

A study on awareness about package inserts among postgraduate medical students: an observational questionnaire based study**Rohini Gupta^{1*}, Apoorva Malhotra², Pavan Malhotra²**¹Department of Pharmacology,
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work is properly cited.**ABSTRACT****Background:** A package insert is a document approved by the administering licensing authority, which is provided with the package of a drug. A good package insert can prove to be of immense help to doctors as they are evidence based and are updated from time to time. The objective to study the awareness about package inserts among postgraduate medical students.**Methods:** The present study was a cross-sectional observational study carried out on 68 postgraduate medical students of Acharaya Shri Chander College of Medical Sciences and Hospital Sidhra, Jammu (J & K) in the month of February 2017 after taking approval from the institutional ethical committee. Pre-validated self-administered questionnaire was used to elicit responses from the students. The questionnaire consisted of specified questions regarding knowledge and opinion about package inserts.**Results:** In the present study, 86.7% of the students understand the relevance of Package inserts (PIs). About 72% of the students think that PIs are a necessary add-on to drug information and 70.6% of the students think that information given on package inserts is necessary for the patients. However, only 2.9% of the students had the knowledge of Drug Acts governing the information to be provided on PIs in India. About 86.8% of the students think that PIs should also be in regional language apart from in English language.**Conclusions:** It was found from the present study that the majority of the postgraduate students were aware about the package inserts available with the medicines but the information provided on package inserts was not optimally used by them. To achieve the target of optimally utilization of information provided in the package inserts, the PIs should be designed by considering the needs and information of two differently educated target groups i.e; patients and doctors.**Keywords:** Awareness, Knowledge, Package inserts, Postgraduate students, Questionnaire**INTRODUCTION**

A package insert is a document approved by the administering licensing authority, which is provided with the package of a drug.¹ India is a highly populated country and the doctor patient ratio in India is 1:1700 which is much less than the recommended 1:1000.² Thus in such a set-up, it is not possible on the part of the doctor to provide detailed information to the patient about the drug

prescribed for a particular illness. Moreover, it is very difficult for the patients also to remember each and everything described by the doctor about the intake of the drug. Thus, in such circumstances, package inserts serve as a source of information for the patients in providing complete and adequate information regarding the prescribed medicines in addition to the instructions given by the doctor. At the same time, for the physicians also package inserts serve as an important source of drug

information prescribing effectively and safely as many a times, it is not possible for the doctors to go through the research articles and look for recent advances in relation to a particular drug.³ Since, a good Package Insert (PI) is evidence-based and is updated time to time as relevant preclinical and clinical data becomes available, therefore, it can prove to be of immense importance to physicians also.⁴

In India, the concept of package insert is governed by the 'Drugs and Cosmetics Act (1940) and Rules (1945)'. The section 6 of Schedule D (II) of the rules lists the headings according to which information should be provided in the PIs. The 'Section 6.2' mandates that the PIs 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 list of excipients, incompatibilities, shelf-life as packaged, after dilution or reconstitution, or after first opening the container, special precaution for storage, nature and specification of the container and instruction for use/handling.⁵⁻⁷

It has already been known from the previous studies that PIs help to bridge the information gap between health-care providers and patients and enhance patients' knowledge about medications.⁸ It has also been seen that quality of information given in the PIs has a major influence on the patients' compliance and thus lead to improved therapeutic outcomes.⁶ Thus in view of this, the present study was planned to assess the knowledge and awareness towards PIs among postgraduate medical students in a tertiary care teaching hospital of North India.

METHODS

The present study was a cross-sectional, observational study carried out on 68 postgraduate medical students of Acharaya Shri Chander College of Medical Sciences and Hospital Sidhra, Jammu (J&K) in the month of February 2017. The study was commenced after taking approval from the institutional ethical committee. Self-administered, prevalidated questionnaire was used to elicit responses from the students about their knowledge and opinion regarding the package inserts. The questionnaire consisted of various questions like type of information which should be available on package inserts, questions relating to laws and drug acts governing the information provided on the package inserts and also the questions eliciting the opinion of the postgraduate doctors that whether it is necessary to tell the patients to read thoroughly the information provided on package inserts (PIs) or not etc.

