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RESEARCH ARTICLE
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TITLE: CRITICAL ANALYSIS OF DRUGS DISPENSED OVER THE COUNTER WITHOUT PRESCRIPTION FOR COMMON COLD AND SORE THROAT BY PHARMACIES OF A SOUTH INDIAN CITY.

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ABSTRACT

Background: In developing countries, people directly approach pharmacies for medicines without a doctor's prescription for minor ailments. Though there are some medications licensed for dispensing as over the counter drugs (OTC) drugs, the pharmacists in the medical shop tend to give drugs that are not approved for OTC dispensing. Use of OTC drugs has increased rapidly in the few years. The OTC Pharmaceuticals market in India is projected to grow by 10.98% (2024–2029), resulting in a market volume of US$947.40 million in 2029. The misuse of OTC drugs can adversely affect the health of the common man.

Methods: A cross-sectional descriptive observational study was carried out targeting the pharmacies in a south Indian city. The investigator visited 50 medical shops like a common man and requested medications for common cold and sore throat. The drugs were collected in a zip-lock bag. The pharmacy name and collected drugs were coded in numbers. Collected drugs were stored in the department of pharmacology. Data analysis was done in Microsoft Excel.

Results: All the pharmacies responded to by the investigator. The fifty pharmacies dispensed around 16 classes of drugs as OTC from the pharmacy. 32% dispensed irrational fixed dose combination drugs (FDCs), and 18% dispensed rational FDCs. WHO has classified antibiotics into Aware class which means Access, Watch, Reserve. 60% of dispensed antibiotics were in the watch group, and 40% of drugs were in the access group of antibiotics. Around 80% followed standard treatment guidelines (STG), and 20% followed non-standard treatment guidelines.

Conclusion: The study showed that the pharmacists rampantly dispensed the drugs without any prescription. It can lead to irrational use of drugs by the consumers which were dispensed over the

counter by the pharmacies. This might increase the cost of health care in the future and may cause serious adverse effects. In addition, proper diagnosis may be missed, and drug interactions can occur. So, we conclude that strong guidelines, regulations, and awareness should be made and implemented to prevent the irrational dispensing of drugs over the counter.

Keywords: OTC drugs, common cold, sore throat, standard treatment guidelines (STG).

Introduction

Over-the-counter medicine is also known as OTC, or non-prescription medicine. All these terms refer to medicines that one can buy without a prescription [(1)]. In developing countries, people directly approach pharmacies for medicines without a doctor's prescription for minor ailments. They are commonly used for a broad range of minor illnesses, including but not limited to headaches, colds, sore throats, and heartburn [(2).] Though there are some medications licensed for dispensing as OTC drugs, the pharmacists in the medical shop tend to give drugs that are not approved for OTC dispensing. The OTC Pharmaceuticals market in India is projected to grow by 10.98% (2024–2029), resulting in a market volume of US$947.40 million in 2029 [(3).] Reasons for self-medication could be modern lifestyle, busy working schedule, lack of time to seek a doctor appointment, waiting for a longer period for consultation, milder illness, the long distance of medical pharmacy shops, the unaffordable fees of doctors, and too much information from the internet and magazines that makes people overconfident in treating their own illnesses [(4).] Misuse of OTC drugs can adversely affect the health of the common man. Therefore, this study aims to analyze the drugs dispensed over the counter by pharmacies without a doctor's prescription.

Methods

The investigator visited 50 medical shops like a common man and requested medications for common cold and sore throat. The drugs were collected in a zip-lock bag. The pharmacy name was coded in numbers. The collected drug was mentioned as a sample coded with numbers. Collected drugs are stored in the department of pharmacology. Data analysis was done in Microsoft Excel.

The dispensed drugs were analyzed for the following criteria:

Standard treatment guidelines (STG),
Duplication of the drugs,
Irrational FDCs,
Non-OTC drugs,
Antibiotics in the “AWARE” groups as per WHO, and
In addition, the total number of drugs dispensed and the class to which they belong.

Results

Dispensed Class of Drugs

There were around 16 classes of drugs dispensed as without prescription from the pharmacy. Among those, around forty tablets of antihistamines and antibiotics were dispensed. Twenty-three tablets of cough suppressants, antihistamines, and nasal decongestants combinations were dispensed. Nasal decongestants were around seventeen. Corticosteroids dispensed were twelve in number. Proton pump inhibitors and combination of CNS stimulants (methylxanthine class) and nasal decongestants were 11 tablets in each group. (Table 1).

Table 1: Dispensed Class of Drugs

S.NO	Class of drugs	Formulation	Number of tablets
1.	Expectorants+ bronchodilators+ Mucolytics	Tablets	1
2.	H_2 blockers	Tablets	1
3.	Mucolytics	Tablets	1
4.	oral antiseptics	Lozenges	1
5.	Anticholinergics	Tablets	1
6.	Multi-vitamins	Tablets	1
7.	Anthelmintics	Tablets	2
8.	Bronchodilators	Tablets	2
9.	NSAIDs	Tablets	10
10.	CNS stimulant (methylxanthine class) + nasal decongestants	Tablets	11
11.	Proton pump inhibitors	Tablets	11
12.	Corticosteroids	Tablets	12
13.	Nasal decongestants	Tablets	17
14.	Cough suppressants + Antihistamines + nasal decongestants	Tablets	23
15.	Antihistamines	Tablets	40
16.	Antibiotics	Tablets	40
Total			174

