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A Systemic Review on Safety and Efficacy of Self-Medication



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ABSTRACT

Self-medication is a universal phenomenon which is widely practiced over the world, as many drugs are dispensed over the counter without the guidance of physician. Studies reported that 81% of adults use OTC medicines as a first response to minor ailments. The main reasons for using self-medication was consultations with doctors were more expensive and timeconsuming. However, inappropriate self-medication with OTC drugs can have serious implications including deaths, especially paediatrics, geriatrics, pregnant and lactating mothers, and patients with co-morbidities. NSAIDs and Analgesics are the most commonly consumed drugs in the world. Older adults also have been reported to take more OTC analgesic, non-opioids such as NSAIDs used for acute and chronic pain. Improper usage of OTC drugs leads to morbidity and mortality, which is alarming, and efforts are being made by the physicians, caregivers, and pharmacists to counsel and guide the patients regarding the rational use of drugs. Antibiotic resistance is an important global challenge and threat to public health. The potential risk of self-medication is associated with possible adverse reactions, drug interactions, incorrect dosage administration, masking of a severe underlining diseases, risk of dependence and abuse. Unfortunately, children are more vulnerable to adverse drug events than adults. This review aims to study about the prevalence, efficacy and side effects of selfmedicating drugs like analgesics, NSAIDs, antimicrobials, antihistamines, decongestants, probiotics and also to create awareness among community for rational usage of drugs. Pharmacist plays a key role in advising the patient on the proper and safe use of medicinal products intended for self-medication.

INTRODUCTION

Self-medication is a growing public health issue worldwide, defined as the 'use of medicine without medical prescription or medical consultation in order to prevent or treat self-recognised/self-diagnosed condition or a symptom to promote healthcare.' [1, 2] It is a universal phenomenon which is widely practiced especially in developing countries. [3, 4] Studies reported that 81% of adults use OTC medicines as a first response to minor ailments. The reasons for indulgence in self-medication includes: socio cultural belief; relatively high cost of hospital treatment; previously used prescriptions; mild illness, poverty, illiteracy, lack of time, health centres not being socially accessible; easy availability of over the counter (OTC) drugs; poor drug regulatory practice; urgency of the problem (emergency use) and congestion (overcrowding in hospitals). [2,4,5,6,7]

However, inappropriate self-medication with OTC drugs can have serious implications (including deaths), especially in paediatrics, geriatrics, pregnant and lactating mothers, and patients with co-morbidities. ^[8] Pregnancy is a special state where intake of medication is a challenge and a major concern as these drugs may cross the placenta and harms the foetus. But practice of self-medication is common among these women (90%) due to pregnancy related problems like back pain, headache, nausea, vomiting, heartburn and haemorrhoids. ^[9] Use of OTC drugs in older adults was associated with polypharmacy, multiple comorbid illnesses and physiological changes, which can increase the risk of adverse drug reactions. ^[10]

A study in India showed that 58.91% of mothers medicated their children with non-prescribed medication for common health problems. They also reported that analgesic, anti-pyretic, and anti-cough medicines are the most commonly used medications. Accordingly, the main reported reason for using self-medication on their children was that consultations with doctors were more expensive and time-consuming. Unfortunately, children are more vulnerable to adverse drug events than adults. [11] Furthermore, teenagers are not always known exactly how to use drugs and need more information about this topic to prevent side effects. The major reasons for supporting the self-medication are the quickness and the affordability of drugs. [11] In some cases they may particularly benefit from over-the-counter access, as they experience disproportionately high rates of unintended pregnancy and face unique challenges accessing contraceptives. [12]

NSAIDs and Analgesics are the most commonly consumed drugs in the world. ^[6,13] Older adults have also been reported to take more over-the counter (OTC) analgesic, non-opioid medications such as NSAIDs which are used for acute and chronic pain, due to their physiologic and metabolic changes that may influence response to medications. ^[14] Worldwide, over 73 million prescriptions of NSAIDs are written yearly, and approximately 30 million people take NSAIDs daily. The data of global and Indian studies showed that the total number of NSAIDs prescription ranges from 15% to 40%. ^[15] The studies also revealed that 90% of migraine sufferers reported using OTC drugs and 44% reported using prescription drugs. ^[16] It also reported that use of medication in adolescents to treat symptoms related to pain was found to be 70.2%. ^[1]

