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Original Research Article

A questionnaire-based study to assess the awareness about package inserts amongst the resident doctors in a medical college of North India

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ABSTRACT

Background: A package insert (PI) is a document certified by the administering licensing authority, provided along the package of a drug. They are a valuable source of knowledge and can be of tremendous help to doctors as doctors are evidence based. The objective of this study was to assess the awareness about package inserts among residents in a teaching hospital in north India.

Methods: The present study was a cross-sectional, observational study carried out on residents in SKIMS Medical College, Srinagar (Jammu and Kashmir) to assess the awareness of participants regarding PIs. The questionnaire was pre-validated and then was used to elicit responses from the residents about their knowledge and opinion regarding the PIs.

Results: A total of 96 residents participated in the study. About 67.7% of the participants agreed that PIs augment drug information but only 47.9% of the residents referred PIs as a source of knowledge for indication/contraindication/adverse effects. 57.29% asserted it is important to tell the patient to read the package insert. Unfortunately, only 8.3% of the study participants had the knowledge of DRUG ACTS governing the information to be provided on PIs in India.

Conclusions: The present study revealed that the residents have good attitude and knowledge towards PIs. However, the information provided on Package Inserts was not optimally used by them. The results of this study strongly suggest that there is a need to create awareness among resident doctors about PIs.

Keywords: Knowledge, Attitude, Package inserts, Resident doctors

INTRODUCTION

A package inserts (PI) also known as a prescription drug label or prescribing information is a document approved by the administering licensing authority, and is provided along with the package of a drug.¹

The PI or patient leaflet information (PIL) is the printed information that accompanies a drug product that aims to provide essential information for the safe and effective use of the drug to physicians and patients. These PIs are an

essential feature of drug packaging, which ideally are available for the prescription medicines and are considered as the primary source of information for health care professionals and patients regarding the indications, contraindications, risks and adverse effects of drugs.²⁻⁴

PIs are governed by strict regulations, and being readily available with the drug product, PIs can serve as reliable and unerring sources of drug information for health-care providers.⁵ The information in the PI is evidence-based and is updated from time to time, as relevant preclinical and clinical data become available.⁶ PIs serve as an important

source of drug information for prescribing doctors who can update themselves effectively by reading these, as it is not possible for the them to go through the lengthy research articles and recent advances in relation to a particular drug.⁷

Regulatory requirements for drug PI or leaflets vary across nations. In India, the concept of PI 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.^{8,9}

It is known from the previous studies that PIs help to bridge the information gap between health-care providers and patients and thus help in building up their knowledge about medications.¹⁰ 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.¹¹

Thus, in view of this, the present study was planned to assess the knowledge and awareness towards PIs among resident doctors in a teaching hospital of North India.

METHODS

The present study was a cross-sectional, observational study carried out on residents in SKIMS Medical College, Srinagar (Jammu and Kashmir) from January 2022 to March 2022. The study commenced after taking approval from the institutional ethical committee. The questionnaire used in this study was developed for its content and relevance after extensive research of the literature for the similar studies. The questionnaire was pre-validated by piloting among residents and then was used to elicit responses from the residents about their knowledge and opinion regarding the PIs. The questionnaire consisted of

specified questions regarding knowledge and awareness about PIs like questions relating to laws and drug acts governing the information provided on the PIs and also the questions eliciting the opinion of the resident doctors that whether it is necessary to tell the patients to read thoroughly the information provided on PIs or not. After explaining the nature and purpose of the study, written informed consent was obtained from each participant and final version of the questionnaire was distributed amongst the participants. All the residents who agreed to complete the questionnaires and were willing to participate in the study were included in the study. Those who were not willing to participate in the study and those whose questionnaire was incompletely filled were excluded from the study. Also, the residents in whom pilot study was done were excluded from the study. A non-probability sampling technique (convenience method) was employed to reach the representative population in our institute. A total of 118 participants were included. The completed questionnaires were then assessed for responses of the residents about their knowledge and awareness.

The data gathered was analysed with the help of descriptive statistics and responses were expressed in numbers and percentage.

RESULTS

Out of 118 residents only 96 responded. Participation of females – 56 (58.3%) was more, as compared to males – 40 (41.6%) (Table 1).

Table 1: Gender wise distribution of participants.

Gender	N (%)
Male	40 (41.6)
Female	56 (58.3)

Table 2: Assessment of awareness regarding PIs.

Question	Yes	No	May be	Can't say
	N (%)	N (%)	N (%)	N (%)
1. Do you read PIs?	32 (33.3)	64 (56.25)	-	-
2. Do you think PIs are necessary to augment drug information?	65 (67.7)	31 (32.2)	-	-
3. Do you think the dosage instructions are useful part of PI for you?	38 (39.5)	58 (60.4)	-	-
4. Do you think the information given on PI is important for the patient?	54 (56.25)	42 (43.75)	-	-
5. Have you ever read indications, contraindication, drug interactions, adverse drug reaction on PIs?	46 (47.9)	50 (52.08)	-	-
6. Do you think the PI of multi national companies are better than local companies?	15 (15.6)	-	81 (84.3)	-
7. Do you think it is important to tell your patient to read the PI?	55 (57.29)	41 (42.7)	-	-
8. Do you know about drug acts governing the information to be provided on PIs in India?	8 (8.3)	88 (91.6)	-	-

In the present study, only 33.3% of the residents read the PIs. About 67.7% of the residents think that PIs augment drug information but only 39.5% of the residents think that dosage instructions are useful part of PI for them. 56.25% of participants believed that the information given on PIs is necessary for the patients. However, only 47.9% of the residents referred PIs as a source of knowledge for indication/contraindication/adverse effects. 84.3% thought "may be" the PI of multi-national companies are better than local companies. 57.29% asserted it is important to tell the patient to read the PI. However, only 8.3% of the study participants had the knowledge of Drug Acts governing the information to be provided on PIs in India (Table 2).

DISCUSSION

PIs are the bonafide source of information for the medicines. It contains all the necessary information about the drug and is intended for effective use of drugs.^{8,12} Prescribing errors such as incorrect dosage, and incorrect duration of treatment can be decreased by using PIs.¹³

In the present study it was observed that significantly large number of participants 56.25% did not read PIs similar to the study of Sharma et al.¹⁴

More than half of the participants believed that PIs are useful in augmenting drug information but still only 39.5% think the dosage instructions on PI were useful for them. Less than half of them ever looked for indications/contraindications/adverse effects on PIs. This is in concurrence with the previously published studies.¹⁵ 56.25% think the information given on PI is important for the patient. 57.29% think it is important to tell the patient to read the PI, this is akin to the information by Shivkar.¹⁶ The patients who read the PI are more judicious to follow the instructions of health-care providers and are less chances of being erroneous while taking the medication.¹⁷

A total of 84.3% of the participants thought that may be the PI of multi-national companies are better than local companies. A study done by Vikas et al showed that PIs from foreign MNCs were slightly better than the local ones, though both were deficient in completeness of information.¹⁸ But only 8.3% (n=8) had the knowledge of drug acts governing the information to be provided on PIs in India. These results are slightly higher than a similar study done by Gupta et al on postgraduate medical students which showed only 2.9% of students were aware of the drug acts governing the information to be provided on PIs and lower than the study done by Prabha.^{17,19,20}

Limitations

The limitation of this study was that only 96 resident doctors were evaluated regarding awareness about PIs, and the study was done in a single centre.

CONCLUSION

The present study revealed that although the awareness about PIs was good amongst the resident doctors, it was not being optimally used. Results of this study strongly suggest that there is a demand for taking new and innovative steps to intensify knowledge and awareness among resident doctors about PIs. This can be a step forward for effective and successful dispersal of healthcare services in our growing society.

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