Original Study

HOSPITAL PHARMACOLOGY
International Multidisciplinary Journal

ISSN 2334-9492 (Online)

Hospital Pharmacology. 2025; 12(3):1716-1723

UDC: 615.065(540)

doi:10.5937/hpimj2503716C

Analysis of Suspected Adverse Drug Reactions to Over-the-Counter Drugs at a Tertiary Care Teaching Hospital in South India

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SUMMARY

Introduction: Over-the-counter (OTC) drugs play an integral role in healthcare in India. They are commonly used for self-medication and are available without prescription. Many a times, patients taking these medications develop mild to severe Adverse Drug Reactions (ADR). Adverse Drug Reaction Monitoring Centre (AMC) at Vydehi Institute of Medical Sciences functions under the Pharmacovigilance Programme of India. The centre plays a vital role in ensuring medication safety by detecting, monitoring, and reporting ADR.

Aim: To evaluate the ADR reported for OTC drugs to the AMC, and to evaluate the frequency, type, seriousness and causality of the ADR.

Material and Method: This was a retrospective analysis of ADR data from a tertiary care hospital. The data was extracted and evaluated by two separate individuals working independently of each other. ADR entries with incomplete information were excluded. The data points from January 2011 to December 2024 were entered into Microsoft Excel 2024., and Fisher's exact test was used to study the association between categorical variables at $p<0.05$.

Results: A total of 3672 ADR's were reported. Out of them, 11.2% ADR were due to OTC drugs. ADR more commonly involved skin & subcutaneous system 54.8%, and gastrointestinal system 19.6%. The most reported reactions were rash 18.4% and itching 10.9% and common drugs associated were paracetamol 27.05%, and ibuprofen 9.1%. Among all ADR, 2.7% were serious reactions like anaphylaxis and Stevens Johnson Syndrome which resulted in hospitalization.

Conclusion: Healthcare professionals and regulatory bodies should address the concerns about safety of OTC medicines. Prescription to OTC switch should be dynamic, strictly regulated, and evidence-based either from post-marketing surveillance or continuous pharmacovigilance activities.

Keywords: OTC Drugs, Pharmacovigilance, Prescription Switch

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INTRODUCTION

Over-the-counter (OTC) drugs offer a wide range of therapeutic benefits as they are easily available without a prescription and dispensed with clear, easy-to-understand labels [1]. Previous reports have highlighted the fact that consumption of OTC drugs is high, which can be attributed to the increasing market size [2-4]. An Indian study showed that switching prescription drugs to OTC can result in substantial annual savings which can improve overall healthcare outcomes [5-6]. At present India lacks well-documented regulatory framework with respect to switching of prescription drugs and OTC medicines. The Ministry of Health and Family Welfare and Drugs Technical Advisory Board has amended the Schedule K of Drugs and Cosmetics Rules, 1945 and have added OTC drugs. In the initial stage sixteen drugs were approved for OTC sale by retail under a valid licence without any prescription from registered medical practitioner [7].

In many countries even though OTC drugs are marketed after prescription-to-OTC switch based on safety and with the idea of self-medication, their use still carries a risk of ADRs. Measuring the true extent of ADRs related to these drugs is challenging [8-10]. Self-medication or unregulated sale of prescription only drugs as OTC drugs from the pharmacy is an additional menace which increases the prevalence of ADR. The consumer awareness that OTC drugs can cause ADR is limited [11-13]. Frequently, when a patient presents to a hospital with ADR, the exact nature of drugs remains inaccessible due to use of OTC self-medications [14].

The safety monitoring of prescription-to-OTC switches should be continuous and dynamic process which includes periodic label comprehension studies, updating labelling instructions and efforts to communicate with all the stakeholders. Currently there is sparse literature on real world analysis of ADR to OTC or non-prescription drugs in an Indian set-up. Pharmacovigilance at AMC levels add valuable knowledge towards patient safety, which helps regulatory decision-making.

AIM

This study objective was to estimate the prevalence and analyse the patterns of ADRs to OTC drugs submitted to the ADR monitoring centre at a tertiary care teaching hospital in south India.