Improper usage of OTC drugs lead to morbidity and mortality, which is alarming, and efforts are being made by the physicians, caregivers, and pharmacists to counsel and guide the patients regarding the pros and cons of drugs.^[6, 17] Safety was the over-riding consideration when making decisions regarding OTC medicines and its rational use.^[18] The potential risk of self-medication is associated with possible adverse reactions, drug interactions, incorrect dosage administration, masking of a severe underlining diseases, risk of dependence and abuse. ^[5,13,19] The overuse, underuse or misuse of medications results in negative health effects like gastrointestinal haemorrhage, cardiovascular toxicity, renal toxicity, hepatotoxicity, Insomnia, depression, and ultimately death are the outcomes of self-medication. ^[5,7,10,13,20] Common adverse reactions often associated with self-medication may include skin rashes, hypoglycaemia, upper gastrointestinal bleeding, hypercorticism and hepatitis. ^[7]

We conducted a systemic review to summarize and analyse all the published scientific articles regarding self-medication and frequently used Over-The-Counter (OTC) drugs. This review aims to study about the prevalence, efficacy and side effects of self-medicating drugs and also to create awareness among community for the rational use of drugs.

According to the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification, self-reported OTC medicines belonged to ATC categories as follows: analgesics, NSAIDs, probiotics, antithrombotic agents, antacids, antihistamines, decongestants and anti-diarrhoeal. [3,8,10]

Analgesics:

Analgesics are medicines that are used to relieve pain. They are also known as painkillers or pain relievers. Many different types of medicines have pain-relieving properties, and experts tend to group together those medicines which works in a similar way. Two of the most common groups of pain killers are non-steroidal anti-inflammatory drugs (NSAIDS) and opioids (narcotics).

Types of analgesics may differ based on their therapeutic efficacy, potency (how strong they are) and their mode of action in absorption, distribution, metabolism and excretion within the body.

Here, we listed seven different classes of analgesics:

- 1. Analgesic combinations (includes narcotic analgesic combination)
- 2. Anti-migraine agents
- 3. Cox-2 inhibitors
- 4. Miscellaneous analgesics
- 5. Narcotic analgesics
- 6. Non-steroidal anti-inflammatory drugs (NSAIDS)
- 7. Salicylates

The current extensive self-medication with OTC analgesics for children constitutes an important public health issue internationally.^[21] Majority of respondents believed that paracetamol is safe, even in very high doses, and this misconception is very dangerous because high doses of paracetamol can lead to hepatotoxicity and medicine-induced headache.^[11,21] Additionally, PCM is the most frequently used drug in teenage suicide attempts, because it is well-known and accessible at home.^[21] Ibuprofen overdose is a serious problem because it affects the gastrointestinal tract and causes metabolic acidosis, and its toxicity doesn't has a specific antidote.^[11] Acetyl Salicylic Acid (ASA)is most commonly used analgesic, known to cause gastric irritation and ulceration as its side effects, whereas acetaminophen has been associated with liver toxicity.^[16,22] Appropriate use of OTC

analgesics may lead to dependence and withdrawal symptoms, such as headache and malaise.^[16] Although OTC drugs like analgesics can partly to be self-medicated drugs, improper use and abuse could lead to adverse events, especially among children, geriatrics, pregnant and lactating mothers.^[7]

NSAID's

Non-steroidal Anti-inflammatory Drugs usually abbreviated to NSAIDs are a group of medicines that relieve pain, fever and reduce inflammation. NSAIDs are classified according to their preference for COX-1 and COX-2 as shown in **Table 1.**

Table No. 1: Classification of NSAIDs

SR. NO.	CLASS	EXAMPLES OF DRUGS
A.	Non selective COX inhibitors (traditional NSAIDs)	
1.	Salicylates	Aspirin
2.	Propionic acid derivatives	Ibuprofen, Naproxen, Ketoprofen, Flurbiprofen.
3.	Fenamate	Mefenamic acid
4.	Enolic Acid derivatives	Piroxicam, Tenoxicam
5.	Acetic acid derivatives	Ketorolac, Indomethacin, Nabumetone
6.	Pyrazolone derivatives	Phenylbutazone, oxyphenbutazone
В.	Preferential COX-2 inhibitors	Nimesulide, Diclofenac, Aceclofenac, Meloxicam, Etodolac
C.	Selective COX-2 inhibitors	Celecoxib, Etoricoxib, Parecoxib.

