Evaluation of Knowledge and Awareness of Patients about Prescribed Drugs and their Package Inserts: A Cross-sectional Study

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Abstract

Introduction: The package insert (PI) is an officially approved mandatory document inside the package with the intention to provide relevant, recent and unbiased information for rational drug use. The information accompanying the drug is approved by the regulatory agencies. Pharmaceutical companies use PIs as one of the means to promote information regarding marketed products. In India, assessment of the PIs of drugs by patients is rare. Hence, this study is an attempt to assess the importance of different aspects of PIs along with an appraisal of patients' knowledge of the prescribed drug regimen. **Materials and Methods:** In this cross-sectional study around 200 patients between 18 and 70 years of age, taking medications were interviewed with a pre-validated semi-structured questionnaire adapted from the previous studies. **Results and Observations:** Out of 200 patients 87 were taking medications for chronic while 113 for acute diseases. The majority (61.5%) never read while only 13% always read the information in PIs. Dosage (35.5%) and uses (33.5%) were among highest read columns by patients. Females were found to have more knowledge and awareness about PIs. **Conclusion:** PIs have an important impact on the patients compliance and thus on the effectiveness of drug use. However, patients need to be more aware about reading the information in PIs.

Key words: Awareness, knowledge, packet inserts, questionnaire-based study

INTRODUCTION

The package insert (PI) has a significant role in providing essential drug information for patients taking over-the-counter as well as prescription-only medications. In developing countries, it is considered an important source of drug information for health-care providers as well, due to the limited ability to access up to date information about drugs. Studies have shown that the PIs help to bridge the information gap between health care providers and patients and enhance patients' knowledge about medications.[1,2] The quality and quantity of information available in the PIs have been shown to influence patient compliance and satisfaction.[3,4] It is also found that patients who read the PIs are more likely to follow the instructions, given by health care provider and less likely to face serious consequences of drug treatment.[5]

The design and the amount of information in the PIs are usually regulated by the legislative health authorities. In India, the concept of PI is governed by the "Drugs and Cosmetics Act (1940) and Rules (1945)."[2] Section 6 of Schedule D (II) of the Rules lists the headings according to which information should be provided in the PIs.[6] "Section 6.2" mandates that the PI must be in "English" and must include information on therapeutic indications, posology and method of administration, contraindications, special warnings and precautions, drug interactions, contraindications in pregnancy and lactation, effects on ability to drive and use machines,

undesirable effects, and antidote for overdosing. "Section 6.3" mandates pharmaceutical information on the list of excipients; incompatibilities; shelf life as packaged, after dilution or reconstitution, or after first opening the container; special precautions for storage; nature and specification of container; instruction for use/handling. It is not mentioned clearly, whether the PIs are directed only at the physicians or at the patients as well.[7]

This study was undertaken to assess the knowledge and awareness toward PIs among semi-urban population seeking medications at a tertiary care hospital.

MATERIALS AND METHODS

Study design

This is a cross-sectional study involving 200 patients taking medication in a tertiary care hospital, who were interviewed with a pre-validated semi-structured questionnaire designed for them. The questionnaire is adapted from the previous studies and modifications were done in the questionnaire with reference to "Drugs and Cosmetics Act (1940) and Rules (1945)." Section 6 of Schedule D (II) of the rules lists the headings according to which information should be provided in the PIs.[2,6]

Patients of either sex with an age range between 18 and 70 years seeking medication for acute/chronic diseases were included in the study. Wherein patients with a vision problem and psychiatric disorders were excluded from the study. Informed consent was taken from all patients after discussing benefits of the study.

Knowledge of the patients about the drugs prescribed was scored as; 0, 1, and 2 by asking total nine questions related to the drug. For each correct answer score given was 2, for partially correct answer 1 and incorrect/do not know response it was 0. Score range was between 0 and 18.[8]

Statistical analysis

Obtained data was analyzed using descriptive analysis method and is presented as mean score ± standard deviation and percentage.

RESULTS

The demographic and socioeconomic characteristics of patients receiving medicines with PIs are presented in Table 1. The majority of the patients attending hospital were literate (81.5%) but unemployed (71.5%) with low-income group (<Rs. 5000 per month).

The results showed that significantly high number of patient (61.5%), though literate never read PIs. Only 13% of patients always read while 25.5% sometimes read PIs [Figure 1].

Dosages (35.5%) and uses (33.5%) were among the most commonly read columns in PIs. While pregnancy lactation warnings (6.5%) and overdose (2.5%) were among the least read [Figure 2].

Data analysis on knowledge and awareness scores of patients about the prescribed drugs with PIs revealed that the females are more aware and having more knowledge about the prescribed drugs with PIs. The maximum score was found between 7 and 9 [Figure 3].

The majority of respondent, male (female) were totally unaware of knowledge about possible drug interactions 93% (90%), interactions with over the counter drugs 95% (94.9%) and effects of food on the medication and need for change in diet 73.2% (79.7%) [Table 2].

