A Community Pharmacy Study Based on Medications Sold Over the Counter for Chronic Disorders in Mysore City.

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Abstract:

Introduction: Over the counter (OTC) medications are those drugs that can be bought from the pharmacy without the aid of a prescription. In India almost all drugs can be bought over the counter without prescriptions. This leads to misuse of drugs especially antibiotics and other potent drugs. OTC drugs enable people to relieve many annoying symptoms and to cure some diseases simply and without the cost of seeing a doctor. Therefore the research investigators thought that this type of research study may be more helpful for elderly patients suffering from chronic disorders and it can also recognise the role of community pharmacist creating a more awareness to the general public with regarding to over the counter medications in chronic disorders.

Objective of the Study: To enlist the medicines that is sold over the counter for chronic disorders.

Methodology: This was a prospective observational cross sectional study carried out in private community pharmacy of Mysuru city over a period of eight months. Subjects who met study criteria were enrolled in this research study. 4-hr duration (From 4pm-8pm) visit was made to a private community pharmacy selected to carry out this study. Data collection form was used to collect details from the subjects selected for the study. Demographic details of the subjects, name and details of medications purchased were recorded.

Results& Discussion: Total number of subjects visited the pharmacy were 728, among them 434 purchased medications without a medical prescription with chronic disorders during study hours.The details of different medications purchased without prescription by therapeutic categories are Analgesics [74(17.05%)], antibiotics [198(45.62%)] and medication used totreat gastrointestinal conditions[56 (12.90%)]were the most commonly purchased medications.

Conclusion: Our research study concluded that most commonly purchased medications without a medical prescription was analgesics such as aceclofenac + paracetamol followed by antibiotics such as azithromycin.
Key Words: Over the Counter, Chronic, Disorders.

Background of the Study: Over the counter (OTC) medications are those drugs that can be bought from the pharmacy without the aid of a prescription.In India almost all drugs can be bought over the counter without prescriptions.This leads to misuse of drugs especially antibiotics and other potent drugs. OTC drugs enable people to relieve many annoying symptoms and to cure some diseases simply and without the cost of seeing a doctor.They can treat their common and troublesome conditions with easily recognised symptoms, such as hay fever and cold sores.

In India any drug can be purchased without prescription as there are no stringent policies by drug regulatory authorities which is leading lot of problems to most of the patients which goes unnoticed. Patients with more comorbiditieswill always be receiving more number of medications,which needs more screening of over the counter medications while dispensing for example NSAIDs should never be dispensed to patients suffering gastric ulcer, gastrointestinal bleeding as it can worsen the existing medical condition. Therefore any over the counter medications that needs to be dispensed for patients suffering from chronic disorders requires proper evaluation before dispensing.

In India most of the dispensing pharmacists are having qualification status of D.Pharm where they don't have adequate knowledge of pharmacotherapeutics due to poor teaching curriculum framed by Pharmacy Council of India and at the same time they have not underwent any continuing professional development programmes. Dispensing pharmacists with lower qualification status will always have lack of confidence about the subject and poorprofessional skills due to lack of training.

The patients coming to community pharmacies for purchase of medications don't have minimum knowledge about the medicines or how many of the patients arereceived proper directions about safe use of medicines from concerned prescriber is not yet known in most of the circumstances. A study carried out by united nations drug control programme has reflected that self-medications is increasing in south Asian countries especially like India.(1)

According to this research study patients falling under the geriatric group are more prone to have adverse drug events because of social history like alcoholic beverage consumption, smoking etc where it may interact with some over the counter drugs eg acetaminophen etc. There is no specific definition of over the counter medications in Indian community pharmacy practice, in according to drugs and cosmetics act 1945 over the counter drugs fall under schedule K. Different research studies have shown the prevalence of non-prescription drugs vary between 39% to 70%.Older literature summarized more time is required for health care accompanied with high consultation fees of clinician is reason to opt for self-medications where it can provide quick relief of symptoms suffering from minor ailments. Elderly people living with physical inability may find very difficult to approach any health care centre when they have minor health problems, which needs alternative strategy during this situation is self-medications. Multiple drugs having synergistic effect may contribute to toxicity where research studies carried out with regarding to over the counter drugs among elderly population should take new dimension.

One of the research study carried out with regarding to over the counter medications in university of Missouri-Columbia.reflected older adults may have an vital health out comes as a self-initiated behavior. The reason behind of having any kind of more health problems with respect to over the counter drugs among older adults due to be a poorer health status compare to a younger adults and persons in poor health receive more over the counter drugs than those in better health(Bush & Rabin, 1976; Johnsonet al., 1976; Johnson & Pope, 1983).(2) Older

widowed women depend more on over the counter medical products such as analgesics, laxatives, antacids, and vitamins (Landress, 1984; Stoller, 1988).The dependability of over the counter medications are applicable in according to acute or chronic illness symptoms (Chrischilles et al., 1990).

The factor that influences the use of over the counter medications among elderly clients is due to reduction of cost which does not require a physician prescription and increasing the sense of independence (Cupit, 1982; Lamy, 1982; Oster et al., 1990). Raffoul (1986).

The prevalence of chronic disorders like Hypertension, Diabetes mellitus, Chronic Obstructive Pulmonary Disease is increasing as days are passing and patients suffering from chronic medical problems having a illiterate status may not give a clear information while purchasing any over the counter medications At present practicing community pharmacists in India are not well organised when it comes to dispensing a over the counter medication due to lack of training in community pharmacy practice.

Most of over the counter medications such as antacids, NSAIDs, anti-histamines may worsen chronic medical problems if proper precautionary measure is not taken while dispensing over the counter medications. Most of over the counter medications may have adverse impact on chronic disorders if these medications are abused, since there is no stringent regulation for dispensing,if screening of over the counter medications in patients suffering from chronic medical disorders is not done properly, drug induced problems in a chronic disorder may be unnoticed.

Thereforethe research investigators thought that this type of research study may be more helpful for elderly patients suffering from chronic disorders and it can also recognise the role of community pharmacist creating a more awareness to the general public with regarding to over the counter medications in chronic disorders. There are very few research studies carried

out with respect to over the counter medications in an Indian community pharmacy setting. As a result, research investigators have chosen this research study which may give a good platform for future research study in over the counter medications for chronic disorders.

Specific Objective of the Study: To enlist the medicines which is sold over the counter for chronic disorders.

Methodology: This was a prospective observational cross sectional study carried out in private community pharmacy of Mysuru city over a period of eight months. Subjects who met study criteria were enrolled in this research study.

Study procedure:

1. **Development of data collection form:**

A suitable data collection form was designed to collect and document details from the subjects related to name, age, gender, literacy status (elementary/primaryschooling- 1^{st} to 8^{th},secondary/senior secondary/highschool- $9^{th}$to$12^{th}$and graduates or postgraduates), occupation, smoking habit, alcohol consumption and details of medicines purchased.

2. **Computerization of data collection form:**

3. A computerized format of data collection form using Microsoft Excel 2015 was created for the documentation of the collected data and also for easy accessibility, retrieval and analysis of collected data.

4. **Selection of subjects for the study:**

Subjects who met study criteria were included into the study.

5. **Collection of data:**

4-hr duration (From 4pm-8pm) visit was made to a private community pharmacy selected to carry

out this study. Data collection form was used to collect details from the subjects selected for the study. Demographic details of the subjects, name and details of medications purchased were recorded.

Data Analysis:

Raw data collected was entered into Microsoft Excel 2015, double checked for accuracy, and analyzed using descriptive statistics. The results were presented in absolute figures (percentages) as depicted in tables, figures and charts in according to the requirement.

Results and Discussion:

I. Characteristics of the study population:

Total number of Subjects visited the pharmacy were 728, among them 434 purchased medications without a medical prescription with chronic disorders during study hours.

Table 1: shows demographic characteristics of subjects, 255 (58.79 %) of whom 179 were males (41.24%) 76 were females. Majority of them belong to the age group of 31-50 years (249 [57.37%]).

Table 1: Demographic details of the study population (n = 434)

Demographic Characteristics	Categories	Total (%)
Age	18-30	65(14.97)
	31-50	249(57.37)
	>50	120(27.64)
Gender	Male	255(58.75)
	Female	179(41.24)
Smoking habit	Yes	131(30.18)
	No	303(69.81)
	Mild	36(8.29)

Alcohol Consumption	Moderate	26(5.99)
	Excess	0(0)
	No	372(85.71)
Literacy Status	Illiterate	63(14.51)
	Primary	62(14.28)
	Secondary School	100(23.04)
	High School	102(27.64)
	Degree and Above	107(24.65)

followed by the age group of above 50 years (27.64% [120]).102% (27.64) were educated up to high school and 30.18% (131) had a habit of smoking and 8.29% (36), 5.99% (26), were consuming alcohol in mild and moderate quantities respectively.