Duplication of drugs

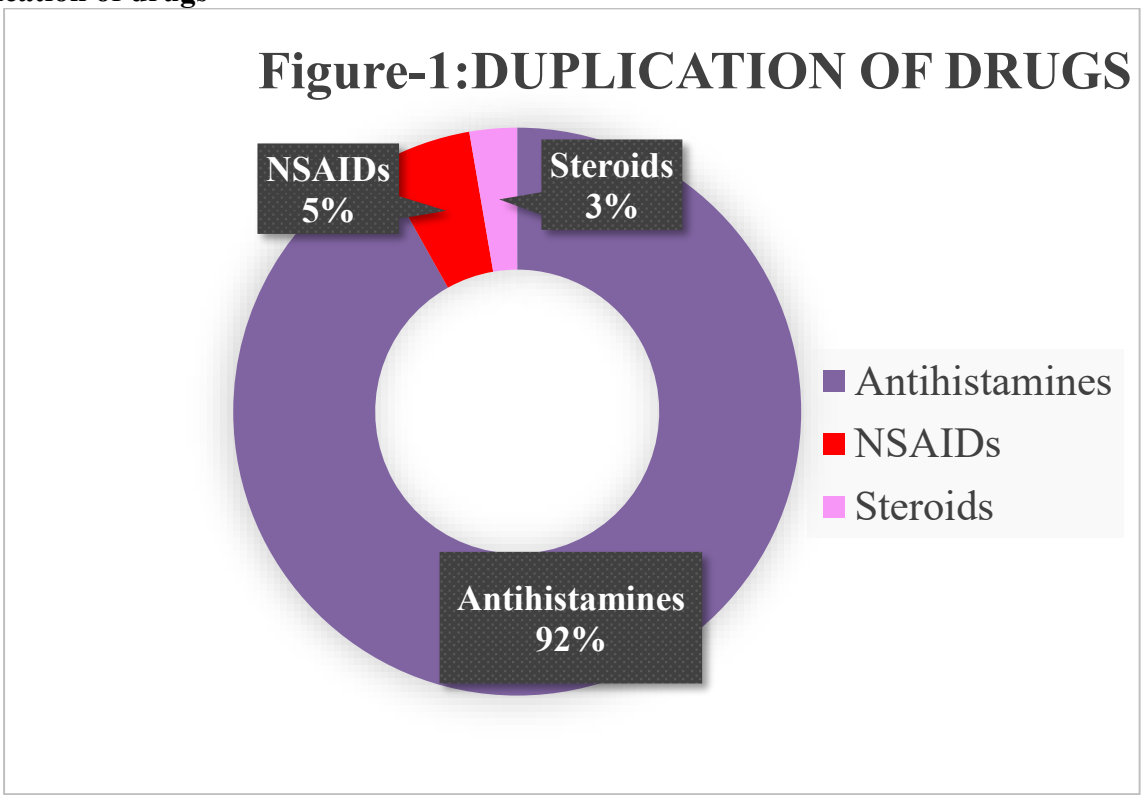


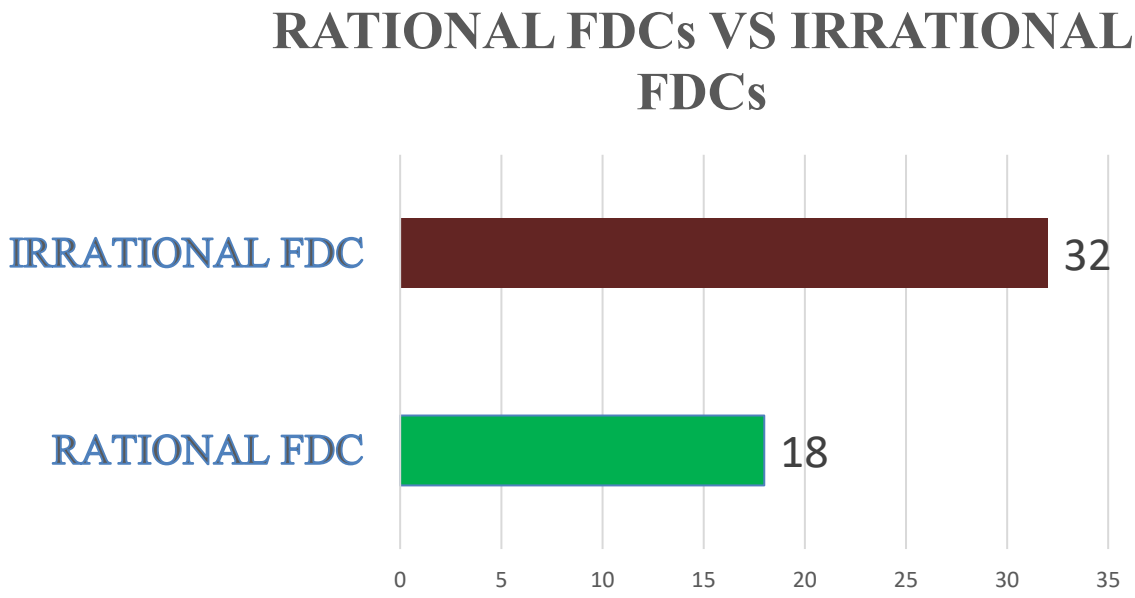
Table 2: Duplication of drugs

Drugs	No of pharmacies
Antihistamine	34
NSAIDs	2
Steroids	1

Rational Fixed dose combinations (FDCs) vs Irrational Fixed dose combinations

Figure 2 shows the thirty-two irrational FDCs, six pharmacies have given Tablet Caffeine 25 mg + Chlorpheniramine Maleate 2 mg + Paracetamol 500 mg + Phenylephrine 5 mg, three pharmacies have given Tab Caffeine 30mg + Chlorpheniramine Maleate 2mg + Paracetamol 500mg + Phenylephrine 12.5mg, and one pharmacy has given Tab Caffeine 30mg + Diphenhydramine 25mg + Paracetamol 325mg + Phenylephrine 5mg. Eighteen pharmacies have provided approved fixed-dose combinations [(5)] such as dextromethorphan hydrobromide(10 mg), chlorpheniramine maleate (2 mg), and phenylephrine hydrochloride (5 mg) capsules.

