 20.
Whether the doctors witnessed drug interactions between OTC products and prescription drugs:

The survey found that 75% of the doctors are unaware of the interactions and the adverse effects their patients witness. We come to a conclusion that patients do not convey a full picture of what they use for maintaining good health, be it complementary health approaches like herbs, *churnas*, multi-vitamins, health tonics or other dietary supplements. There are no specific bifurcations mentioned in the healthcare system which can give an idea about why the interactions take place or whether the interaction is due to prescription drugs or medicines taken concomitantly with prescribed ones. Adverse events are noticeably found in individuals consuming complementary OTC drugs. Patients must be made aware of the fact that herbal medicines may contain many compounds and that all its constituents may not be known. Possibilities of product contamination and drug interactions are high in case of complementary medicinal approach and this might lead to adverse effects. Special measures are to be undertaken by the healthcare society in order to report such events. Doctors must urge the patients to report smallest and the slightest of interaction observed during the therapy. People must be educated about reporting adverse events to a pharmacovigilance centre.
Whether the interactions are reported to pharmacovigilance centre:

From the statistics we came to know that very few practitioners (about 5%) report the interactions encountered by their patients. Reporting a serious drug event to a pharmacovigilance centre is of utmost importance these days since people suffer from various disorders at a time. OTC drugs taken concomitantly with prescription drugs might prove lethal to the patients. All the adverse events must be documented to a pharmacovigilance centre so that proper measures can be taken to minimise the possible risks and increase the benefit. Pharmacovigilance centre must recognise the systems approach for monitoring and improving the safe use of medicines. All safety aspects of the drug therapy must be monitored and addressed properly. Pharmacy, being a branch of medicine that serves as a link between patients and practitioners must emphasise on therapy management and patient assessment. Health care system must give importance to literature searches, spontaneous reports and clinical trial data and update themselves about the practice of OTC medicines and the risk-benefit ratio associated with them. Comprehensive medication review, patient’s assessment, patient and their medication related information must be documented in pharmacovigilance centre and emphasis must be given on publishing all drug related mishaps and benefits in periodic safety update reports.
Whether the practitioners’ advice the patients to avoid the consumption of OTC drugs with prescription drugs:

Out of the total number of surveyed doctors, only 27% of the respondents advised their patients not to consume OTC drugs along with prescription drugs. It states that majority of the doctors refrain from advising their patients about the ill effects caused by the concomitant usage of the drugs. The increasing number of OTC abuse has compelled the doctors to expand their duties from prescribing drugs to counsel the patients about appropriate and rationale medicinal therapy. Since patients often do not express their desire for counselling, it is the duty of healthcare professionals to discuss the all possible benefits and risks related to the concomitant drug therapy.

CONCLUSION:

We acknowledge that this type of self-administered questionnaire is largely dependent on information provided by the respondents.

From the interpreted results it is observed that many people consume OTC drugs for various disorders. The most common form of OTC being ayurvedic herbals might prove fatal to the patients. The elderly population are at high risk because they are encountered with various disorders at a time. The probability of they consuming one or more drugs is high hence might lead to various drug interactions. In addition to the prescribed drugs, consumption of OTC might lead to interactions at pharmacodynamic and/or pharmacokinetic levels. Especially herbs, they might interfere with the absorption, distribution, metabolism and excretion of drugs resulting into lack of therapeutic efficacy and side effects.

It has become very cardinal for the doctors to know what their patients consume as medicines. Most of the patients lack knowledge about the complete profile of the drugs they consume. They
are not even aware of the dose regimen, duration of action, treatment, side effects and toxic reactions of the drugs. They must be educated about the hazards of practicing concomitant therapy.

Appropriate measures need to be burdened by the healthcare society onto the population to reduce the incidence of concomitant drug therapy related mishaps. Chemists and pharmacists along with practitioners must judiciously support the use of prescription drugs only. Any patients asking for OTC drugs must be given prior information about the hazardous interactions that these drugs might cause. Pharmacovigilance and Risk Management have garnered lot of importance in the pharmaceutical world. The healthcare professionals must take the responsibility of documenting all the interactions to a pharmacovigilance centre. The pharmacovigilance centre must progress with further necessary measures in order to minimise the risk of all possible fatality. Adverse drug reactions and serious adverse events need to be studied in more depth which will contribute to their avoidance. Patient education and conducting awareness campaigns has become an alarming priority among the healthcare system. For this purpose community pharmacy must be designed to improve the communication between the patients regarding safe medication, proper detection of interactions and OTC consumption related risk management. Community pharmacists must spend time with patients, identify their problems and advise them about rationale drug therapy. A new approach to improve health must be strongly encouraged amongst the population. This would definitely help in maintaining the quality of life of an individual as well as the society.

REFERENCES:


