Drug-related problems associated with self-medication and medication guided by prescription: A pharmacy-based survey

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Abstract:
Objectives: The objective of this study is to identify and compare the nature of the drug-related problems (DRPs) associated with self-medication and non-self-medication (drug use guided by a prescription).

Materials and Methods: The cross-sectional, observational study was conducted on 1100 adult participants at a convenience sample of six retail private pharmacy counters. The data collection form was based on the Pharmaceutical Care Network Europe version 6.2 classification for DRPs. Descriptive statistics was used to represent the prevalence of DRPs. Chi-square test was used to find out the association between the type of medication and DRPs. Odds ratio (OR) with confidence interval (CI) was computed to find the factors determining the occurrence of DRPs. P < 0.05 was considered to be statistically significant. Data were analyzed using SPSS version 16.0.

Results: The prevalence of self-medication was 18.72%. The prevalence of DRPs was 17.36%. In the self-medication group, the prevalence of DRPs was high (40.78%) as compared to the non-self-medication group (11.97%). DRP related to inappropriate drug dosing was observed in 44.83% and 40.45% subjects in self-medication and non-self-medication group, respectively (P < 0.001). The subjects in the self-medication group were about 5 times likely to have a DRP (OR: 5.06, CI: 3.59-7.14, P < 0.001).

Conclusions: Self-medication is associated with a higher risk of various DRPs. Since retail pharmacy outlet is often the first point of contact between the patient and the health care system in a developing country, interventions like drug information activities at the retail pharmacy is likely to bring down the DRPs associated with self-medication.

Key words: Drug related problems, inappropriate drug use, medication request, self-medication

Self-medication is defined as the selection and use of medicines by individuals to treat self-recognized illnesses or symptoms.¹ The practice of self-medication is common in India and many other parts of the world.²,³ Medicines for self-medication are also called “over the counter medications” and are available without prescriptions.⁴ Although “over the counter medications” are meant for self-medication and are of proved efficacy and safety, their side effects and interactions have serious implications.⁵,⁶ The World Health Organization reports have cited self-medication as a common problem leading to the incorrect use of medicine.⁷ Ideally, drug use should involve procuring and using medications guided by a prescription obtained after consulting a registered medical practitioner. Pharmacists often sell medicines without verifying prescriptions. Drug-related problems (DRPs) are defined as an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes.⁸ Although preventable, they constitute a frequent safety issue leading to patient harm and increased health care costs. The term DRP embraces medication errors, adverse drug events, and adverse drug reactions.⁹ They are known to be a major problem associated with pharmacotherapy and are an important cause of morbidity and mortality and they interfere with the patient’s experiencing an optimum outcome of medical care.¹⁰

Earlier studies have also evaluated DRPs associated with medications. These publications have mostly focused on hospital admissions or discharge. Such studies might not fully reflect the magnitude of DRPs arising out of...
of the inappropriate use of drugs by self-medication in a developing country. It has also been reported that drug use is influenced by the socioeconomic and demographic characteristics of drug consumers. The high cost of medicines, nonavailability of doctors makes health care unaffordable and inaccessible. Consequently, in developing countries pharmaceutical outlets often serve as the first contact point of healthcare. Using the retail pharmacy outlet to enroll participants for the survey would give a better idea of the self-medication practices and associated DRPs. To the best of our knowledge, there are no studies that have compared the occurrence of DRPs arising out of self-medication and use of medicines guided by a prescription (non-self-medication) by interviewing drug consumers at the private retail pharmacy. The unique feature of the survey was to enroll the study participants at the retail pharmacy outlet to avoid selection bias and make the sample more representative than hospital-based studies. Therefore, this survey was planned, with a patient-based approach at the private retail pharmacy, with the objective of providing a quantitative description of the nature of DRPs associated with self-medication and non-self-medication. The use of the term prescription medication was avoided in the study as it implies the sale of certain drugs (restrictive drugs) only on production and verification of a prescription.

