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ASSESSMENT OF IMPACT OF TEACHING ON KNOWLEDGE AND AWARENESS AMONG MBBS STUDENTS ABOUT THE DRUG PACKAGE INSERTS

Smita Y. Wankhede[1]*, Milind L. Pardeshi[2], Vishal V. Ghorpade[3] and Balasaheb B. Ghongane[4]

[1]Junior Resident 3, Department of Pharmacology, B.J. Medical College, Pune, Maharashtra, India.

[2]Associate Professor, Department of Pharmacology, B.J. Medical College, Pune, Maharashtra, India.

[3]Assistant Professor, Department of Pharmacology, B.J. Medical College, Pune, Maharashtra, India.

[4]Professor & Head Department of Pharmacology, B.J. Medical College, Pune, Maharashtra, India.

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***Corresponding Author**
Dr. Smita Y. Wankhede
Junior Resident 3,
Department of Pharmacology, B.J. Medical College, Pune, Maharashtra, India.

ABSTRACT

Background: Patients Package Inserts (PPI's) are the printed leaflet that contains information based on regulatory guidelines for the safe and effective use of a drug. Patients who read the PPI's are more likely to follows the instructions, especially if the information in the PPI's agrees with instructions of the physician and or pharmacist. **Methods:** A questionnaire consisting of questions related to drug package inserts and its importance, were formulated in the form of pre-test. These questionnaire were distributed in the students and data was collected. After that a short lecture was delivered on DPI and same questionnaire were given again as a post test and the data collected was analysed. **Results:** Total 100 second year MBBS students answered the questionnaires. In the pre-test, 56% were aware of the term drug package inserts and 31% knew that it is in English language. Only 10% were aware that DPI is the authentic source of information for new drug. 75% opined, it is mandatory with new drug. Lastly nobody was knowing about the Rule & Act by which package inserts are governed. After delivering lecture, in post-test highly significant improvement was observed. All were knowing the term

DPI and answered correctly about the language used and DPI as an authentic source of information. **Conclusions:** Awareness regarding DPI can be improved by adding a short lecture to the curriculum of second MBBS.

KEYWORDS Teaching, Awareness, Drug package inserts, Medical students.

INTRODUCTION

The drug package inserts also known as patient package insert (PPI), an information leaflet included by law in the packaging of prescription drugs. It is approved by the administrative licensing authority. During the 1970s, the patient package insert (PPI) was widely promoted as a way to increase patient knowledge and to encourage proper use of medications.[1] The leaflet is meant to be clear and understandable.[2] A package insert primarily directed at the prescribers, is intended to provide information for the safe and effective use of the respective drug.[3] Doctors in developing countries lack easy access to independent medication information.[4] In India, prescribers are likely dependent on product information provided by pharmaceutical companies which has been determined to be far from adequate and not conforming to WHO recommendations.[5] Package inserts by virtue of being amenable to strict regulations and being readily available with the drug product can serve as reliable and accurate sources of drug information.[6]

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.[7] [8] Latest amendment of the act was enforced in 2013. The Drugs and Cosmetics Rules do not specify the user of package insert but it appears to be directed to the healthcare professionals. Also, the text in 'Schedule Y' of the rules does refer to package inserts as prescribing information.[9] Patients may independently consult the package leaflets to clarify their doubts, such as information on medicine administration.[10] The benefits of reading the leaflet include increased knowledge of the correct method of taking the drug and the possible side effects.[11]

Undergraduate 2nd year MBBS students who are already introduced to the subject of pharmacology, are well familiar about various drugs and its importance in various diseases. These students can very well understand the importance of contents of drug package inserts, provided they are supplied with the necessary information in their curriculum itself. They are the upcoming prescribers who need to be updated for their knowledge of drug while prescribing it to the patients. Hence this study was conducted to know the awareness among

2nd year MBBS students about the knowledge of drug package inserts and its importance and to assess the improvement if any, in their knowledge after a short introductory lecture on drug package inserts.

MATERIAL AND METHODS

This was a questionnaire based pre- and post-lecture comparative study. It was conducted among the 2nd year MBBS students of a teaching institute in Maharashtra state in the year 2016. A questionnaire consisting of 20 question with multiple choice options related to drug package inserts were framed for pre-test. The questionnaire was based on questions regarding knowledge about the drug package inserts in general and its importance. These questionnaire was distributed in the form of pre-test in the students and data was collected. After that a short lecture of about 30 minutes was delivered on the drug package inserts and same questionnaire was given again as a post test.