MATERIAL AND METHODS

This was a phase IV academic retrospective study of the ADRs reported to the AMC at Vydehi Institute of Medical Sciences & Research Centre, Bangalore, India which is a tertiary care teaching hospital. The data was reviewed for the period from January 2011 to December 2024. The retrospective data was retrieved after the required permissions from the Institution and the Institutional Ethics Committee (21/06/2025 and VIEC/2025/APP/35)

Details of reported reactions were obtained from the suspected ADR forms submitted by healthcare professionals (doctors & nurses) to the AMC which was part of routine pharmacovigilance functioning in a hospital setup. The ADRs related to OTC drugs for above mentioned period were segregated, and screened by two independent reviewers separately. ADRs included for analysis were based on documented OTC drug or those procured without prescription in the form of self-medication with plausible temporal association with the event. A report was considered to be complete if it had an identifiable patient, reporter and suspected drug with dose, duration, therapy start and stop date. All such ADR reports were then analysed for demographic characteristics, pattern and type of reactions, body systems involved, causative drugs, and seriousness of reaction with their outcome, management and causality assessment based on WHO Uppsala Monitoring Centre (UMC) Causality Assessment Scale [15].

Descriptive statistics including numbers and percentages were used for demographic and ADR data. The Fisher's exact test was used for comparing categorical variables and the statistical significance was set at $p<0.05$. All analyses were performed using Microsoft Excel (Microsoft® Corp., Redmond, WA).

RESULTS

A total of 3672 ADRs were reported by various healthcare professionals through both spontaneous and stimulated reporting for a period of 2011 to 2024. Of these, 11.2% (414) of ADRs occurred due to OTC drugs.

Among the ADRs caused by OTC

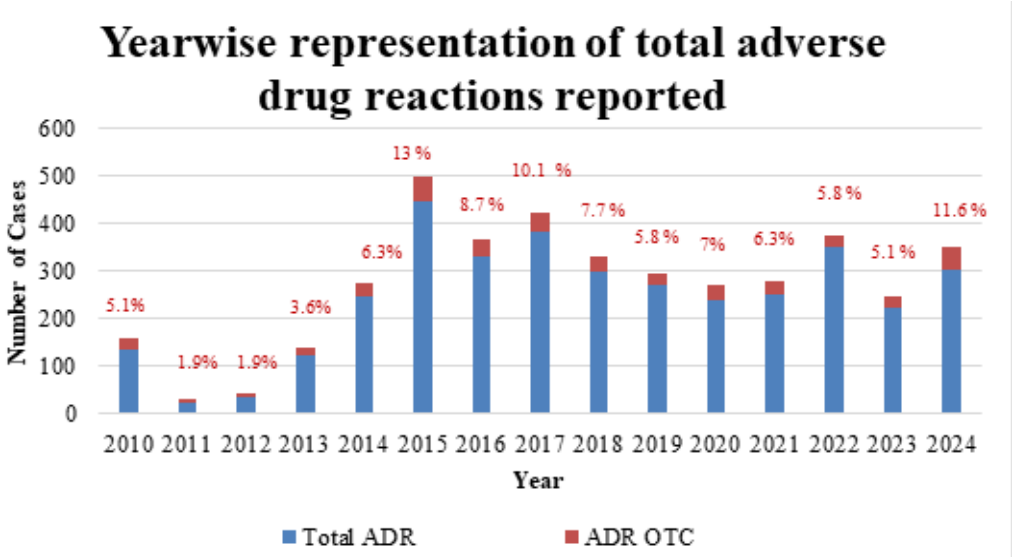

Figure 1. Year wise representation of total adverse drug reactions reported

Table 1. Demographic details of patients with ADR occurring with OTC drugs

		N=414 (%)
Age group	Child	12 (2.9)
	Adolescents	24 (5.9)
	Adults	351 (84.7)
	Elderly	27 (6.5)
Gender	Female	254 (61.3)
	Male	160 (38.7)
OTC Drug consumed as	Monotherapy	229 (55.3)
	Fixed dose combination	185 (44.7)
Drug dispensed	Generic	284 (68.5)
	Brand	130 (31.5)
Dosage form	Oral	371 (89.7)
	Topical	43 (10.3)