**Materials and Methods**

**Study Area**

The study site – Berhampur, is one of the major cities in eastern India, in the state of Odisha. The population of in the city has good access to health facilities. There is one government medical college with super specialty and tertiary care; one district headquarter hospital, many government dispensaries, more than 100 pharmacy shops, traditional healers, and private clinics.

**Study Design**

It was a cross-sectional, observational study conducted in the private retail pharmacy from April 2015 to August 2015. For the study protocol, self-medication was defined as the taking of drugs without a relevant prescription (i.e., drugs sold without a prescription, using an old prescription or using drugs prescribed for another person). The Pharmaceutical Care Network Europe (PCNE) version 6.2 (PCNE Foundation, The Netherlands, Europe) classification for DRPs was used as a guide for categorizing the DRPs. An inappropriate choice of drug, inappropriate drug dosing, potential for drug interaction, possibility of suffering from an adverse drug reaction and using a drug treatment more expensive than necessary were the parameters used for defining a DRP for the survey.

**Ethical Approval**

The study protocol and patient informed consent procedures were approved by the Institutional Ethics Committee of MKCG Medical College, Berhampur, Odisha (protocol approval number IEC/344/16-02-2015).

**Primary and Secondary Objectives**

The primary objective of the study was to compare the nature of the DRPs associated with self-medication and non-self-medication. The secondary objectives were to find out the prevalence and pattern of self-medication as well as to identify the factors that are likely to cause DRPs.

**Sample Size Calculation**

The sample size was calculated based on the assumption there would be an difference of 20% in the occurrence of DRPs between the self-medication and non-self-medication groups (i.e., estimated risk difference in DRP of 0.2) and an absolute precision of 5% (i.e., population risk difference of 0.05) at a confidence level of 95% (two-sided). With such assumptions the minimum sample size was calculated to be 461 using nMaster 2.0, (Designed and Developed by Department of Biostatistics, Christian Medical College, Vellore, India). To account for the clustered nature of the sampling design, considering a design effect of two the calculated sample size was doubled resulting in a sample size of 922. This was increased by 10% to account for nonresponses, resulting in a final sample size of 1014. Finally, 1100 subjects were included in the study. The largest possible sample size was taken to reduce random error.

**Sampling Techniques**

The study was performed at a convenience sample of six busy private retail pharmacy counters in the city. To prevent selection bias three pharmacies were selected nearer to the hospitals and the three were selected away from the hospital areas. To limit the potential for sampling bias, the total sample size was divided among the six pharmacy counters included in the study. As rates of hourly visits of customers varied markedly within each day, time slots were defined a priori covering the 24-h day. Subsequently, these predefined time slots, throughout the 5 months of the study were randomly allocated for each participating pharmacy using a random digit table. During each data collection session, consecutive customers with a medication request were included in the absence of any exclusion criteria, only after obtaining their informed consent.

**Participant Enrollment and Data Collection**

All adult patients asking for medicine or presenting a symptom at the participating pharmacy during one of the predefined time slots were eligible for study enrollment. At the time of their coming to the pharmacy, patients and/or their relatives were informed about the study and the relevance to participate. Informed consent was obtained, and consenting patients and/or their relatives were subsequently included in the absence of exclusion criteria. The investigators along with one assistant specifically trained for the study collected the data in every participating pharmacy.

**Exclusion Criteria**

Patients unable to participate because of language barriers, having presented with an unstable medical illness, patients or representatives seeking medication for pediatric population (<14 years) and those declining participate in the study were precluded because their inclusion would have affected the description of the self-medication and non-self-medication behavior and DRPs.

