



KNOWLEDGE AND AWARENESS ABOUT THE DRUG PACKAGE INSERTS IN MEDICAL INTERNS

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ABSTRACT

Drug package inserts are the most important written information about the drug for patients as well as doctors, hence it is very important for the upcoming doctors i.e., interns to have knowledge about it. The main objective of this study is to assess the knowledge and awareness of the upcoming doctors i.e., interns about the drug package inserts. A questionnaire consisting of 18 questions related to drug package inserts was formulated. These questionnaire were distributed in the interns and the data collected was analyzed for their knowledge and awareness regarding drug package inserts. Total 250 medical interns answered the questionnaires, out of which 70% of them don't know the meaning of the drug package inserts. It should be in regional language was the opinion of 66% interns. 75% opined, its font size should be large. 90% confirmed, it is useful from patient's point of view but when asked how, nobody was able to explain. When compared between two colleges, 10.2% of college 1 and 42.76% of college 2 interns knows the definition of drug package inserts. 97% of college 1 and 85% of college 2 agreed that they are useful from patient's point of view. There is a need of more awareness amongst the interns and certain changes must be done in the drug package inserts.

Keywords: Knowledge, Awareness, Drug package inserts, Medical intern.

INTRODUCTION

Drug Package Inserts (PI) is a document, approved by the administrative licensing authority, which is provided within the package of a drug. A drug package insert primarily made for the prescribers, is intended to make available information for the safe and effective use of that drug [1]. In India, prescribers are mostly dependent on drug information provided by pharmaceutical companies which has been noticed to be inadequate and not fulfilling with WHO recommendations [2]. As package inserts stick to the strict rules and being readily available with the drug product, it can serve as reliable and accurate sources of drug information [3]. The verbal medication information that patient receive from their healthcare providers is incomplete or not understood. Studies have shown that package inserts help bridge the information gap between prescribers and patients and enhance patient's knowledge about medication [4]. It is also found that patients who read

the package inserts are more often to follow the instructions, especially if the information in the package insert matches with the instructions of the prescribers [5]. In India the concept of package inserts is governed by Section 6.2 and 6.3 of Drug and Cosmetic Act 1940 and Drug and Cosmetic Rules 1945 [6, 7] Section 6.2 mandates that the package insert 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 precautions for storage, nature and specification of container, and instruction for use/ handling [8].

Interns are the upcoming prescribers who need to be updated for their knowledge of drug while prescribing it to the patients. Hence the present study was conducted to know the awareness among the interns about the knowledge of drug package inserts and its importance among themselves and patients as well.

MATERIALS AND METHOD

This was a cross sectional, questionnaire based study. It was conducted among the interns of two colleges who has passed MBBS and are in phase of internship training in Maharashtra state in the year 2015. The questionnaire included questions regarding knowledge about the drug package inserts in general and also focusing important queries in concern with patient's point of view. The data filled by interns was entered into excel sheet and was analyzed for the results. Ethical committee approval was taken before starting the study.

Statistical analysis was done using Microsoft excel 2013. Unpaired t test was used for comparison between two colleges.

RESULTS

Out of 250 interns, 30% know the term drug package inserts i.e. 70% don't know the meaning of the word 'drug package inserts'. 42% always read it, 28% read sometimes and 30% never read. 66% opinioned it should be in mother tongue and 75% opined font size should be larger

so that it can be read easily. 62% read package inserts for adverse drug reactions and 37% reads for contraindications. (Figure 1) 90% agreed it should be according to patient's point of view but when asked nobody was able to explain. Package inserts in India needs improvement was the opinion of 70% interns but they fail to explain how it can be improved. Lastly nobody was able to answer that in India, by which rule package inserts are governed.

When compared between the two colleges, 10.2% of college 1 and 42.76% of college 2 interns knows the meaning of the term drug package inserts. Significant difference between 2 colleges seen. ($p < 0.05$) (Figure 2).

35.71% of college 1 and 46.05% of college 2 interns always read the drug package inserts. Difference between 2 colleges is statistically significant. ($p < 0.05$) (Figure 3).

When compared between some important points like PI should be in mother tongue or not, how are languages of PI and regarding usefulness in patient's point of view, the results were not statistically significant (Figure 4).

But when asked about the headings for which PI are look for by interns, 13.27% of college 1 and 51.97% of college 2 said they used it for looking contraindications and 86.73% of college 1 and 48.03% of college 2 said they used it for adverse effects. Difference between 2 colleges for these comments was statistically significant. ($p < 0.05$) (Figure 5).

