

**ASSESSMENT OF AWARENESS REGARDING PACKAGE INSERTS AMONG MEDICAL STUDENTS OF A MEDICAL COLLEGE AT CHENNAI****Dr. SHIVALI RAI*¹ , MRS SHEELA D² AND Dr. C B THARANI³**¹*Assistant professor, Department of Pharmacology, Saveetha Medical College Chennai.*²*Tutor, Department of Pharmacology, Saveetha Medical College Chennai*³*HOD, Department of Pharmacology, Saveetha Medical College Chennai***ABSTRACT**

A package insert is an officially approved document provided in drug package to provide additional information about the drug. This study was conducted to assess the awareness regarding package inserts among medical students . The aim was to assess the awareness regarding package inserts among Medical students and too create awareness and to enlighten the importance of package inserts to medical students. MBBS students of Saveetha Medical College after obtaining informed consent were included in the study. Each batch was addressed about the study with prior permission of the Dean and respective HOD . This is a planed observational study using a standard questionnaire which consists of 9 questions with Yes/No format. 384 medical students took part in the study. Results expressed as percentage of total responses to that question. It was noticed that the awareness of package inserts was better among the interns. Most of them used package inserts to know the adverse effects and contraindication . From our study we conclude that a lot has to put in to make the package insert user friendly and enhance its use. Stringent rules need to be enforced to improve the quality

KEYWORDS: Awareness, Package inserts, medical students , Information, adverse effects.**Dr. SHIVALI RAI**

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INTRODUCTION

Package insert is an officially approved document that accompanies a drug and is intended to provide information for its safe and effective use. The primary source of drug information is a Package Insert (PI). It is a printed leaflet that contains information based on regulatory guidelines. It is also known as prescription drug label or prescribing information. A good Package insert contains the essential, and accurate information about a drug. It is updated time to time based on the pre-clinical and clinical data.¹ regulatory requirements for drug package insert vary across nations. United States Food and Drug Administration (US-FDA) and European Medicines Agency (EMA) amend their regulations governing the content and format of labeling for drug products from time to time. In India, the concept of package insert is governed by the 'Drugs and Cosmetics Act (1940) and Rules (1945).² 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 indications, posology, method of administration, contraindications, special warnings and precautions, drug interactions, contraindications, pregnancy and lactation, use of machinery, undesirable effects, and antidote for overdosing. The 'Section 6.3' mandates pharmaceutical information on list of excipients, incompatibilities, shelf life, special precaution for storage, nature and specification of container and instruction for use and handling³. But it's not mentioned clearly if the package

inserts are directed only at the physicians or the patients⁴ Similar study by V K Gupta showed significantly large number of medical students (42%) do not even read package inserts. The present study was undertaken to assess the awareness of package inserts among medical students⁵

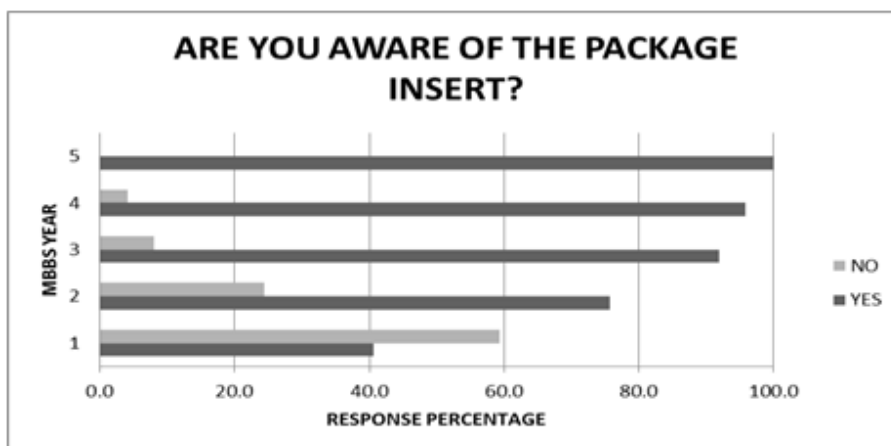
MATERIALS AND METHODS

MBBS students of Saveetha Medical College after obtaining informed consent were included in the study. MBBS students from first year to interns were included in the study. Each batch was addressed about the study with prior permission of the Dean and respective HOD. Students not willing to participate in the study were excluded. It was a planned observational study using a standard questionnaire. Sample size was estimated to be above 384 assuming the proportion of people with the knowledge on package insert is 50% for 20% relative precision at 5% significance. 384 medical students took part in the study. Random sampling technique was used. Results expressed as percentage of total response to that question. Descriptive statistics was done. It consisted of 9 questions with Yes/No format.