Figure: 2 Rational FDCs vs Irrational FDCs

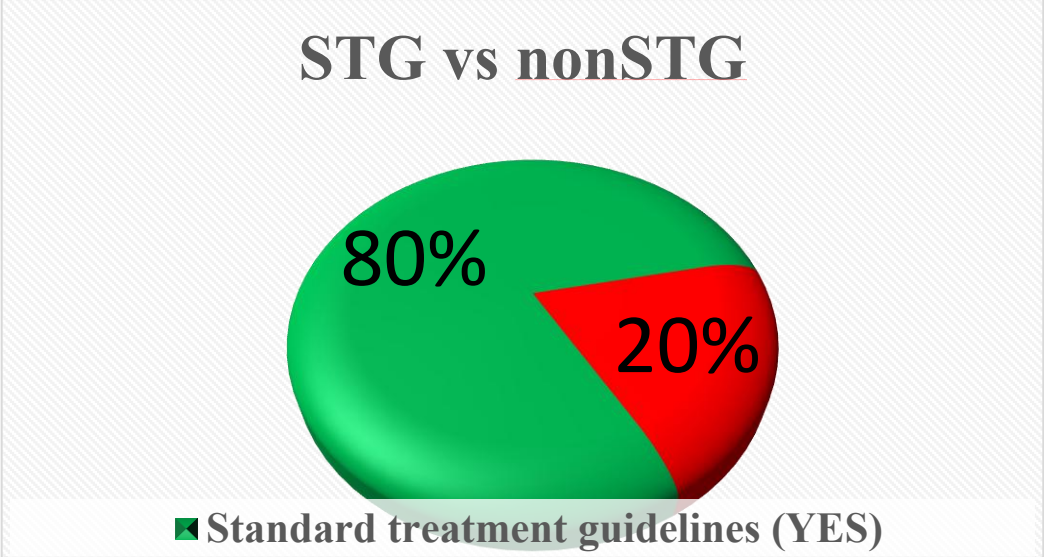


Standard treatment guidelines (STG) versus Nonstandard treatment guidelines (non-STG)

In this study, 8o percentage followed Standard treatment guidelines and 20 percentage followed non-standard treatment guidelines (figure 3).

Figure 3: STG vs non-STG

A cold has no known remedy. Antibiotics are not necessary; it will heal itself. When the side effects of antibiotics might still be harmful, and they are not necessary [6]