The general mode of action of NSAIDs involves the inhibition of cyclooxygenase (COX) or prostaglandin-endoperoxide synthase (PGHS-1 and PGHS-2), regulatory enzymes, involved in the biosynthesis of prostaglandin (PG) which is strongly implicated in inflammation as shown in **Figure 1**. PGHS-1/COX-1 is believed to be a housekeeping gene engaged in multiple biological functions including protection of gastric mucosa while PGHS-2/COX-2 is responsible for inflammation. Some NSAIDs are non-specific inhibitors of both the enzymes while others are specific, notably "coxibs" that specifically inhibit COX-2. [23] Various studies have shown that the use of selective cyclooxygenase-2 (COX-2) inhibitors is associated with a lower risk of gastrointestinal complication. [17]

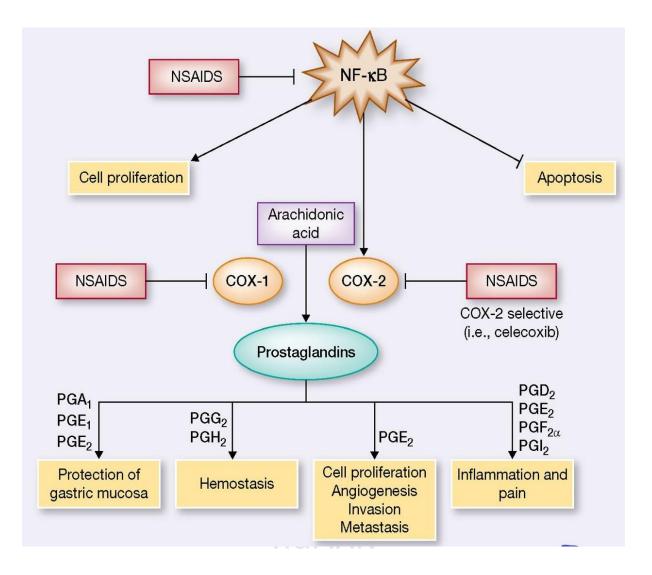


Figure No. 1: Diagram representing the mechanism action of NSAIDs

The preference of paracetamol, as frequently prescribed NSAID which can be attributed to its safety profile. ^[15] Many studies reported that ibuprofen 200mg or ketoprofen 12.5mg are effectively used for dysmenorrhoea, uterine cramps, pain associated with malignancy and postoperative dental pain. ^[13] The NSAIDs are infamous for multiple severe side effects including gastrointestinal toxicities (gastric mucosal erosions, ulcers, bleeding and perforation) ^[23,24], cardiovascular risks, renal injuries, and hepatotoxicity as well as hypertension and other minor disorders. ^[23]

In the clinical setting, proton pump inhibitors (PPIs), including esomeprazole have proven to be effective in the prevention of NSAID-induced gastric injury as well as in promoting the healing of NSAID-induced ulcers. ^[24] Additionally, there are some speculations regarding the use of NSAIDs against coronavirus. ^[23] Aceclofenac, celecoxib, and ibuprofen were associated with the lowest relative risk whereas piroxicam and ketorolac had the highest

relative risk of upper gastrointestinal complications. The intermediate relative risk was observed for diclofenac, ketoprofen, tenoxicam, naproxen, and indomethacin. [17]

ANTI-MICROBIALS

An antimicrobial is an agent that kills microorganisms or inhibits their growth. Antimicrobial medicines can be grouped according to the microorganisms they act primarily against. For example, antibiotics are used against bacteria, and antifungals are used against fungi.

Worldwide distribution of antimicrobials as OTC drugs was found to be 50%. ^[25] Multidrugresistant bacterial strains, which are highly resistant to many antibiotic classes, has raised a major concern regarding antibiotic resistance. ^[26] The purchase of antimicrobial drugs without prescription is estimated to be 58% in Asia, 47% in southern Europe, 30% in eastern Europe, 25% in South America, 39% in Middle East. ^[27] The major type of antibiotic commonly used in self-medication was the penicillin's, followed by macrolides, cephalosporin's, fluoroquinolones, and tetracycline. ^[26]

Table No. 2: Characteristics of antimicrobial drugs used in self-medication

TYPE OF ANTIMICROBIAL	CLASS OF ANTIMICROBIAL
Antibacterial	B-lactam, Tetracycline, fluoroquinolone, macrolide, quinolone, aminoglycoside, others
Antimalarial	Artemisinins, 4-aminoquinolines, 8- aminoquinlines Cinchona Alkaloid Sulfonamides/sulfone Diaminopyrimidine
Antifungal	Azoles
Anthelmintic	Imidazole

The antimalarial medicines commonly used in self-medication includes chloroquine, sulfadoxine-pyrimethamine, halofantrine, Artemether-Lumefantrine, and quinine. While the antibacterial agents used includes ampicillin, tetracycline, penicillin, metronidazole, ceftriaxone, kanamycin, ciprofloxacin, amoxicillin, fradiomisin-gramisidin, norfloxacin and doxycycline. The agents commonly used in treating symptoms of viral infections such as flu included are ampicillin, tetracycline, metronidazole, ceftriaxone, kanamycin, and cotrimoxazole. Amoxicillin alone or in combination with potassium clavulanate are the most commonly dispensed antibiotics without prescription as they were considered as

effective and safest first line antimicrobial agent for upper respiratory tract infection, otitis media, and dental infections.^[27]