RESULTS

In the first year of MBBS 40.6% of students were aware that package insert existed whereas in internship 100% were aware of package inserts (table 1).

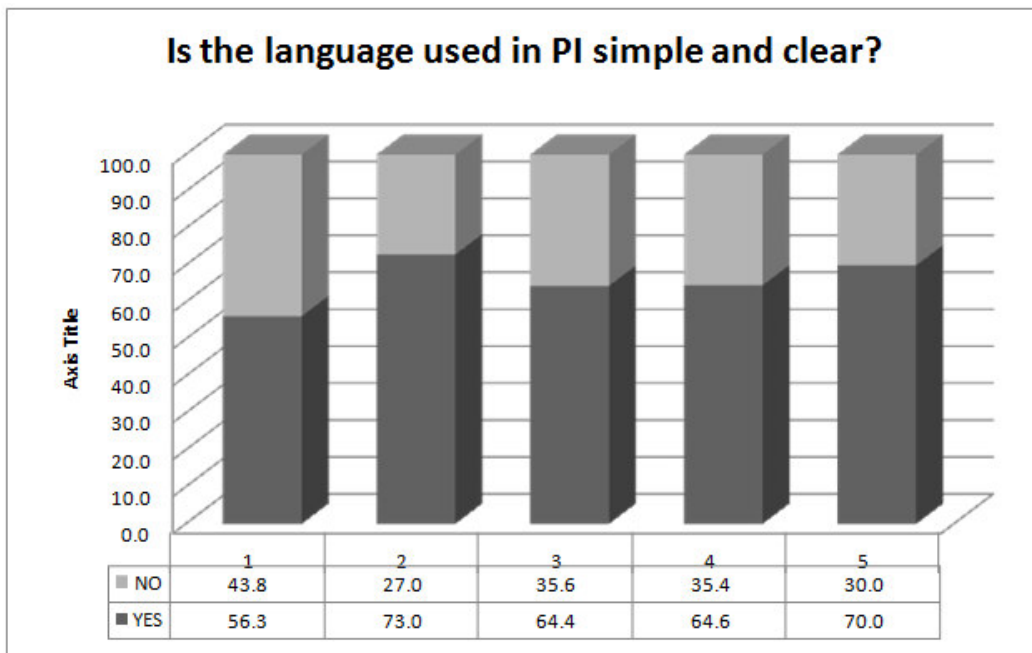
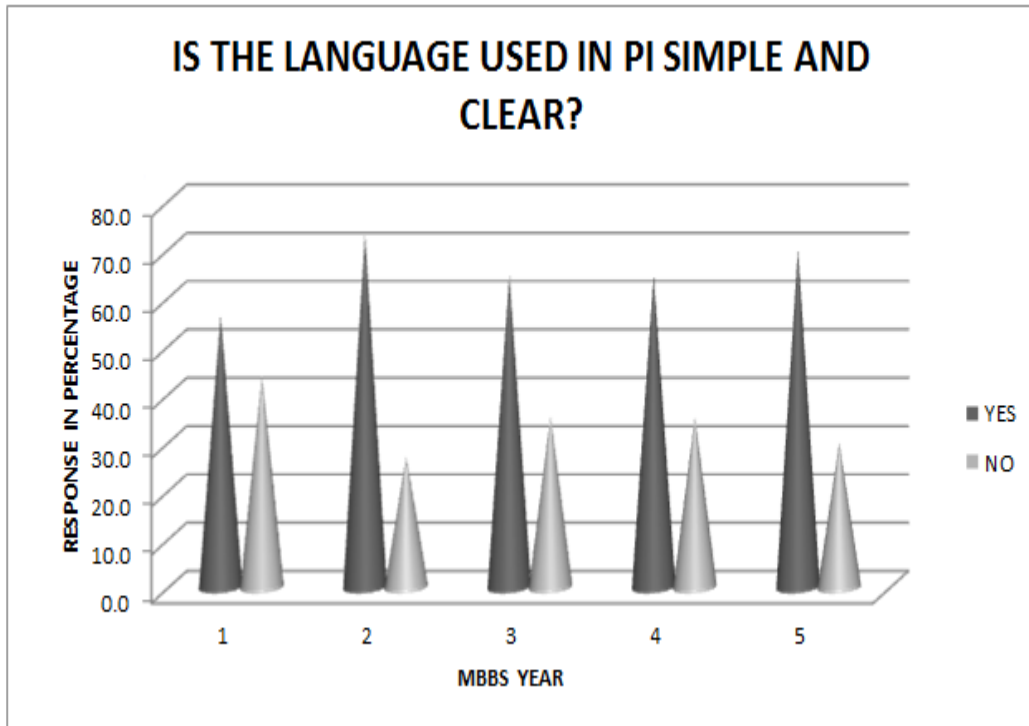
Table 1
Awareness of package inserts among MBBS students