II. Therapeutic classes of medications purchased without a medical prescription with chronic disorders:

The details of different medications purchased by therapeutic categories are listed in **Table 2**. Analgesics [74(17.05%)], antibiotics [198(45.62%)] and medication used totreat gastrointestinal conditions[56 (12.90%)]were the most commonly purchased medications. Other categories of medications purchased were; antihypertensives[55 (12.67%)], antidiabetic[40 (9.21%)], and COPD [11 (2.53%)].

Table 2: Therapeutic classes of medications purchased without prescription with chronic disorder (**n = 434**)

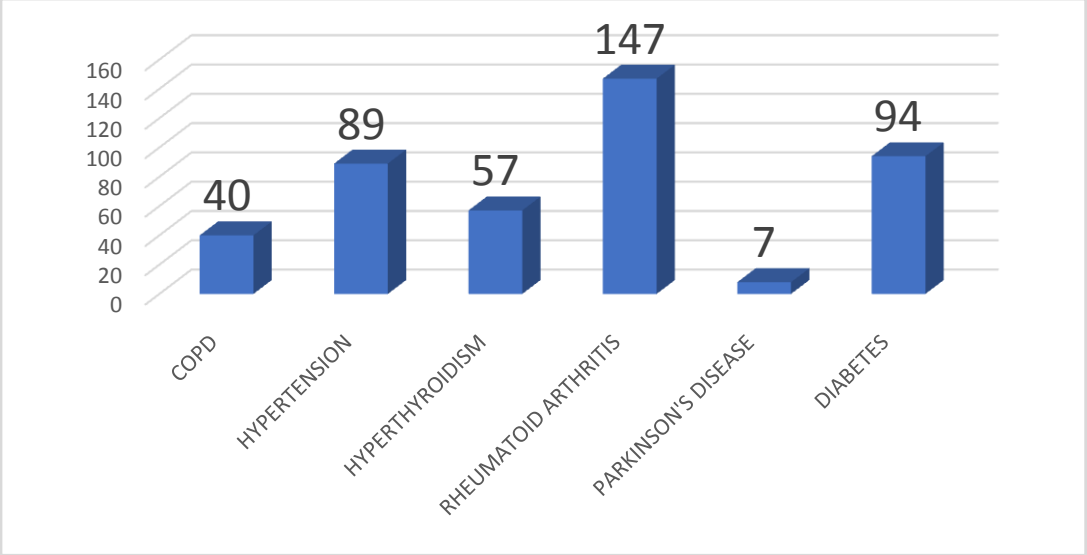
Sl.No	Therapeutic Class	Common Drugs	No.	Total (%)
1.	Analgesics	Tramadol + paracetamol	2	74(17.05)
		Aceclofenac + Paracetamol	48	
		Diclofenac	4	
		Etoricoxib	4	
		Ibuprofen + Paracetamol + Caffein	2	
		Diclofenac +Paracetamol	13	

		Ibuprofen	1	
2.	Antibiotics	Amoxicillin + Calvulanic acid Azithromycin Cefixime + Calvinic acid Ciprofloxacin Amoxicilline Ciprofloxacin + Timidazole Cefixime Norfloxacin Azythromycin Albendazole	 14 82 1 1 22 3 31 1 32 11	198(45.62)
3.	GI medications	Pantoprazole Omeprazole + Domperidone Omeprazole Rabeprazole Ranitidine	35 4 9 3 5	56(12.90)

4.	Antihypertensives	Amlodepine + Atenolol Telmisartan + Hydrochlorthiazide Carvedilol Metoprolol Amlodepine Telmisartan + Amlodipine Levosartan + Ipratropium bromide	18 14 3 6 4 9 1	55(12.67)
5.	Antidiabetics	Metformin Glimepiride + Metformin Insulin Glimipride +Metformin + Pioglitazone	8 9 15 8	40(9.21)
6.	Asthma – COPD	Acebrophyllin Budosenide	5 6	11(2.53)