**Study Tools**

A data collection form that was used in the study to explore the medication behavior and the associated DRPs was pretested in one participating pharmacy for operational convenience. The design of the data collection form was guided by PCNE version.
6.2 classification for DRP.[7] The data collection form had two parts. The first part collected data on the patient demographics (gender and age), the type of medication requested (self-medication or non-self-medication) if self-medication whether it was a first-time or a repeat self-medication request and the number of drugs requested. A history of adverse drug reaction on the use of medication for a similar illness was recorded. This was used to find out the possibility of suffering from an adverse drug reaction on the use of either type of medication (self and nonself).

The second part collected the information on the drug use like the name of the drug, indication for which it is intended to be used, dosing schedule, duration of treatment. The collected data were analyzed and interpreted for the assessment of DRPs using Martindale – The Complete Drug Reference, 36th Ed., Drug Information Handbook of Lexicomp, 24th Ed., and Drug Interaction Facts 1st Ed. A dose or duration of treatment that was inappropriate, i.e., more or less than the therapeutic dose range and/or duration mentioned in drug information books used for the study was taken as a DRP. The number of DRPs per patient in each of the category of PCNE version 6.2 classification, which was modified to suit the study setting, was calculated to estimate the prevalence of DRPs.

**Statistical Analysis of Data**

Descriptive statistics was used to represent the study population characteristics, indications for the medication, prevalence of DRPs. Chi-square test was used to find out a significant association between the type of medication and the various DRPs. Odds ratio (OR) with confidence interval (CI) was computed to find out if the factors such as the type of medication, number of drugs used, and age of the patient are determinants of DRPs. P < 0.05 was considered to be statistically significant. All the data were entered immediately after the dialogue with the customer in the data collection forms and which was randomly checked for quality and completeness by the investigators. Data were transferred from the case report forms to SPSS version 16.0 (copyright SPSS Inc., 2007, Chicago, Illinois, USA) and analysis were performed by the investigators.

**Results**

The prevalence of self-medication was 18.72%. The study documented 206 self-medication and 894 non-self-medication requests [Table 1]. In the self-medication group, 13.82% were doing self-medication repeatedly. Of the subjects in the self-medication group, 64% were males and 12% of the subjects were more than 60 years of age. There was no difference in the gender and age distribution between subjects with and without self-medication.

**Indications for Self-medication**

The most common indication for self-medication was fever, whereas pain was the commonest indication in the non-self-medication group [Table 2]. Majority of the DRPs were observed when medication was for relieving pain, i.e., 21.38% and 15.88% in the self-medication and non-self-medication groups, respectively.

**Drugs Used for Self-medication**

Nonsteroidal anti-inflammatory drugs (NSAIDs) (38%), followed by gastrointestinal (GI) drugs (16%), cough remedies (14%), and antimicrobials (10%) were the commonly used drugs for self-medication [Table 3]. The most common NSAIDs was paracetamol and its fixed dose combination drugs (FDC), whereas azithromycin was the most common antibiotic used for self-medication. The use of NSAIDs for self-medication resulted in a significant proportion (63%) of the DRPs (Fisher’s exact test P < 0.001). The major DRP observed with self-medication with NSAIDs was the possibility of drug-induced gastric ulceration and potential drug interactions. Self-medication with cough remedies constituting the FDC of dextromethorphan, guaiphenesin, bromhexine that were recently banned contributed to 8% of the DRPs in this group (P < 0.001). Self-medication with atenolol and amiodipine for the treatment of chronic cardiovascular conditions like hypertension was seen in 1.5% of participants in this group.

**Prevalence of Drug Related Problems**

The prevalence of DRPs was 17.36%. In the self-medication group, the prevalence of DRPs was high (40.78%) as compared...
to the non-self-medication group (11.97%). In the self-medication group, 20.38% encountered one DRP whereas only 2.57% subjects in the non-self-medication group had one DRP. More than three DRPs were seen in 3.39% and 0.003% in the self-medication and non-self-medication group, respectively. The survey documented 365 DRPs in 206 self-medications and 894 non-self-medication requests [Table 1].