Frequency in reading package inserts was seen to be 18.8% as always and interns read 83.3%. only 37.5% of first year students 43.2% second year student, 40% third year, 58.3% of final year students and 60% interns knew package insert are regularly updated. 62.5% of first year student felt there was no standard guideline 78.4% of second years medical students knew a

standard guideline existed where as in interns only 53.3% knew standard guideline existed. On asking if the language used in PI is simple and clear 56.3% first year medical students felt it was clear and simple 73.0% of second year, 64.4% of third year 64.6% of final year and 70% of interns felt it was simple and clear (table 2)

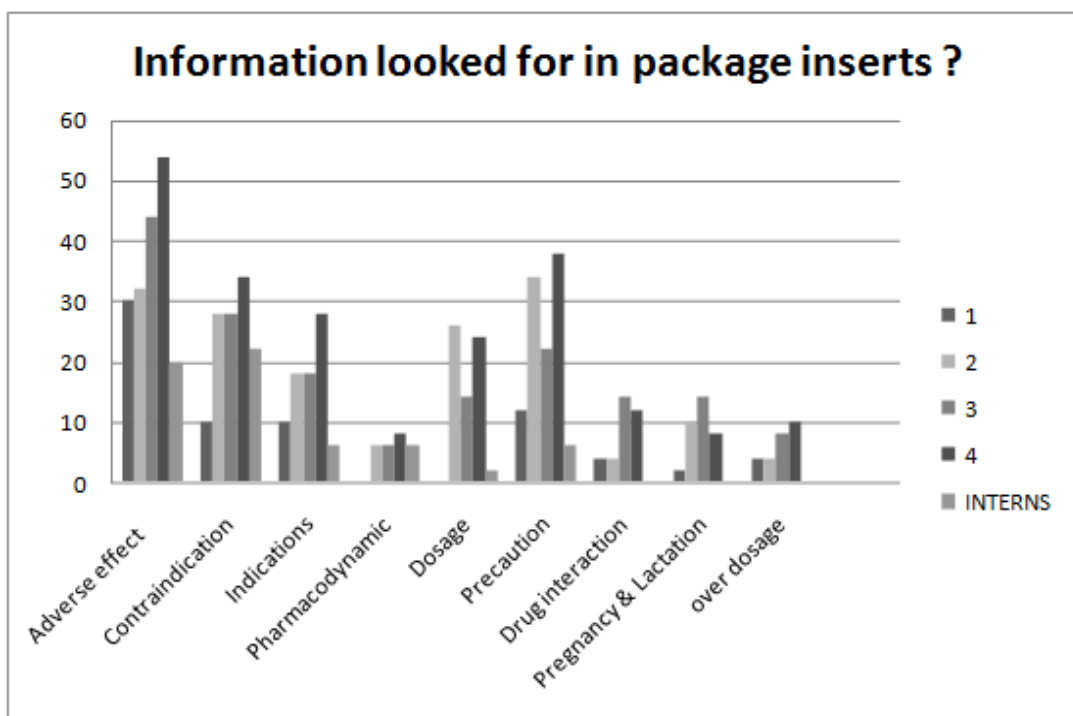
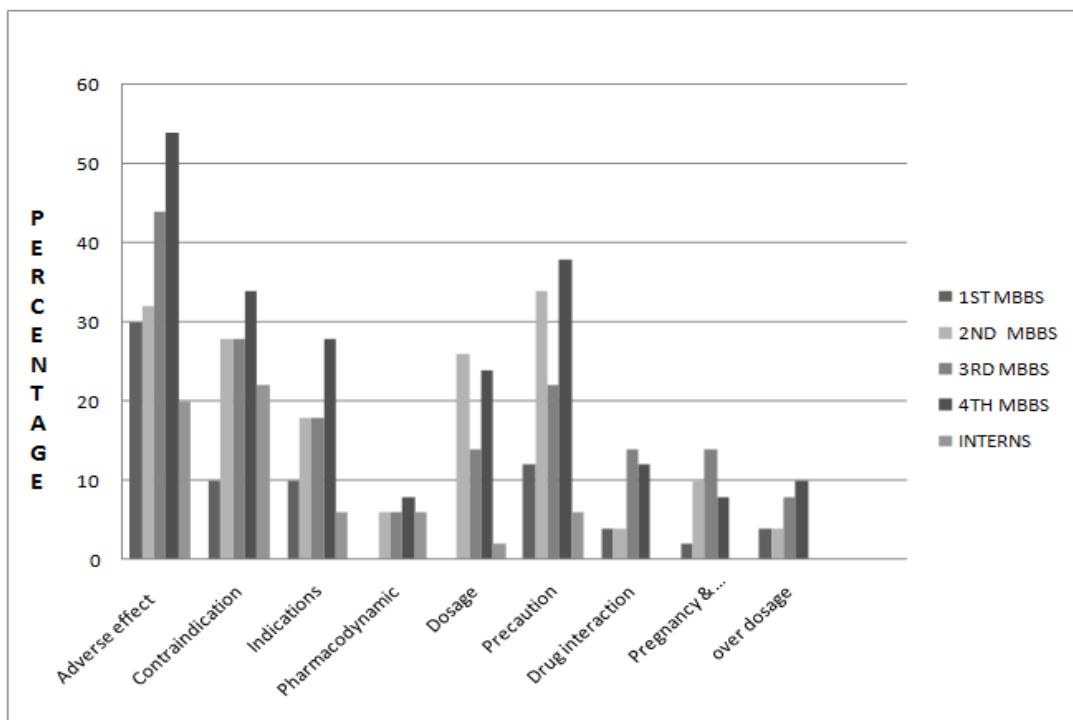
Table 2
About the language used in package insert