Fig 1. Comments of 250 inters in percentage

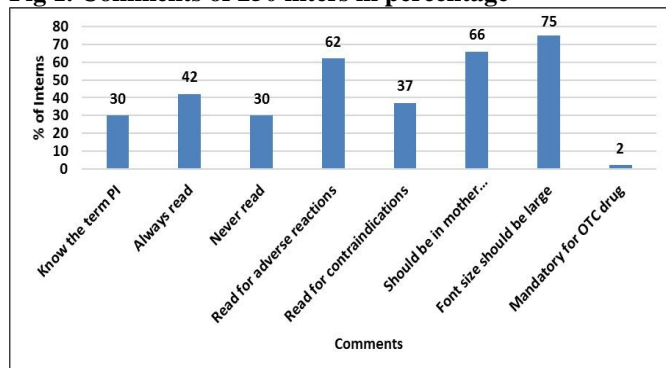


Fig 2. Comparison between 2 colleges for Knowledge of the term Drug Package Inserts

Do you know term Package inserts

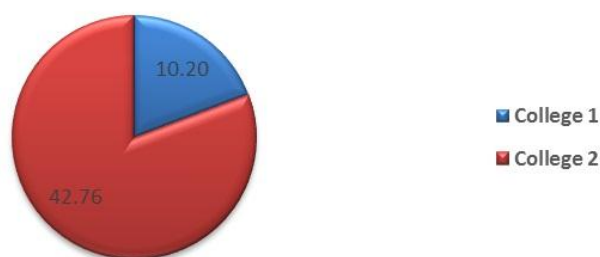


Fig 3. Comparison between 2 colleges for frequency of reading drug Package Inserts

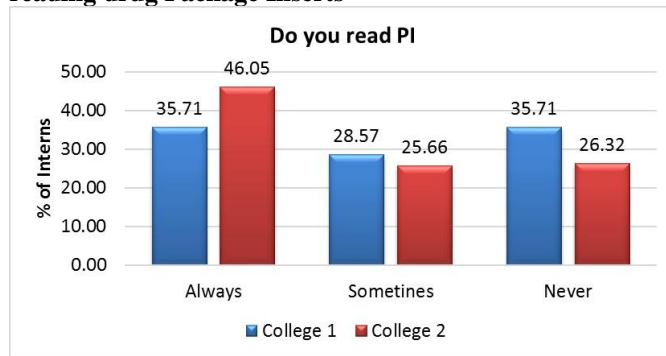


Fig 4. Comparison between 2 colleges for important comments in drug Package Inserts

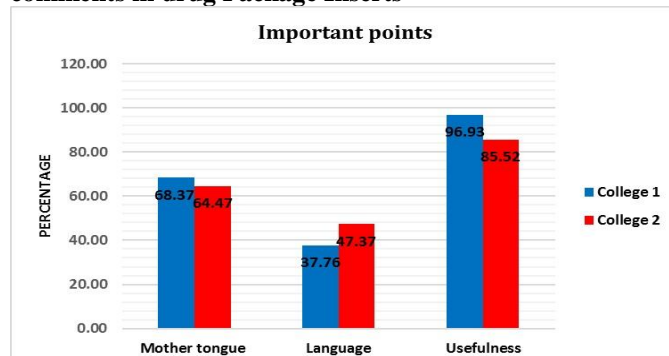
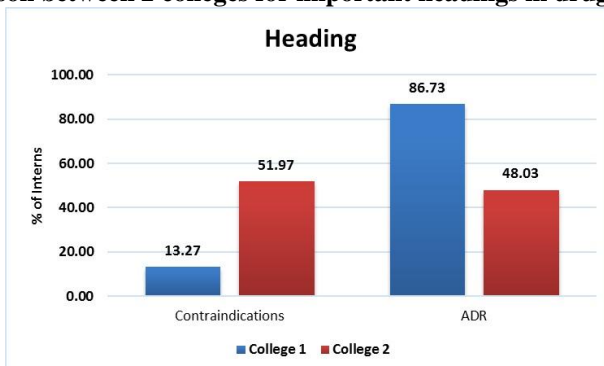


Fig 5. Comparison between 2 colleges for important headings in drug Package Inserts

DISCUSSION

The result of the study depicted many problems associated with package inserts as well suggested the limited knowledge among interns regarding drug package inserts due to lack of awareness about its importance. This study also concludes that most of the package inserts seen by the intern's were in English only, which was expected according to the rule [7].

Some researchers reported that the provision of oral and written medication information in the patient's own native language had been linked to improvement in the health outcomes [8]. Every intern has suggested increasing the font size of package inserts as 95.5% of them found small font size and difficult to read. Other studies done on package inserts font size also suggest that most of the package inserts are not according to recommended font size (11-12) [9]. The medication's PIs and the medical representatives were considered among the most frequently used sources of medication information by physician and pharmacists [10]. This might explain the importance of awareness of drug package inserts in interns. Most of the interns (67%) opined that package inserts are reliable, useful and accurate source of information because they lacked easy access to independent and up-to-date information about medications, which is scarce or even sometimes downright lacking, in developing countries [11].

According to 43% of intern's language, technical terminology and font size are the barriers for understanding

of package inserts which should be worked on. This results matches with the results of other researchers [1, 12-14].

CONCLUSION

The package inserts are the good and reliable source of information for doctors as well as patients. Doctors should go through drug package inserts before prescribing any new drug to avoid any medical errors.

As package inserts are one of the most frequently used sources of written drug information, approaches to optimize them should be explored as soon as possible. This especially refers to difficulties in understanding the extensive information provided, and suggests a more suitable structure of package inserts. Hence there is need to present the package inserts in accurate information with headings for well understanding of the user. Lastly it should be easy to read and should also be present in regional language. This study also suggest there is a need to increase awareness about the importance of drug package inserts among the upcoming doctors.

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Nil

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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