**Type of Drug-Related Problems**

The most frequent DRP observed was related to inappropriate drug dosing. It was observed in 44.83% and 40.45% subjects in self-medication and non-self-medication group, respectively ($P < 0.001$). A problem in the choice of the drug was observed in 28.96% and 20.45% of the study subjects in the self-medication and non-self-medication groups, respectively ($P < 0.001$) [Table 4]. The potential for the occurrence of an adverse drug event was seen in 6.89% subjects in the self-medication group, whereas, this was higher, i.e., 13.64% in the non-self-medication group. The difference in the occurrence of a potential drug interaction between the two comparison groups was 0.32% ($P < 0.001$). From the history of occurrence of adverse drug reactions, it was observed that the potential for an adverse reaction like GI upset was 72% followed by cutaneous adverse drug reaction like rash, generalized pruritus (13%). NSAIDs had the highest potential (67%) for an adverse drug reaction followed by antimicrobials (24%) in the self-medication group. In the non-self-medication group, apart from NSAIDs (59%) and antimicrobials (18%), oral

**Table 3: List of drugs used for self-medication and occurrence of drug-related problem**

| Category (name of the drugs) | Number of SM requests (n=206) | Occurrence of DRP (n=84) | Fisher’s exact test ($P$) |
|-----------------------------|-------------------------------|--------------------------|--------------------------|
| NSAIDs (paracetamol, diclofenac, and their FDC) | 79 (38) | 53 (63) | <0.001 |
| Antimicrobials (cefuroxime, ciprofloxacin, norfloxacin, amoxicillin-clavulanic, azithromycin, and omizadole) | 21 (10) | 10 (12) | 0.640 |
| Gastrointestinal drugs (ondansetron, proton pump inhibitors, domperidone sucralfate, and antacids) | 32 (16) | 7 | <0.001 |
| Cough remedies (FDC containing dextromethorphan, guaiphenesin, and bromhexine) | 28 (14) | 4 (8) | <0.001 |
| Anti-allergic, anti-histaminics (levocetirizine, FDC of levocetirizine, and montelukast) | 4 (2) | 3 (4) | 0.306 |
| Topical preparations (FDC of fusidic acid and betamethasone) | 1 (0.5) | 0 (0) | 1.00 |
| Central nervous system drugs (lorazepam, alprazolam) | 11 (5) | 3 (4) | 0.530 |
| Ear drops (ciprofloxacin, FDC of ciprofloxacin and clotrimazol) | 4 (2) | 0 (0) | 0.147 |
| Eye drops (FDC of moxifloxacin and dexamethasone) | 1 (0.5) | 0 (0) | 1.00 |
| Cardiovascular drugs (atenolol, amiodipine) | 3 (1.5) | 2 (2) | 0.568 |
| Urogenital diseases (alkalizer, flavoxate, FDC of fluconazole, omizadole, and azithromycin) | 7 (3) | 2 (2) | 0.703 |
| Others (tonics/multivitamins, OAD, gonadal hormones, and OCP) | 15 (7) | 0 (0) | <0.001 |