The data filled by the students was entered into excel sheet 2013 and was analysed and compare for the result before and after the test by using paired t test to determine the significance of training. A p value was calculated and $p < 0.05$ was considered statistically significant. Ethical committee approval was taken before starting the study. Informed written consent was taken before starting the pre-test and Ethical approval was taken from the institutional ethical committee before starting the study.

RESULTS

Total 100 students participated in this study. Results of pre-test and post-test were analysed separately and were compared during analysis. In pre-test, 56% of students were knowing the term drug package inserts and only 45% were knowing the importance of reading the drug package inserts before taking any new medication. Package inserts are written only in English language according to drug and cosmetic act and rule was known to 28% of students where as 10 % of them were knowing that it is the authentic source of information for a new drug **(Figure1).**

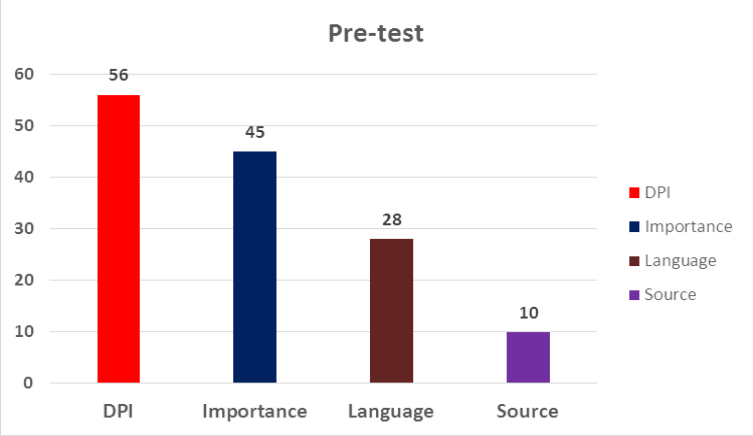

Figure 1: Pre-Test results of Term DPI, language used, Importance and source of DPI

Whereas results of post- test showed that all of them answered the questions regarding Drug package inserts, importance of using them, language in which they are written and authenticity of DPI. This result of post- test was statistically significant when compared with pre-test.

In pre- test, when asked about alternative name for drug package inserts, only 4% were knowing that it is also called as Patient's Package Inserts. Only 9% were knowing the aim behind providing drug package inserts with the medication. When asked regarding regulatory body for the DPI in India, 10% of them answered correctly whereas 3% students were knowing that CDSCO approves DPI in India. **(Figure2).**

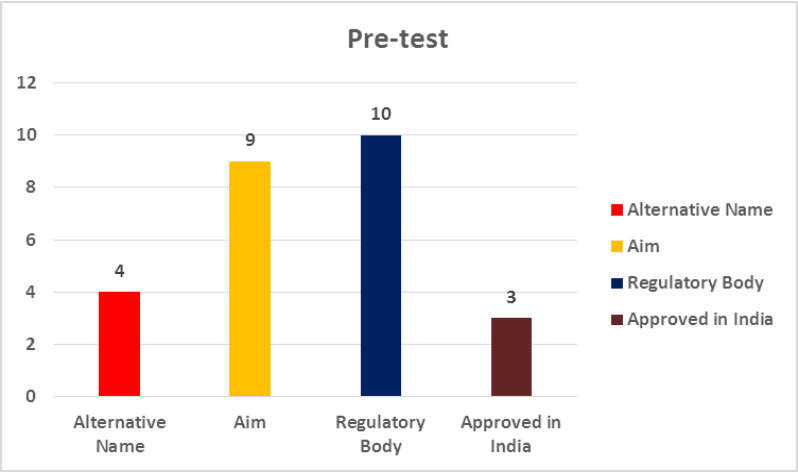

Figure 2: Pre-test results of alternative name, aim and regulatory body and DPI approval in India

Post –test results were quite satisfactory and statistically significant when compared to pre-test. All were knowing the alternative name of Drug package inserts and 76% of them

answered correctly regarding aim of DPI, 89% were knowing the regulatory body governing DPI whereas 91% were able to answer correctly that CDSCO approves the DPI in India **(Figure3).**