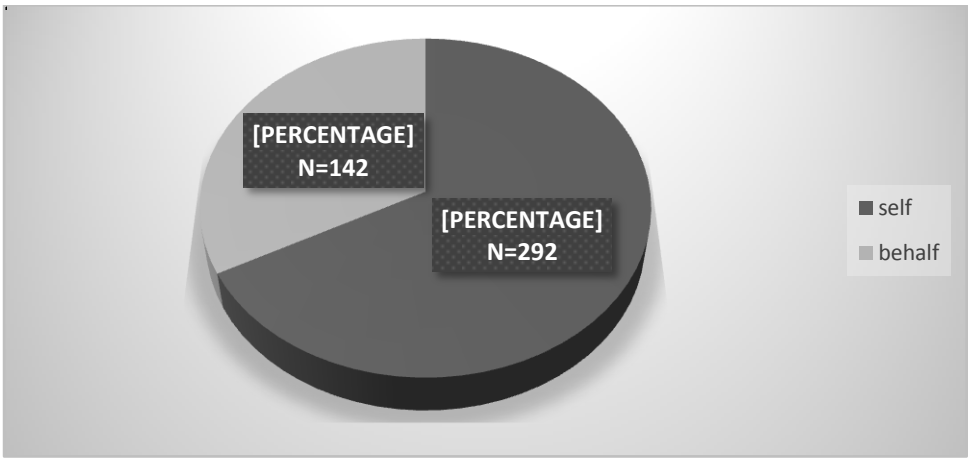
The most common chronic disease conditions for which OTC medications were used are; Rheumatoid Arthritis [147 (33.87%)], followed by Diabetes [94 (27.40%)], Hypertension [89 (20.50%)], hyperthyroidism [57 (13.13%)], COPD [40 (9.21%)], and Parkinson`s disease [1.61% (7)] [Figure 1]

Figure 1: Subjects purchased OTC medications with chronic disorders (n = 434)



Out of 434 subjects, 292 (62.28%) purchased medications without a medical prescription for self-use and 142(32.71%) purchased on behalf of others (i,e. Family members, friends, neighbours etc..)[**figure 2]**

Figure 2: Method of purchasing OTC medications (N=434)



Methods of obtaining OTC medications by the study population:

Medications sold without a prescription were done so by the following: 154 (35.48%) of the subjects purchased medications by describing symptoms to the pharmacist and 280 (64.51%) purchased medications by providing a used container/tablet strip, medication name written on a piece of paper (not a medical prescription) and asking for medications verbally, as shown in [**Table 3.]**

Table 3: Methods of obtaining OTC medications by the study population **n = 434**

Sl.No	Method	Total (%)
1.	Describing symptoms and asking for medications	35.48% (154)
2.	Providing a used container/tablet strips, medication name written on a piece of paper (not a medical prescription) asking for drug verbally	64.51% (280)

In India any over the counter drug can be easily purchased from the community pharmacy as there are no stringent regulations amended from drug regulatory authorities of India.

This research study was carried out in a private community pharmacy located in Mysuru city where drugs were dispensed from with and without medical prescriptions by legally qualified registered pharmacist. The main aim of carrying out this research study is to find out how many subjects as well as registered pharmacists aware about precautions that need to be taken while dispensing over the counter drugs to subjects suffering from chronic disorders. The dimension of the selected community pharmacy was 1000 Sq. Ft which have facilities like placing drugs in the dispensing racks, computer system which helps in maintaining the inventory control of pharmacy as well as refrigerator. Where some drugs have to be stored in freezing condition in according to the stability of individual medical products. A person who is practicing a dispensing in this community pharmacy was diploma in pharmacy and provide a easy accessibility to all the medications in according to the requirement of the subjects.

Most of the subjects visiting the community pharmacy were illiterate as well as 12^{th} standard which was observed during the research study. Subjects with poor qualification status such as 5^{th}, 8^{th} ,10^{th} etc. have difficulty in understanding about the nature of disease and its progression where this can always approach to any community pharmacy and purchase

medicines without bringing a notice about the past medical history to pharmacist or healthcare professional which can always end up with worsening of existing medical problem if over the counter drug is contra indicated Ex:- Aspirin which is contra indicated in the management of gastric ulcer. Another reason what we founded in our research study was self-medication practice is becoming more prominent as they can have an easy accessibility of drugsfor the existing minor symptoms which can ultimately prevent waiting time, consultation fees of consultant clinician. Among the demographic details of study population majority of the age group found was 31-50 years of 249 which is accountable to (57.37%). Similar findings were observed from Tito at al. Nagaraj at al. [4] where majority of the subjects belongs to the age group of 21-40 years male subjects were more compared to female in this research study which is accountable to 58.75% and similar findings were observed among gender distribution by Nagaraj at al.