**Table 4: Type of drug-related problems seen in self-medication and non-self-medication group**

| Type of DRP | SM (%) | NSM (%) | $\chi^2$, $P$ | OR (CI) |
|-------------|--------|---------|--------------|---------|
| Drug choice problem | 42 (28.96) | 45 (20.45) | 54.19, <0.001 | 4.83 (3.07–7.59) |
| Inappropriate drug | 14 (9.65) | 4 (1.82) | 1.82, >0.05 | 1.00 (0.50–2.02) |
| Inappropriate drug formulation | 0 | 2 (0.90) | <0.001 | 1.00 (0.38–2.54) |
| Duplication of therapeutic group | 8 (5.52) | 7 (3.18) | 1.82, >0.05 | 1.00 (0.50–2.02) |
| Contraindication for the drug | 3 (2.07) | 3 (1.36) | <0.001 | 1.00 (0.38–2.54) |
| Drug treatment given but not necessary | 17 (11.72) | 19 (8.37) | 1.82, >0.05 | 1.00 (0.50–2.02) |
| Indication present but no drug given | 0 | 10 (4.54) | <0.001 | 1.00 (0.38–2.54) |
| Drug dosing problem | 65 (44.83) | 89 (40.45) | 60.15, <0.001 | 3.94 (2.74–5.68) |
| Dose inappropriate | 20 (13.79) | 40 (18.18) | <0.001 | 1.00 (0.38–2.54) |
| Duration of treatment inappropriate | 45 (31.03) | 49 (22.27) | <0.001 | 1.00 (0.38–2.54) |
| Drug interaction problem | 18 (12.41) | 28 (12.73) | 13.13, <0.001 | 2.96 (1.60–5.46) |
| Potential interaction | 10 (6.89) | 30 (13.64) | 1.07, 0.303 | 1.46 (0.70–3.05) |
| Adverse drug reaction | 10 (6.89) | 28 (12.73) | 1.48, 0.222 | 1.57 (0.75–3.30) |

**SM:** Self-medication, **NSM:** Non-self-medication, **OR:** Odds ratio, **CI:** Confidence interval, **DRP:** Drug-related problem
antidiabetics (15%) followed by antihypertensive (6%) were the potential to cause an adverse drug reaction.

The subjects in the self-medication group were about 5 times likely to have a DRP (OR: 5.06, 95% CI: 3.59–7.14). Although the likelihood of DRPs in subjects taking more than six drugs and in elderly more than 60 years was more, this was not statistically significant [Table 5]. Thus, self-medication is a determinant for the occurrence of DRPs.

Discussion

In this study, the prevalence of self-medication was 18.72%. Some other studies have observed the prevalence of self-medication to be between 12.7% and 95%. In another Indian study, its prevalence was 37% in urban and 17% in rural population. In a study in rural Maharashtra, its prevalence was 81.5%. Similarly, in another Indian study, its prevalence was 73%. The observation in the survey that males used either type of medication more than females is similar to the reports of many other studies from India on the gender predisposition to self-medication, contrary to data from some western reports. It was observed from literature review that, the prevalence of self-medication and its pattern widely varied across different studies. This may be due to their varying nature of definitions used, region selected, and methodology adopted. In this study, the lower prevalence of self-medication as compared to other Indian studies may be due to different study setting, i.e., the private retail pharmacy counter was adapted for sampling. In this study, DRPs were identified for 40.78% of the subjects doing self-medication, whereas it was seen in 11.97% in the non-self-medication group. Some other surveys have recorded DRPs in 21% of self-medication requests. In the present study, the prevalence of DRPs was 17.36%. In a study done in the west, the prevalence of DRP was 23.7%, contrary to an Indian study where its prevalence was 68.78%. The wide variability in the occurrence of DRPs may be due to different study settings and approaches. In spite of these differences, the results of this study underline that self-medication is frequently associated with a higher risk of occurrence of DRPs. In the present study, the most common DRPs observed were related to “inappropriate drug dosing.” Another Indian study has reported “improper drug selection” followed by “inappropriate drug combination” to be the common DRPs. Some western studies have observed “inappropriate drug use,” followed by DRPs related to the “duration of drug use” to be the most frequent DRPs. In one report, where the prevalence of DRP was 63.7%, “side effects” were observed to be the second most common DRP (23.3%). It was observed that the common indications for either type of medication were fever, followed by pain (including a headache). Similar was the observation in some other studies, where the most common used drugs for self-medication was paracetamol (56.5%), followed by drugs for GI problems (40.5%) and other NSAIDs (39.9%). In a Western study, pain followed by respiratory and GI complaints were the frequent indications. This indicates that, universally, pain and fever are the most common indications for which self-medication is sought. The observation that NSAIDs were the most common drug category used for self-medication is corroborated by the findings of other studies done across India. In the present study, it was observed that 10% of participants used antibiotics for self-medication, this is in contrast to the reports of a study done in South India where the self-medication of antibiotics was as high as 39.3%. In a South Asian study antimicrobials followed be NSAIDs were the commonly suspected drug categories causing adverse drug reactions. In another Western study, self-medication-related ADRs were predominantly GI complaints caused by NSAIDs. They have also reported drug-drug interactions occurring between self-medication and prescribed medication. This is similar to the observations in the present study. In the present study, there was a significant association between self-medication of cough remedies (FDC containing dextromethorphan, guaiphenesin, bromhexine) and the occurrence of DRPs. A published study on the rationality assessment of the FDC preparations for cough and cold available in the Indian market has revealed that most of such preparations were irrational and had no benefit in the treatment of common cold. In a recent Gazette Notification in March 2016 the Ministry of Health and Family Welfare, Government of India has “prohibited the manufacture for sale for human use” many such FDCs. The use of some of the self-medications for managing chronic disease conditions such as hypertension, diabetes, urinary tract infections, and asthma was observed in this study. This is alarming since intake of medications for chronic disease conditions should be as per physician advice. Subjects in the age group between 41 and 60 years were more likely to self-medicate and the likelihood of DRPs in subjects taking more than six drugs and in elderly more than 60 years was higher in this study. Some other researchers have reported the incidence of DRPs to be highest in patients aged between 51 and 60 years. They have also observed that patients receiving 6–10 drugs had more DRPs.