Table 1: The demographic-socioeconomic variables of patients receiving medicines with PIs

Character	Variable	Number (%)
Gender	Male	101 (50.5)
	Female	99 (49.5)
Mean age±SD (years)	Male	54.3±2
	Female	53.8±3
Education	Literate	163 (81.5)
	Non-graduate	135 (67.5)
	Graduate	20 (10)
	Postgraduate	8 (4)
	Illiterate	37 (18.5)
Occupation	Employed	57 (28.5)
	Unemployed	143 (71.5)
Monthly income (Rs)	<5000	150 (750
	5000-15000	49 (24.5)
	>15000	1 (0.5)
Patients with chronic disease	Total	87 (43.5)
	Read PI	32 (36.78)
Patients with acute disease/minor ailments	Total	113 (56.5)
	Read PI	39 (34.5)

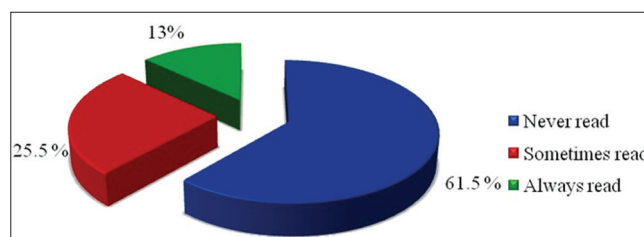PI: Package insert, SD: Standard deviation

Figure 1: Percentage of population reading package inserts

DISCUSSION

PIs are the authentic source of information for the new molecules in the market. The quality and quantity of information available in the PIs have been shown to influence patient compliance and satisfaction. The patients who read
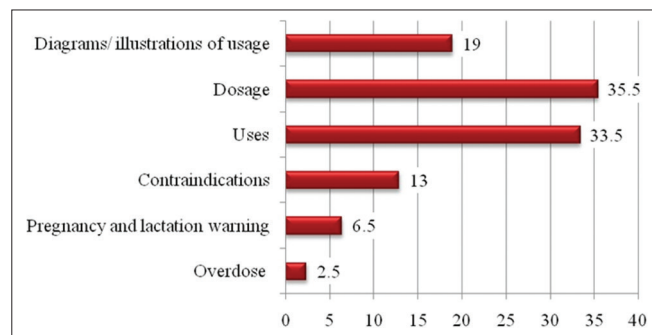

Figure 2: Percentage of package inserts columns read by patients
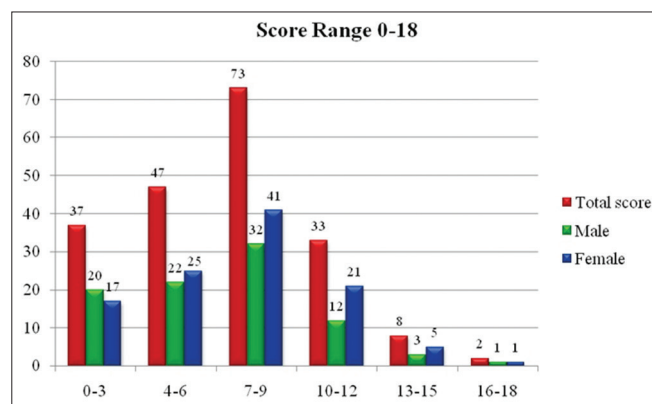

Figure 3: Knowledge and awareness scores of patients about the prescribed drugs with package inserts

the PIs are more likely to follow the instructions, of the health care provider and are less likely to face serious consequences of drug.[9]

Results of this study strongly suggest that there is need for escalating knowledge and awareness among patients about the importance of PIs. Unfortunately, this study revealed that only 13% patients always read the information in PIs. This figure is disappointing compared to the results of studies carried out in developed countries, and countries such as Saudi Arabia, Palestine where the reported percentage was 79.8%, 88% and 45%, respectively.[10-12] However, the results of another study carried out in India are comparable to our study that stated this percentage to be 12%. In this study, however, the lack of awareness and knowledge was said to be due to low literacy rate (26.7%),[13] surprisingly in our study, it was 81.5%. Overdose (2.5%), pregnancy and lactation warning (6.5%), and contraindications (13%) were the least read columns of PIs. The majority of harmful effects are because of lack of awareness and knowledge about this information. Gender specific comparison, however, revealed that females are more knowledgeable and aware about PIs. These results are in agreement with earlier studies.[11-13] Certain individual items scores, such as knowledge about possible drug interactions, interactions with over the counter drugs and effects of food on the medication and need for change in diet showed no significant gender-specific difference, about 70-95% patients were totally unaware of this information. Hence, patient education about PIs must be at utmost importance.

In Indian scenario, the doctor-patient ratio is inadequate, i.e., 1:1700; where expected one is 1.5:1000 equivalent to the world average ratio.[14] Hence, for health professionals, it is difficult to offer comprehensive information of medicines to the patients. These limitations set a definite gap, both

Table 2: Gender specific comparison of knowledge and awareness about the drugs with PIs			
Answer to questions	% Correct male (female)	% Partially correct male (female)	% Incorrect/don't know male (female)
Knowledge about brand and generic name	9.9 (10.1)	56.4 (34.3)	32.6 (64.64)
Awareness about time to take medicine relative to meal, sleep and activities	55.4 (47.4)	43.5 (57.5)	1.9 (1.01)
Knowledge about missed dose	0.9 (0)	60.3 (60.6)	37.6 (49.4)
Knowledge about serious complication if occurs	61.3 (66.6)	22.7 (26.26)	14.8 (10.10)
Knowledge about possible drug interactions	0.9 (0)	4.9 (0)	93 (90)
Knowledge about possible drug interactions with over the counter drugs	0 (6.06)	3.9 (7.07)	95 (94.9)
Awareness about effects of food on the medication and need for change in diet	4.9 (0)	20.7 (16.16)	73.2 (79.7)
Awareness about the methods and importance of monitoring drug treatment	9.9 (0)	60.3 (57.57)	28.7 (34.3)
Awareness about need to tell other health providers about drug therapy with reasons	17.8 (0)	65.3 (66.6)	14.8 (14.14)

PI: Package insert

communicative as well informative between doctors and patients. This results in self-medication, medication errors, and adverse drug reactions,[15] altogether they increase physical, mental and financial burden on the population. To conclude PIs have an important impact on the patients compliance and thus on the effectiveness of drug use. However, patients need to be motivated about reading the information in PIs. All these issues can be resolved through educating patients about PIs.

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