The inappropriate use of antibiotics can lead to unnecessary adverse effects, drug interactions, antibiotic resistance, masking symptoms of underlying diseases like Clostridium difficile colitis which happens due to disturbance in the normal bacterial flora in the colon. [25,27] Globally the economic burden of antibiotic resistance is an essential concern. [27] Educational interventions targeting the general public and enforcing regulations on the non-prescription use of antibiotics, to prevent their irrational use and to reduce the spread of antibiotic resistance. [26] However, Safe and effective use of medications is one of the greatest challenges faced by healthcare providers in medicine.

Antihistamines

Antihistamines are a class of agents that block histamine release from histamine-1 receptors and are mostly used to treat allergies or cold and flu symptoms. Antihistamines are classified into three types: H1 antagonist, H2 antagonist, and H3 antagonist.

Antihistamines are very good at relieving symptoms of allergic reactions such as edema, inflammation, itch, rash, a runny nose, sneezing, red and watery eyes. This makes antihistamines very effective in the treatment of allergic rhinitis, colds, flu, food allergies, hay fever, hives, insect bites and stings. Most commonly antihistamines are cetirizine, levocetirizine, loratadine, and promethazine. [28]

Over the counter, symptomatic medications for cough and cold raise particular concerns as a result of their potential undesirable effects like drug interactions, side effects and delay of diagnosis. ^[28] Side effects of first generation antihistamines may include; abdominal pain, blurred vision or double vision, constipation, dry eyes, dry mouth, drowsiness or sedation, low blood pressure, mucus thickening in the airways, rapid heartbeat and urinary problems.

A side effect of second generation antihistamines includes abdominal pain, coughing, drowsiness, fatigue, headache, nausea and sore throat.

Decongestants

Decongestants are medicines that relieve congestion by reducing swelling, inflammation and mucus formation within the eye or nasal passages. They have no other effect on symptoms such as a runny nose or sneezing.

Most decongestants work by activating alpha-adrenergic receptors either by binding directly to them or stimulating the release of norepinephrine, a chemical transmitter. Activation of these receptors causes vasoconstriction (a narrowing of the blood vessels within that area). This decreases blood flow and helps to shrink swollen tissue, relieving congestion. They are often used in combination with antihistamines.

The indications for self-medication include eye drops to treat allergies, nose drops for nasal congestion, topical creams for muscle pain. ^[19] Decongestants only provide short-term relief from congestion and do not cure the underlying cause or condition. Intranasal decongestants, nasal saline solution, intranasal glucocorticoids and oral decongestants were the most commonly used rhinitis products. ^[29] Most commonly used medicines were pseudoephedrine, phenylephrine, loratadine and promethazine. ^[28]

Some decongestants such as pseudoephedrine acts on alpha adrenoreceptors are associated with heart related side effects such as elevated blood pressure, palpitations, and tachycardia. Decongestants acts on alpha adrenoreceptors which are also located in other areas of the body, may increase intraocular pressure in the eye and aggravate urinary obstruction. Using nasal congestions regularly for longer than three to five days has been associated with ebound congestion. It will recur immediately once you stop using, or prompting repeat use of the nasal decongestants. If prolonged use of decongestants are unabated, a form of rhinitis called rhinitis medicamentosa will develop, which is very difficult to treat. If taken in overdose, it can cause kidney failure, psychotic symptoms, stroke and seizures.

Insomnia and irritability are the most common side effects of oral decongestants. Others may include dizziness, headache, excitability, nervousness, and tremors.

Probiotics

Probiotics are live microorganisms that are ingested to promote health, formally defined by the WHO as viable microorganisms that, when ingested in a sufficient amount can be beneficial for health. The most commonly used bacterial probiotics are of the lactic acid producing species *lactobacillus* and *bifidobacteria*. [30] Probiotics are mostly used in gastroenterology and to boost the immunity in immune compromised patients. *Lactobacillus spp*. are useful in the prevention and treatment of ulcerative colitis, respiratory tract infections, eczema, lactose intolerance, irritable bowel syndrome. [31] There are different mechanisms by which intestinal microbes are thought to cause disease. The first is through altered immunological interaction between the microbial environment and host. The second is through translocation of bacteria in the setting of permeable intestinal mucosa. The third is through simple alteration of the small or large bowl flora that leads to malabsorption and consequently to diarrhea. [30]