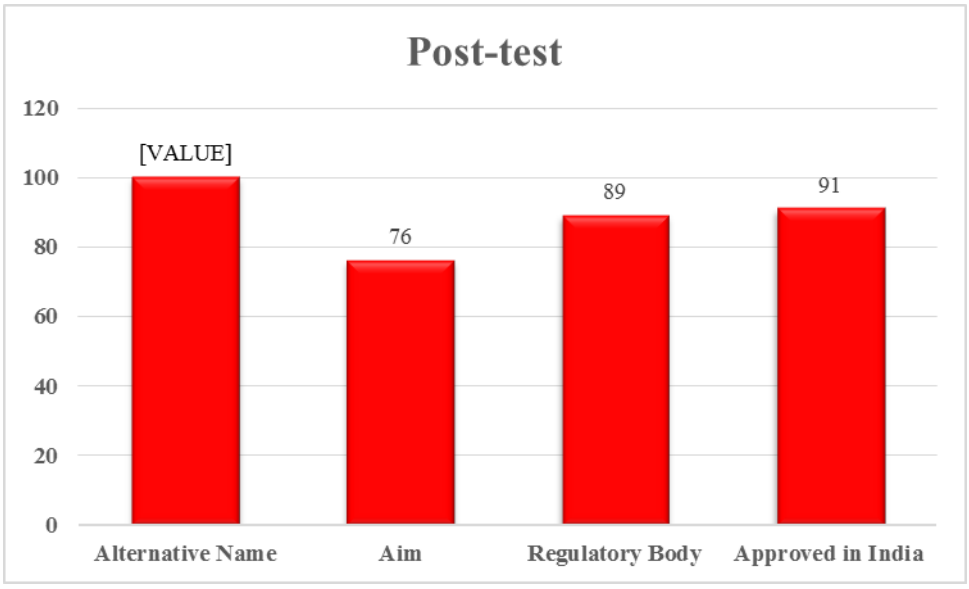

Figure 3: Post-test results of alternative name, aim, regulatory body and DPI approval in India

When asked regarding normal font size of drug package inserts, only 6% were knowing the correct font size of 11-12 recommended by Drugs and Cosmetic Act 1940 and Rule 1945. While only 2% answered correctly the user of DPI according to Drugs and Cosmetic Rule. 28% of students were of the opinion that package inserts in India needs improvement but when asked how nobody was able to answer it **(Figure 4).**

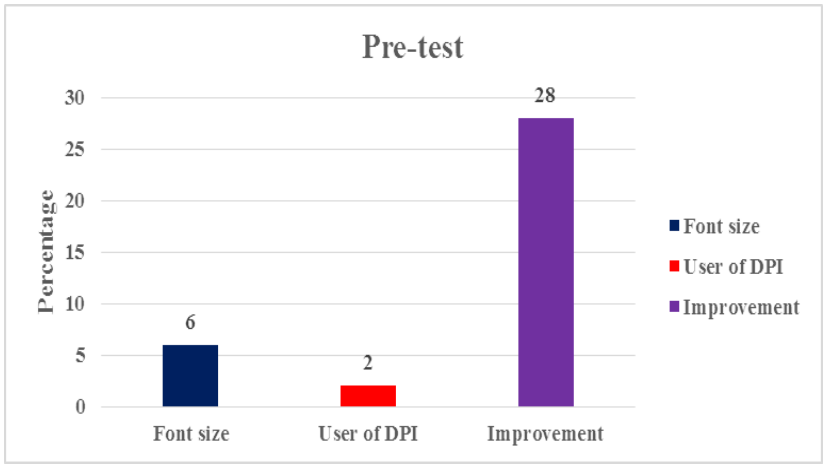

Figure 4: Pre- test result of questions asked on font size, user and improvement

When answers given in post-test were compared with pre-test, 87% were knowing that font size of DPI. 76% answered correctly user of DPI according to Drugs and Cosmetic Rule and

90% of students were in the opinion that package inserts in India needs improvement which was statistically significant when compared with pre-test.54% of them answered to the question that DPI needs improvement in terms of font size, simple and regional language **(Figure5).**

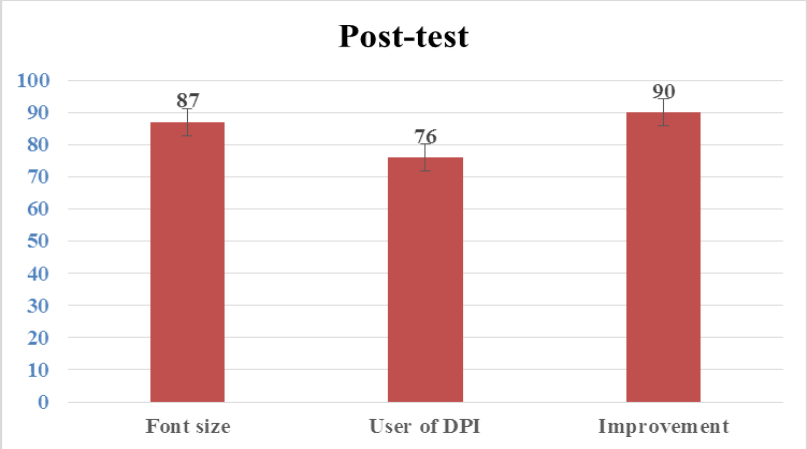

Figure 5: Post- test result of questions asked on font size, user and improvement