Table 2. Indication for consuming OTC drugs

Indication (MedDRA term)	N=414	%
Musculoskeletal and connective tissue disorders	112	27.1
Gastrointestinal disorders	80	19.3
General disorders and administration site conditions	64	15.5
Skin and subcutaneous tissue disorders	42	10.1
Surgical and medical procedures	28	6.8
Respiratory, thoracic and mediastinal disorders	24	5.8
Infections and infestations	19	4.6
Nervous system disorders	17	4.1
Blood and lymphatic system disorders	14	3.4
Reproductive system and breast disorders	10	2.4
Injury, poisoning and procedural complications	2	0.5
Renal and urinary disorders	2	0.5

drugs, 61.3% (254) occurred in females and 38.7% (160) in males. The majority of ADRs (84.7%, n=351) occurred in the age group of adults followed by elderly 6.5% (27). The mean age of patients who experienced an ADR was 37.7 years. Most of the drugs were consumed as monotherapy which constituted to 55.3% (229) and 89.7% (371) were in oral dosage forms and 68.5% (284) of the drugs were dispensed under the generic names. The demographic data and year-wise distribution of reported ADRs are represented in Table 1 and Figure 1 respectively.

When ADRs were classified according to the System Organ Classification (SOC), *skin and subcutaneous tissue disorders* accounted for 54.8% (n = 227) of cases, followed by *gastrointestinal disorders* (19.6%, n = 81) and *nervous system disorders* (8.2%, n = 34) (Figure 2). The most frequently reported ADRs were rash (18.4%, n=76), itching (10.9%, n=45), and acute gastritis (7.7%, n=32). Single ADRs were reported in86.3% (n=357) while multiple reactions occurred in 13.7% (n=57) as more than one reaction.

With respect to indication, patients most commonly consumed OTC drugs for musculoskeletal and connective tissue disorders (27.1%, n=112) and gastrointestinal disorders (19.3%, n=80) as shown in Table 2.

Most common drugs causing ADRs: Paracetamol was most common drugs causing ADR (27.05%, n=112), followed by Ibuprofen (9.1%, n=38), and Diclofenac (5.7%, n=24). Among fixed-dose combinations, Paracetamol with Tramadol (7%, n=29) followed by Paracetamol with Aceclofenac (2.6%, n=11)

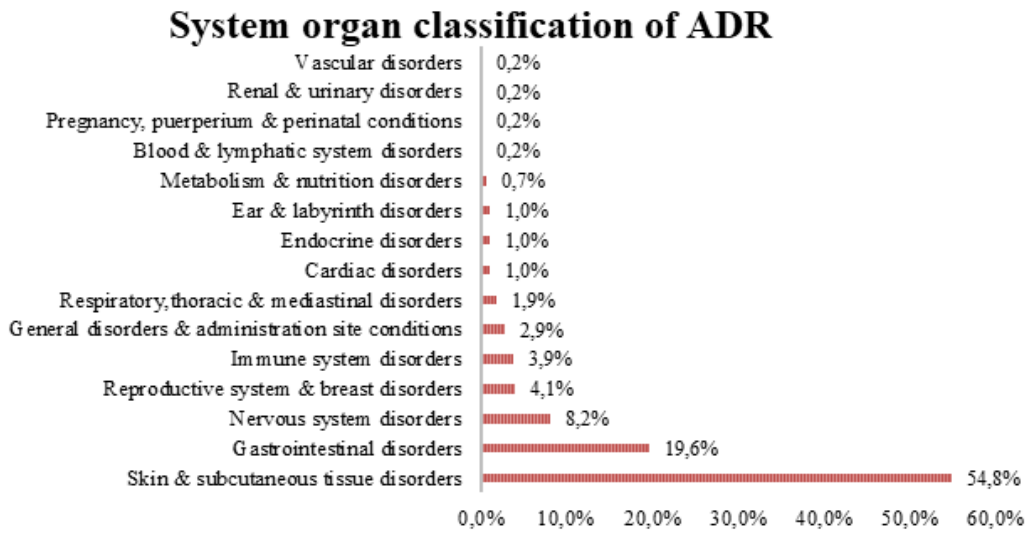

Figure 2. Representation of ADR using System Organ Classification

were the most commonly associated with the reactions.

Topical steroid combinations (7%, n=29) and the combination of Mifepristone with Misoprostol for inducing abortion (1.9%, n=8) were the common prescription-only drugs that were procured for self-medication resulting in an ADR.