Most of the commercial probiotic products consist of combinations of probiotic strains and are available in the form of powder, capsule, tablets, drops, chewing gum, lozenges, straws, stick, packs, bottle caps etc. Some probiotic preparations in India pharma industry are Sporolac, Darolac, Lacto genes DT, and Alacfort. [32] Darolac was the most commonly available drug followed by Bifilac and Flora-bc. [31]

Generally, probiotic drugs are considered safe and well tolerated but, under certain conditions like patients suffering from severe infections, overdoses may cause mild side effects which include bloating, flatulence etc.^[31] The joint FAO/WHO guidelines on probiotic evaluation reported that probiotics may theoretically be linked to four specific types of side effects in patients with underlying medical conditions: "(1) systemic infections; (2) deleterious metabolic activities; (3) excessive immune stimulation in susceptible individuals; and (4) gene transfer". The at-risk population groups are broadly characterized by the weakened immune system, gut dysbiosis and/or impaired intestinal barrier. Therefore, it is important to carefully assess the safety associated with deliberate administration of living microorganisms (i.e., probiotics). ^[34]

Probiotic may cause potential risks and their consequences associated with the clinical administration as shown in the **Figure 2.** (A) Probiotic translocation by the violation of gut integrity: in leaky or inflamed or pre-mature gut, probiotics (Saccharomyces cerevisiae,

Lactobacillus, Bifid bacterium) might traverse the intestinal mucosa and enter into bloodstream or vital organs causing systemic or localized infections. (B) Virulence factors and harmful metabolites of probiotics might lead to opportunistic infections and metabolic disturbances, respectively. (C) Horizontal transfer of antibiotic resistance genes from probiotics to pathogenic gut bacteria and vice-versa might lead to the development of antibiotic resistant pathogens. (D) Exaggerated immune response through elicited cytokine production might lead to autoimmune disease or inflammation.

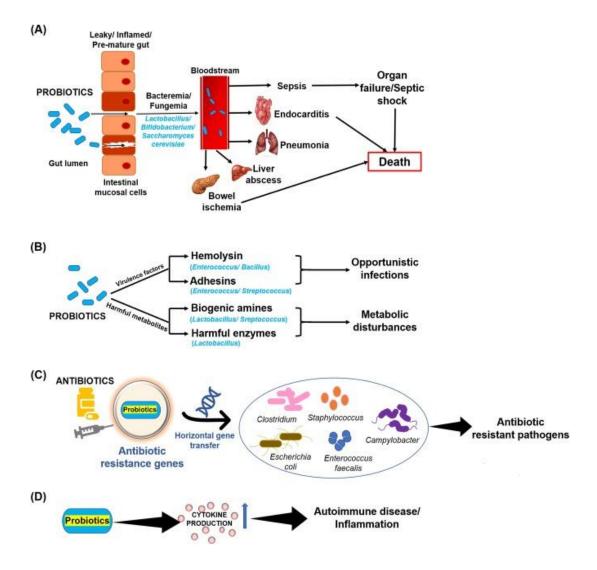


Figure No. 2: Schematic representation of the potential risks and their consequences associated with the clinical administration of probiotics.

ROLE OF PHARMACIST

Community pharmacies are the primary source of OTC drugs, and pharmacy staffs are the only group of healthcare professionals involved in self-medication. Pharmacist has a crucial role in patients' education, considering progressive switching of medications from a prescription to an OTC status. This pharmacist-led self-medication approach would also be consistent with the position of the WHO and various task forces including public authorities and academics who highlight the key role of pharmacists in advising the patient on the proper and safe use of medicinal products intended for self-medication. The majority of pharmacists considered that evidence-based practice improved the quality of patient care. ^[18] This belongs to their core professional responsibility.

CONCLUSION

This review explores the scope of self- medication practices among community pharmacies, in terms of medication use, therapeutic efficacy and its side effects. Analgesics, NSAIDs and Antimicrobials are most commonly consumed drugs in the World. Majority of the respondents were unaware of risk associated with frequent use of OTC drugs. Though OTC drugs are relatively safe, their inappropriate use may lead to serious complications, especially in terms of ages (paediatrics and geriatrics), pregnant and lactating mothers, and patients with comorbidities. Antibiotic resistance is an important global challenge and threat to public health. Different awareness programmes, timely monitoring and interventions from the government is needed to prevent the rampant of OTC drugs. Hence there is a need of pharmacist role in creating awareness about the rational use of drugs.

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