Table 5: Factors associated with the occurrence of drug-related problems in study subjects

| Factors                        | Number of subjects (n=1100) | Number of subjects with DRPs (n=191) | OR (CI)          | P       |
|--------------------------------|----------------------------|-------------------------------------|-----------------|---------|
| Type of medication             |                            |                                     |                 |         |
| Self-medication                | 206                        | 84                                  | 5.06 (3.59–7.14)| <0.001  |
| Non-self-medication            | 894                        | 107                                 |                 |         |
| Number of drugs                |                            |                                     |                 |         |
| 1–5                            | 547                        | 93                                  | 1.05 (0.76–1.43)| 0.752   |
| 6 and more                     | 553                        | 98                                  |                 |         |
| Age (in years)                 |                            |                                     |                 |         |
| <60                            | 825                        | 130                                 | 1.52 (0.40–1.52)| 0.478   |
| >60                            | 275                        | 61                                  |                 |         |

OR: Odds ratio, CI: Confidence interval, DRPs: Drug-related problems

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There are very few studies with a comparable design and setting. One of the major limitations of the present study was the use of convenience sampling technique to select the six private retail pharmacies; this could have missed certain information likely to have been obtained from other pharmacies. The present study does not describe the situation outside the pharmacy outlets and hence, it may not be representative for the total frequency and types of DRPs in relation to self-medication and non-self-medication use in general.

**Conclusion**

This study infers that self-medication is associated with a five times higher risk in the occurrence of DRPs. It is certain that DRPs lead to an adverse outcome and increased health care costs.\(^6\) Drug information programs directed to the priority groups who are more likely to use self-medication will prevent or at least improve the quality of self-medication, and this would minimize the occurrence of various DRPs. Symptomatic treatment by self-medication often delays the visit to a physician, and the clinical setting most likely gets modified enough, leading to a medication error. The findings of this survey hypothesize that, interventions at the level of the retail private pharmacy, which is often the first point of contact between the patient and health care system in a developing country, in the form of counseling in relation to use of medicines by self-medication is likely to bring down the associated DRPs. Other interventions to prevent DRPs, like, promotion of drug information activities may be adopted to make citizens aware of the risks associated with the use of drugs without medical consultation.

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**Conflicts of Interest**

There are no conflicts of interest.

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