71.1% of third year medical students felt pharmaceutical company considered it as one way of promoting their products, likewise 34.3% of first year 51.4% of second year, 52.1% of final year and 43.3% of interns felt the

same. On asking what information they looked out in the package insert most of them felt adverse effect and contraindication (Table 3).

Table 3
Information looked for in package inserts



DISCUSSION

Very few studies have been undertaken on awareness of package inserts in one study by Gupta VK et al showed 42% of students do not read package ⁷ insert hence we took up this study .The result of this study showed various areas which medical students weren't aware of in package inserts.Students weren't sure if package insert served as a document which ensures the safe and effective use of the medicine. Need to advocate reading Package insert and promote it as a useful resource of drug information. Students weren't

aware of standard guidelines were used in package inserts. In a study by SandipNatwarlalSolanki et al⁸ on package review the reviewed package inserts contained all the sections as required by the Drugs and Cosmetics Act. Total 15 headings were evaluated under both Section 6.2 and 6.3, highest value for the presence of heading were 12 out of 15 heading evaluated. That shows the best value of compliance was 80%. Package inserts should be detailed and dosage should be added.study done by Sharma Sanat et al⁹ noticed that most of them looked at package inserts for adverse effects contraindications and indications which matched

our study but an additional information was that they felt it should be in respective mother tongue. As package inserts are seen and used by non practioners it is a good idea to add the local language script. From our study we feel should add description and usage of package insert as one of the topic in medical school.

CONCLUSION

Package insert is a tool mainly intended to guide the prescribers, but now it has become more of a legal formality. The traditional concept of package insert, followed in India needs a revision for its more effective use such that imparting information is better. It can be modified for better use among patients as well as prescribers .

CONFLICT OF INTEREST

None.

Abbreviations

Package insert – PI

QUESTIONNAIRE

1. Are you aware of the package inserts?
a. YES b. NO
2. Frequency in reading the package inserts

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- a. Always b. Sometimes
3. Preference given to the package inserts depends upon
a. Disease b. Drug
4. Does the package inserts serve as a document which ensures the safe and effective use of the medicine
a. Yes b. No
5. Are the package inserts regularly updated with the newer information?
a. Yes b. No
6. Any standard guidelines are followed for package inserts
a. Yes b. No
7. Does the language used in package inserts are simple and clear?
a. Yes b. No
8. Do you think the pharmaceutical company considered it as one way of promoting their products?
a. Yes b. No
9. Is there any chance of occurrence of bias in favour of the product?
a. Yes b. No
10. The information often looked for in package inserts (multiple answer)
a) Adverse effect b) Contraindication c) Indications d) Pharmacodynamic properties e) Dosage f) Precaution g) Drug interaction h) Pregnancy & Lactation i) over dosage.

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