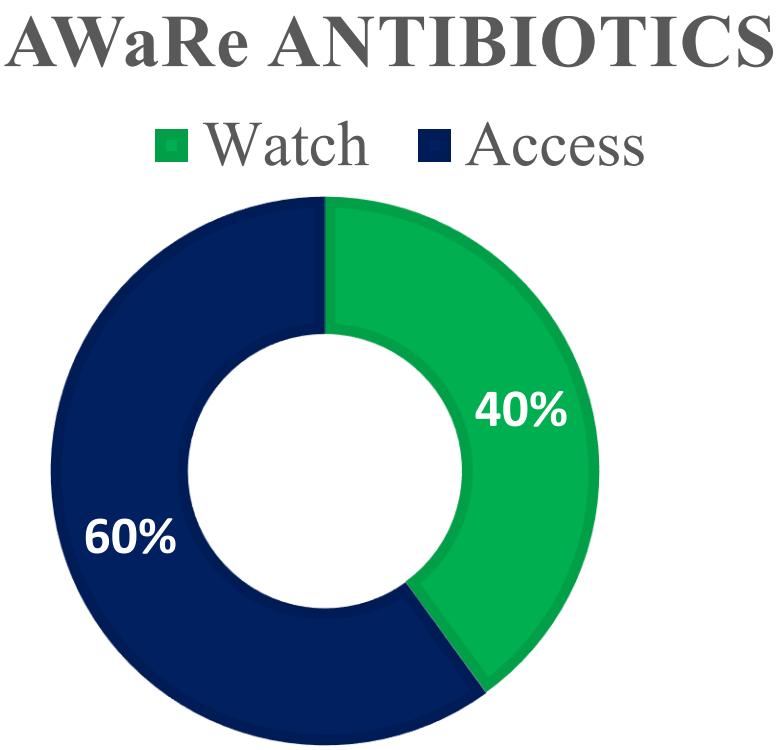


Figure 4: Aware Antibiotics

In this study, a total of 50 pharmacies among 40 pharmacies are distributed into 40 counts of antibiotic tablets, which are classified under as WHO aware group antibiotics [7]. such as macrolide antibiotics like Azithromycin 250 mg and 500 mg, Erythromycin 500 mg, Ciprofloxacin 250 mg, Ofloxacin 200 mg, Cephalosporin antibiotics third generation Cefpodoxime proxeni 200 mg, and 500 mg, Cefixime 200 mg, and capsules Cefixime 200 mg and Penicillin-like antibiotics Amoxicillin 250 mg, 500 mg, and Amoxicillin 500 mg + Clavulanic Acid 125 mg beta-lactamase inhibitors were dispensed by pharmacists as over-the-counter drugs (without a prescription).Antibiotics (Table:3)

Aware Antibiotics

Figure 4 shows that 60% of drugs were in the watch group of antibiotics, and 40% of drugs were in the access group of antibiotics.

Molecules	Class	No of Molecules
Tab Azithromycin 500mg	Watch	1
Tab Azithromycin 250mg	Watch	1
Tab Cefpodoxime Proxetil 200mg	Watch	1
Tab Ciprofloxacin 250mg	Watch	1
Tab Erythromycin 500mg	Watch	1
Cap Cefixime 200mg	Watch	2
Tab Ciprofloxacin 500mg	Watch	2
Tab Cefixime 200mg	Watch	3
Cap Amoxicillin 250mg	Access	3
Tab Ofloxacin 200mg	Watch	4
Cap Amoxicillin 500mg + Clavulanic Acid 125mg	Access	9
Cap Amoxicillin 500mg	Access	12

Table 3: Antibiotics list

Discussion

In the current study, from fifty pharmacies 16 class of drugs were collected. Most of the drugs were antibiotics and antihistamines. such as tablet azithromycin 250 mg and 500 mg, Cefpodoxime proxetil 200 mg, ciprofloxacin 250 mg and 500 mg, erythromycin 500 mg, Cefixime 200 mg, Ofloxacin 200 mg, and capsules Cefixime 200 mg, Amoxicillin 250 mg, 500 mg, and Amoxicillin 500 mg + Clavulanic Acid 125 mg were dispensed by pharmacists as over-the-counter drugs (without a prescription). Previous studies have shown that antibiotics are usually dispensed for viral and self-limiting conditions, including fever, cold, cough, and sore throat.[8] These practices of antibiotic dispensing clearly indicate that retail pharmacies not only flout the rules for dispensing drugs (both Schedule H and H1) without a prescription but also gave antibiotics in cases where they are not required [9,10]. In the present study, antibiotics dispensed were 60% in the access group and 40% in the watch group of antibiotics.

Irrational FDCs, drugs and dose can cause undesirable effects and toxicity. Irrational FDCs also impose an unnecessary financial burden on consumers [11]. Average number of drugs dispensed is 7-12 / pharmacy. Polypharmacy will lead to long term adverse drug reactions like liver and kidney damage. One or two doses of antibiotics can lead to drug resistance. Need to create extensive awareness about OTC among the public. Awareness about adverse effects of drugs to be spread among public. List of safe OTC drugs and their appropriate use to be educated. Pharmacy guidelines for dispensing drugs should be made stringent. Strict regulations on OTC drugs to be drafted with healthcare professionals.

It was concluded that our analysis brings out the irrational use of drugs through OTC. This might increase the cost of health care in the future. Strong guidelines, regulations, and awareness are to be implemented to prevent the irrational dispensing of drugs over the counter.

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