The questionnaire was pre-validated by carrying out a pretest assessment in 5 postgraduate students and appropriate modifications done. Final version of the

questionnaire was distributed to the participants after explaining the nature and purpose of the study. All the students who agreed to complete the questionnaires and were willing to participate in the study were included in the study. About half an hour was given to the participants to fill the questionnaire. The completed questionnaires were then assessed for responses of the students about their knowledge and awareness regarding package inserts. Written informed consent was obtained from each participant included in the study. Postgraduate students posted in different departments of the hospital were approached and explained the purpose of the study. 70 gave consent to participate in the study. Out of 70 only, 68 duly filled questionnaires were used for final analysis. Those who were not willing to participate in the study and those whose questionnaires were not duly filled were excluded from the study. Also, the students in whom pilot study was done were excluded from the study. The data was analyzed with the help of descriptive statistics and the responses elicited were expressed in percentages.

RESULTS

Table 1: Questionnaire to assess the knowledge of the postgraduate students on Package inserts.

S. no.	Questions	n (%)
Q1	Do you understand Package Inserts (PIs)	59 (86.7)
Q2	Do you think that PIs are a necessary add-on to drug information	49 (72)
Q3	Do you know about drug acts governing the information to be provided on PIs in India	2 (2.9)
Q4	Do you think that the information given on package inserts is necessary for the patients	48(70.6)
Q5	Have you ever looked for indications/contraindications/Adverse effects/Drug interactions on package inserts	31(45.6)
Q6	Do you think that Package inserts should be in regional language along with English language	59(86.8)
Q7	Do you think that PIs should be used for all the drugs	46(67.6)
Q8	Do you think that it is necessary for a doctor to tell the patients to read the Package Inserts thoroughly	45(66.1)

In the present study, 86.7% of the students understand the relevance of Package inserts (PIs). About 72% of the students think that PIs are a necessary add-on to drug information and 70.6% of the students think that information given on package inserts is necessary for the patients. However, only 2.9% of the students had the knowledge of drug acts governing the information to be provided on PIs in India and only 45.6% of the students

had ever looked for indications/Contraindications/Adverse effects/Drug Interactions on PIs. About 86.8% of the students think that PIs should also be in regional language apart from in English language and about 66.1% of the students think that it is necessary for a doctor to tell the patients to read the PIs thoroughly as shown in Table 1.

DISCUSSION

Package Inserts (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.⁹ In the present study, majority of the postgraduates about 86.7% understand the relevance of PIs and about 72% of the students were of the view that PIs are a necessary add-on to drug information but still only 45.6% of the students had ever looked for indications/Contraindications/ Adverse effects/ Drug interactions on PIs. It may be because they don't feel any need to read it or are short of time due to overburdened patient load. This is consistent with the previously published studies.¹⁰ About 70.6% of the students think that information given on PIs is necessary for the patients and about 86.8% of the students think that PIs should also be in regional language apart from English language and about 66.1% of the students think that it is necessary for a doctor to tell the patients to read the PIs thoroughly. This is consistent with the previously published studies.¹¹ Though it is important to distribute the PIs along with the prescription drug according to the guidelines, but the advantage of distributing it isn't being achieved. It should be available for the patients to provide essential drug information like dose, side-effects and any other additional information which would be useful to them. However, the language used is technical and challenging for the patients to comprehend. Patients' misunderstanding of instructions on prescription drug labels is common and a likely cause of medication error and less effective treatment. Many patients belong to the rural background; therefore, it is necessary on the part of the doctors to counsel the patients and spend more time with them so that they can be made more aware regarding the information provided in the PIs. Many patients are not literate and hence, the objective of informing the patient can be achieved by adding graphic representations and figures showing methods of drug administration. The problem of illiteracy can be overcome by separately addressing such patients.¹²

It has been documented from the previous studies that patients of all literacy levels had better understanding of warning labels that contained single-step versus multi-step instructions.¹³ It has also been documented from the previous studies that although the PIs appear to have improved over the past decade, there is still a definite need to further refine the clinical information contained to minimize the risks to the patients. Both the regulatory authorities and drug manufacturers should implement appropriate measures to regulate the quality and quantity of information in the patient package inserts which will

better direct health practices to the benefit of the patients.^{14,15}

CONCLUSION

It was found from the present study that the majority of the postgraduate students were aware about the package inserts available with the medicines, but the information provided on package inserts was not optimally used by them. To achieve the target of optimally utilization of information provided on the package inserts by the doctors as well as by the patients, the package inserts should be designed by considering the needs and information of two differently educated target groups i.e.; patients and doctors. There is a need to make necessary changes in the PIs for optimum utilization of the information by physicians and patients alike. Some kind of new and innovative steps like the language used should be simple so that it is easily understandable to the patients and making use of pictorial presentations for illiterate patients should always be encouraged to be used in package inserts. To achieve its goals, the drug's package insert should be clear and comprehensible to convey the intended use of the product, provide an adequate direction for use, warn against potential harmful effects and provide instructions for appropriate length of treatment and when to seek medical advice.

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