Regarding seriousness, 2.4% (n=10) of ADRs were classified as serious, resulting in hospitalization or causing prolonged stay in hospital, while 97.6% (n=404) were non-serious. Paracetamol & Aceclofenac were the common drugs associated with serious ADR as portrayed in Table 3. Serious ADR did not show any statistically significant association between gender (Fisher's Exact test, p=0.42).

The analysis was conducted using WHO scale and 88.6% (n=367) of reactions showed a causal relation of probable followed by possible 8.9% (n=37) and certain 2.5% (n=10).

DISCUSSION

The aim of this study was to analyse and assess the ADRs to OTC drugs amongst the total spontaneous ADR reports earlier studies showed variable extent of ADRs reporting for OTC medicines ranging from 4% to 22.8% for wide range of non-prescription drugs. Our findings fall within the above range, 11.2% [9, 16]. As this is a hospital-based analysis, many mild ADRs for drugs used as self-medication may have been not reported. The Pharmacovigilance Program of India has launched direct consumer or patient reporting of adverse reactions from September 2017 and this initiative serves as a tool to identify such OTC drugs induced ADRs [17].

In the present study, ADRs were most frequently reported in female with mean age of 37.1 years. Previous studies conducted in India and other countries also showed females were more susceptible to adverse effects. It is attributed to features like women are more likely to

Table 3. List of serious ADR with OTC drugs and their indication

Serious adverse reaction (N)	Indication	Suspected Drug
Anaphylaxis (4)	Arm pain	Aceclofenac
	Gastritis	Pantoprazole
	Low back pain	Etoricoxib
	URTI	Nimesulide
SJS (2)	Fever	Paracetamol
	Fever & joint pain	Aceclofenac
Scrotal swelling (1)	Fever	Paracetamol
Epigastric pain & hemetamesis (1)	Knee pain	Naproxen
Duodenal perforation (1)	URTI	Aceclofenac
Hyponatremia & hyperosmolarity (1)	Fever	Paracetamol

self-medicate with OTC, may be due to usage of more drugs and are bothered with physical and mental health problems [10, 18]. This trend has been attributed to usage of higher doses with respect to their body weight as a result of gender-based difference in pharmacokinetic and pharmacodynamic effects. In an aggregated evidence-based study on data conducted by Vigibase® showed women within reproductive age group have higher prevalence of ADR [19-21].

Analysis of Czech pharmacovigilance database revealed that most common ADR were skin and subcutaneous, gastrointestinal and nervous system which was similar to our findings, while a study in French pharmacovigilance database by Berreni et al. reported that ADR to gastrointestinal system were more common [22-23].

Around 2.4% of ADR were classified as serious with anaphylaxis being the most common reaction. OTC drugs played limited role in ADR's leading to hospitalization according to Schmeidl Sven et al. However, it appears to be less as it can be due to underreporting of ADR's related to self-medicated drugs [7, 21]. Based on Netherlands pharmacovigilance database study by Rolfes et al., suggested that even non-serious reaction could have an impact on patients' quality of life [24].

Although in early 2000, Nimesulide was banned in various parts of world, in 2011 regulatory bodies in India also have banned pediatric use of Nimesulide for fever and pain due to fulminant hepatotoxicity. But its usage in adults as OTC drug is still rampant. Nimesulide was commonly used for fever and it accounted to 4% of the suspected drugs producing ADR ranging from rashes to anaphylaxis. A serious reaction of anaphylaxis to Nimesulide which led to hospitalization occurred which is uncommon as very few cases are reported [25-27]. Two patients in our cohort experienced severe cutaneous adverse reaction (SCARs) after self-medicating with paracetamol and aceclofenac for fever. On dermatologist evaluation it was diagnosed to be Stevens Johnson Syndrome (SJS) and on stopping of the drugs there was positive de-challenge. Paracetamol-induced SJS is particularly concerning given the drug's widespread use and accessibility. In 2013 & 2014, due to identification of positive signal from studies using spontaneous data from United States, Japan and Vietnam, the US FDA issued a public announcement of rare but serious cutaneous reactions with Paracetamol and urged the need of updating package insert of all registered products containing Paracetamol [28-30]. These findings help us to draw a conclusion that prescription-to-OTC switch is not a one-time process and requires periodic safety review and updating the labelling instructions.