In the pre-test, when asked which information should be present in every package inserts,31% students answered Adverse drug reactions (ADR),32% answered ADR and contraindications,14% answered Indications and precautions while 23% answered contraindication and storage conditions **(Figure 6).**

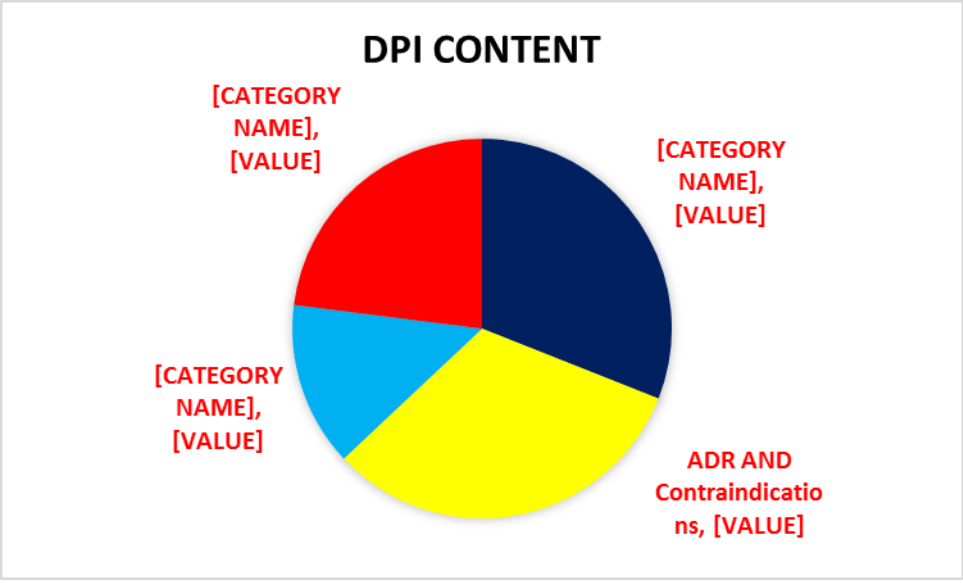

Figure 6: Pre- test result of students read DPI for which Headings

When results of post- test were compared with pre-test statistically significant result was obtained. 80% answered that Indications, precautions, special warnings, contraindication,

adverse drug reactions and storage conditions are equally important and should be present in every package inserts.

Lastly, in the pre-test results, nobody was knowing about the Rule & Act and its latest amendment by which package inserts are governed and also about the contents of section 6.2 and section 6.3 in the Drug and cosmetic act 1940 and rule 1945. While in the post-test, all were knowing the details of drug and cosmetic Act and Rule which was statistically significant result.

DISCUSSION

No study was found on comparison of pre and post lecture study among medical students. However, few KAP studies were found. Many studies suggest that patients may retain only 20% of the information given by their doctors. However it has been observed that when verbal counselling is complemented with visual or written material, patients may remember up to 50% of the information.[12] Hence package inserts are very important source of document for increasing knowledge regarding new medications.

The results of the study suggested the limited knowledge among students regarding DPI due to lack of awareness about its importance. Analysis of KAP pre and post education suggests that a significant improvement in post KAP scores occurred in the students. In this study, 56% students were aware of the term drug package inserts. In a previous study done in 250 interns, only 30 % were knowing the term drug package inserts.[13] It was observed in a study done by Gupta V.K. that significantly large number of students (42%) among 100 students do not even read DPI.[14] Another study suggested that students mostly read DPI for ADR and contraindications.[15][16] This results matches with the result of our study that maximum students look for ADR and Contraindications in DPI. Medical Jargon and technical terms used in classical Package Inserts texts, could also stand as barriers to PIs' texts understanding, so they should be written in easy and understandable language which was suggested by students in post-test.[17] In pre-test only 6% were knowing the normal font size of package inserts while 87% were able to answer correctly in post-test about font size and problems in readability due to small font size. 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][18] The DPIs and the medical representatives were considered among the most frequently used sources of medication information by physician and pharmacists.[19] This might explain the importance of awareness of drug package inserts in medical students.

CONCLUSION

The package inserts are the good and authentic 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 i.e., MBBS students. Regular training sessions must be carried out for all medical professionals including medical students, doctors and pharmacists.

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DECLARATIONS

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