The most common therapeutic class of medications that were purchased without a medical prescription for chronic disorders wereAntibiotics 198 (45.62) following Analgesics 74 (17.05) our research findings were also having some similar findings of Keshari at al. [6] 46.44% of medications were purchased as fixed dose combination for analgesics and antibiotics.

Subjects who purchased over the counter medication for chronic disorder in our research study were reflected as for Rheumatoid arthritis 147 (33.87%) followed by diabetes 94 (27.40%) hypertension 89 (20.50%) etc.

64.51% of medications purchased without a prescription were done so by providing a used container/tablet strips, drug name written on a piece of paper (not a medical prescription) or asking for the drug verbally. In this study, the categories of medications most frequently requested without a prescription were analgesics, antibiotics and medications used to treat gastrointestinal conditions.

Of those surveyed requesting drugs without a prescription, more than fifty percent were literate. This might indicate that educated individuals play an active role on their health and self-care initiatives. Common purchased prescription medications togetherwith non-prescription medications were most of antibiotics with cough syrups, sildenafil citrate with multivitamins and multimineral. When these medications were purchased by subjects,they did not give any valid reasons and even dispensing pharmacist did not make any attempt to find reasons for what purpose they were intend to make purchase of medications such as antibiotics with cough syrups, sildenafil citrate with multivitamins with multimineral products and so on.

Healthcare professionals were the major source of information for the use of prescription medications in this study. In the present study, pharmacists and doctors were found to be the most common source of drug information followed by friend or family member. These are consistent with the earlier reports. Subjects with chronic diseases visit their community pharmacists more frequently than their physician.

Customers selected the use of prescription medications over the counter mostly, as some diseases were simple, familiar with the disease and treatment and there was previous experience with similar problems.10.85% purchased prescription medications as they had previous experience with similar problems. This might indicate that customers purchased prescription medications for their chronic conditions like diabetes mellitus, cardiovascular diseases etc.There is a slight difference in other studies such as a study conducted by Al-Motassem M et al [23]because of difference in designs. 52.71% (136) said they would consult a pharmacist before purchasing any medications from the pharmacy.

Research investigator carrying out this research work had a many problems with respect to the working hours, local language and distance of research location site from the educational

institution.The main intension of the dispensing pharmacist was togain a more profit by selling a medications irrespective of health status of the Subjects where sometimes dispensing pharmacist were changing the brand name without bringing notice to subject or subject consultant and this type of misleading things were happening were more on illiterate Subjects compared to literate Subjects.

Conclusion: Our research study concluded that most commonly purchased medications without a medical prescription was analgesics such as aceclofenac + paracetamol followed by antibiotics such as azithromycin. The key findings of this research study reflected that 292 (62.28%) purchased medications without a medical prescription for self-use and 142(32.71%) purchased on behalf of others (i,e. Family members, friends, neighbours etc..),pharmacists and doctors were found to be the most common source of drug information followed by friend or family member.This research study also concluded that medications purchased without prescription among chronic disorders were Rheumatoid Arthritis [147 (33.87%)], followed by Diabetes [94 (27.40%)], Hypertension [89 (20.50%)], hyperthyroidism [57 (13.13%)], COPD [40 (9.21%)], and Parkinson`s disease [1.61% (7)].Research investigators observed there were no stringent policies from drug regulatory authorities which makes very easy for dispensing pharmacist to sell medications irrespective of prescriptions received at the counter of community pharmacy. In according to the observation made by research investigators, it is necessary to create more awareness to dispensing pharmacist to take more precautions while dispensing medications when any prescriptions of chronic disorders are received at the counter of community pharmacy. Dispensing pharmacist needs to undergo a training about the importance of dispensing over the counter medications among chronic disorders and what will be the consequences if proper precaution is not taken while dispensing medications should be made to understand so that drug related problems can be minimised in prescriptions of chronic disorders in future with more dedication and commitment, so that

the general public may recognise the role of community pharmacist who also plays an important role in a vital health care of the general public.

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