Although, the sales of abortion pills are not permitted without prescription, due to unregulated OTC dispensing ease of access to such drugs may lead to unfavourable maternal outcome. It was found that 1.9% ADR were due to abortion medication consumed by the pregnant women. Nivedita et al., in their study observed that self-medication with medical termination of pregnancy (MTP) pills accounted to 31.2% and strongly advocated to restrict the OTC sales and provide public access of abortion pills only through centres approved for MTP [31].

This study did not assess the possibility of drug interaction between the concomitant medications with OTC drugs as many reports lack the details. As this is a retrospective study, we could not assess the quality of life and the pharmacoeconomics aspect of OTC related ADRs. A future community-based study evaluating these aspects will be useful and will throw light on importance of awareness among public towards education and reporting. Also, this might motivate the Government of India to undertake community engagements and outreach sessions, update the list of OTC based on current scenario, and the information received through the ADR database.

CONCLUSION

Healthcare professionals and regulatory bodies should address the concerns about safety of OTC medicines. Prescription to OTC switch should be strictly regulated; data-driven evidence-based reports derived from post-marketing surveillance or continuous pharmacovigilance activities and approved using a scientifically validated process. Encouragements of consumer reporting of ADRs through toll-free number or mobile based applications are the promising ways in near future to establish the safety of OTC drugs.

CONFLICT OF INTEREST

The author declares no conflict of interest.

ACKNOWLEDGEMENT

Dr Kiran Maiya is the Principal Investigator for the study. We thank Vydehi Institute of Medical Sciences & Research Centre for being instrumental in implementing ADR reporting and permitting us to conduct the study. Also, pharmacovigilance committee members for extending their support & expertise by reporting the cases over the years.

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Analiza suspektnih neželjenih reakcija na lekove koji se izdaju bez recepta u bolnici tercijernog nivoa i nastavnoj bazi u Južnoj Indiji

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KRATAK SADRŽAJ

Uvod: Lekovi bez recepta (OTC) igraju ključnu ulogu u zdravstvenoj zaštiti u Indiji. Često se koriste za samostalno lečenje i dostupni su bez recepta. Mnogi pacijenti koji koriste ove lekove razvijaju blage do teške nuspojave (ADR). Centar za praćenje nuspojava lekova (AMC) na Institutu za medicinske nauke Vydehi funkcioniše u okviru Programa farmakovigilance Indije. Centar ima ključnu ulogu u obezbeđivanju bezbednosti lekova, otkrivanju, praćenju i izveštavanju o nuspojavama.
Cilj: Cilj je evaluirati nuspojave prijavljene za OTC lekove u AMC-u i oceniti učestalost, vrstu, ozbiljnost i uzročnost nuspojava.
Materijal i metode: Ovo je retrospektivna analiza podataka o nuspojavama iz tercijarne bolnice. Podaci su izdvojeni i evaluirani od strane dvoje nezavisnih pojedinaca. Unosi o nuspojavama sa nepotpunim informacijama su isključeni. Podaci od januara 2011. do decembra 2024. godine uneti su u Microsoft Excel 2024, a za proučavanje povezanosti između kategorijskih varijabli korišćen je Fisherov tačan test ($p<0,05$).
Rezultati: Prijavljeno je ukupno 3672 nuspojave. Od toga, 11,2% nuspojava bilo je uzrokovano OTC lekovima. Nuspojave su češće zahvatile kožu i potkožno tkivo (54,8%) i probavni sistem (19,6%). Najčešće prijavljene reakcije bile su osip (18,4%) i svrab (10,9%), dok su najčešći lekovi povezani sa nuspojavama bili paracetamol (27,05%) i ibuprofen (9,1%). Od svih nuspojava, 2,7% bile su ozbiljne reakcije poput anafilaksije i Stevens-Johnsonovog sindroma, koje su izazvale hospitalizaciju.
Zaključak: Zdravstveni radnici i regulatorna tela treba da se bave pitanjima bezbednosti OTC lekova. Prelazak sa receptnih na OTC lekove treba da bude dinamičan, strogo regulisan i zasnovan na dokazima, bilo putem post-marketing nadzora ili kontinuiranih farmakovigilantnih aktivnosti.

Ključne reči: OTC lekovi, farmakovigilanca, prelazak sa recepta

Received: September 11, 2025
Accepted: October 7, 2025