



Research Journal of Pharmaceutical, Biological and Chemical Sciences

Assessment of Awareness and Attitude Towards Package Inserts Amongst Rural Population

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ABSTRACT

A package insert is a document provided along with a prescribed medication to provide additional information about that formulation. It is regarded as the document which ensures the safe and effective use of the medicine under different circumstances. It is usually long and may seem difficult to understand. This study was undertaken to assess the knowledge about package inserts amongst rural population. A prevalidated questionnaire based study was conducted amongst 100 subjects. It was observed that significantly large number of people (40%) do not even read package inserts. 20% looked for indications and contraindications and 25% opined that it should be in mother tongue. The package insert is a good source of information in addition to instructions given by the health care provider. It is a good idea to review the package insert for any new medicine you take and to look at it again if anything about your health changes but there is a need of more awareness amongst the population and certain changes in the package insert.

Key words: Package inserts, Awareness, Questionnaire Based Study.

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INTRODUCTION

The package insert has significant role in providing essential drug information for patients taking over-the-counter as well as prescription-only medications. In developing countries, it is considered an important source of drug information for health-care providers as well, due to the limited ability to access upto- date information about drugs. Studies have shown that the package inserts help bridge the information gap between health care providers and patients and enhance patients' knowledge about medications [1, 2].

The quality and quantity of information available in the package inserts has been shown to influence patient compliance and satisfaction [3, 4].

There are also indications that patients who read the package inserts are more likely to follow the instructions, especially if the information in the package inserts agrees with the instructions of the health care provider [5].

A study carried out in Denmark concluded that patients may be confused by inconsistent information in package inserts, which leads to reduced compliance [6].

The design and the amount of information in the package inserts are usually regulated by the legislative health authorities.

In India, the concept of package insert is governed by the 'Drugs and Cosmetics Act (1940) and Rules (1945)' [3]. Section 6 of Schedule D (II) of the Rules lists the headings according to which information should be provided in the package inserts. '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; contra-indications 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.

It is not mentioned clearly, whether the package inserts are directed only at the physicians or at the patients as well. [7]

The present study was undertaken to assess the awareness and attitude towards package inserts amongst rural population.

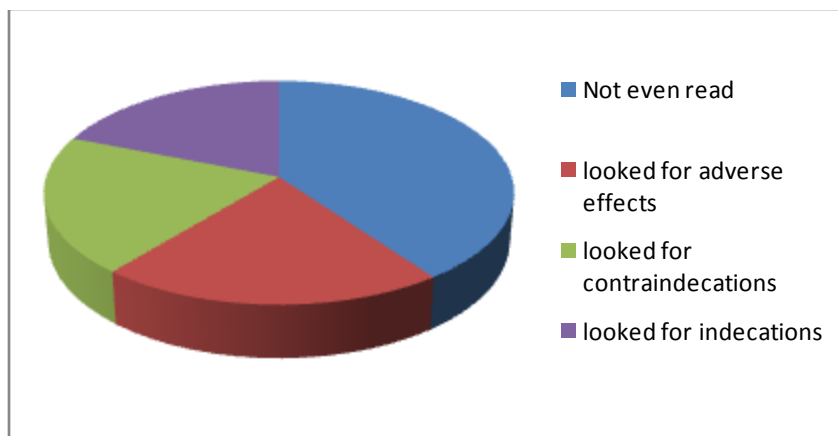
MATERIALS AND METHODS

Methodology

A questionnaire focusing on expectations and preferences of patients regarding package inserts was distributed to the 300 patients who are either prescribed medication or those coming to the pharmacy for self medication. The questionnaire consisted of specific questions regarding knowledge about package inserts and opinion about whether they are helpful or not.

RESULTS

The majority (40% of all volunteers) said that they “never” read the package inserts. Out of 60% who read the package inserts, 21% looked for adverse effects, 20% looked for contraindications and 19% looked for indications. 25% opined that it should be in mother tongue.



Selected comments about package inserts by 100 participants
(Multiple answers were possible)

DISCUSSIONS

The results of the survey depicted many problems associated with package inserts. As package inserts are one of the most frequently used sources of written drug information, approaches to optimise 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 for package inserts. Package inserts should contain only the information that is of paramount importance for the patient, although this is debatable from a legal point of view. The address of the manufacturer is currently mentioned on package inserts, which can take up to 25% of the space available, and this might have to be reconsidered.



CONCLUSION

The package insert is a good source of information in addition to instructions your doctor may give you. It's a good idea to review the package insert for any new medicine you take and to look at it again if anything about your health changes but there is a need of more awareness amongst the population and certain changes in the package insert.

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