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Analysis of the package inserts-A Prospective Observational Study

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ABSTRACT

Background: The package insert is an important source of information which needs to be assessible and can serve to curb the adverse drug reaction. To evaluate package inserts in terms of accessibility of information and adverse drug reaction reporting**. Methodology:** 100 package inserts were collected from June 2018-September 2018 from different pharmacies of the locality and drug store of tertiary care hospital and evaluated in terms of accessibility of information and Adverse drug reaction reporting. Out of 5 points considered in terms of accessibility like information in box, separate colour, special font or bigger font size, table of contents, information in first sheet a score of >4 is Good,2 -4 is Moderate, <2 poor. Results were analyzed in Microsoft excel 2010 and expressed in whole numbers and percentage. **Result:** Out of the 100 package inserts evaluated 19% used special font or colour,15% used box, 10% had bigger font size, information in first sheet and table of contents were present in 4% and 6% of the evaluated package inserts. Number of package inserts in each grades allotted after evaluation good, moderate, poor in terms of accessibility, 4, 55, 41.For adverse drug reaction reporting 4% had toll free number, 5% used online reporting, and 30% used postal address**. Conclusion:** The present study though showed improvement deficiencies should be corrected and properly scrutinized for effective drug use to step up the healthcare services.

Keywords: Accessibility of information, Adverse drug reaction reporting, Package inserts

INTRODUCTION

Package insert is a printed leaflet containing information based on regulatory guidelines for safe and effective use of drugs that is not promotional, false misleading, it is evidenced based and updated time to time as relevant preclinical and clinical data becomes available [1]

Regulatory guidelines vary across countries but in India section 6.2 and section 6.3 of Drugs and Cosmetics Act 1940 and rules 1945 are followed [2] .The final amendment of which was enforced in1986.

Though few studies evaluating adherence to the above said guidelines showed promising results however studies conducted by Mahatme et al [3] evaluating 270 package inserts showed that information provided cannot be easily assessed.[3]

For managing the risks of .medication use and to reduce medication error,these package inserts were made to provide upto date information in a easily readable format reducing significant adverse drug reactions[4]. Optimization of package insert is a due priority in developed countries however it lacks its due attention in India.[5,6].

Since India is a developing country cost of hospitalization due to adverse drug reaction and medication error is a major concern hence

optimization for informing adverse drug reaction is a dire necessity and should be made mandatory. [7,8].

Present study is undertaken to find out whether the packing inserts are complete in terms of accessibility of information, ADR reporting.

MATERIAL AND METHODS:

A prospective observational study was carried out from June 2018-September 2018 using 100 package inserts collected from different pharmacies of the locality and drug store of tertiary care hospital and evaluated in terms of accessibility of information and Adverse drug reaction reporting either by toll free number or internet or postal address of the manufacturer, quality, texture, length and breadth uniformity, date of updating information and date of approval for marketing. For evaluating accessibility following points are considered that is, information provided in box, in a separate colour or special font, a font bigger in size then the entire text, table of contents for easy reference, information in first sheet. Out of 5 points a score of >4 is Good,2 -4 is Moderate,<2 poor[4].Quality was assessed on the basis of the fact that good quality paper when placed on separate sheet with written text did not reveal the text while texture was assessed by noting whether the text written on reverse side is seen through while reading[9].Results were analyzed in Microsoft excel 2010 and expressed in whole numbers and percentage.

RESULTS:

The 100 evaluated package inserts quality and texture has improved however the length breadth dimensions were not uniform,date of approval of the drug in the market was not mentioned in any of the evaluated package inserts, date of updating the information was mentioned in 20%

Among 100 evaluated package inserts only 19% used special font or colour,15% made use of box, 10% used bigger font size,information in first sheet was present in 4%and table of content were present in 6%, rest of package inserts that is 46% had none of the above mentioned methods[Figure 1]

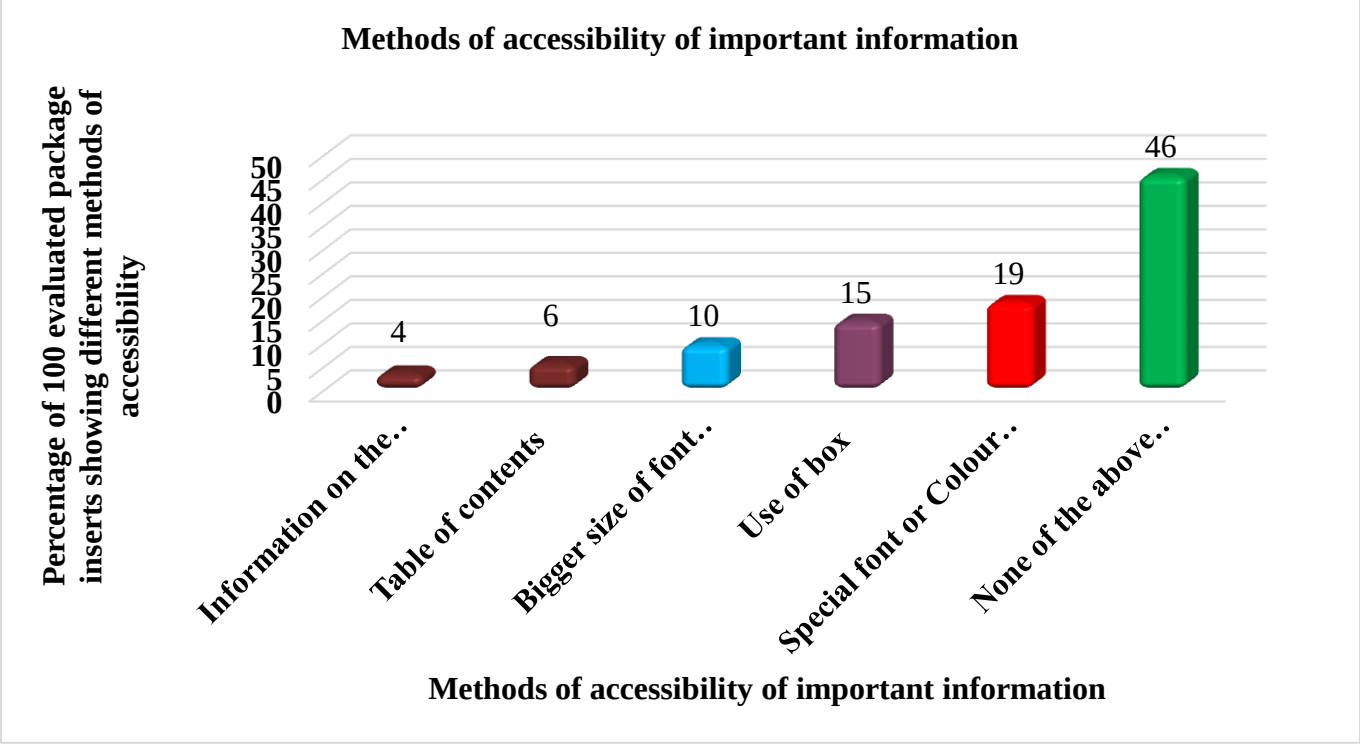

Figure 1: Percentage of 100 evaluated packages inserts showing different methods of accessibility

Most of the package inserts belonged to moderate grade in terms of accessibility of important information [Figure 2]

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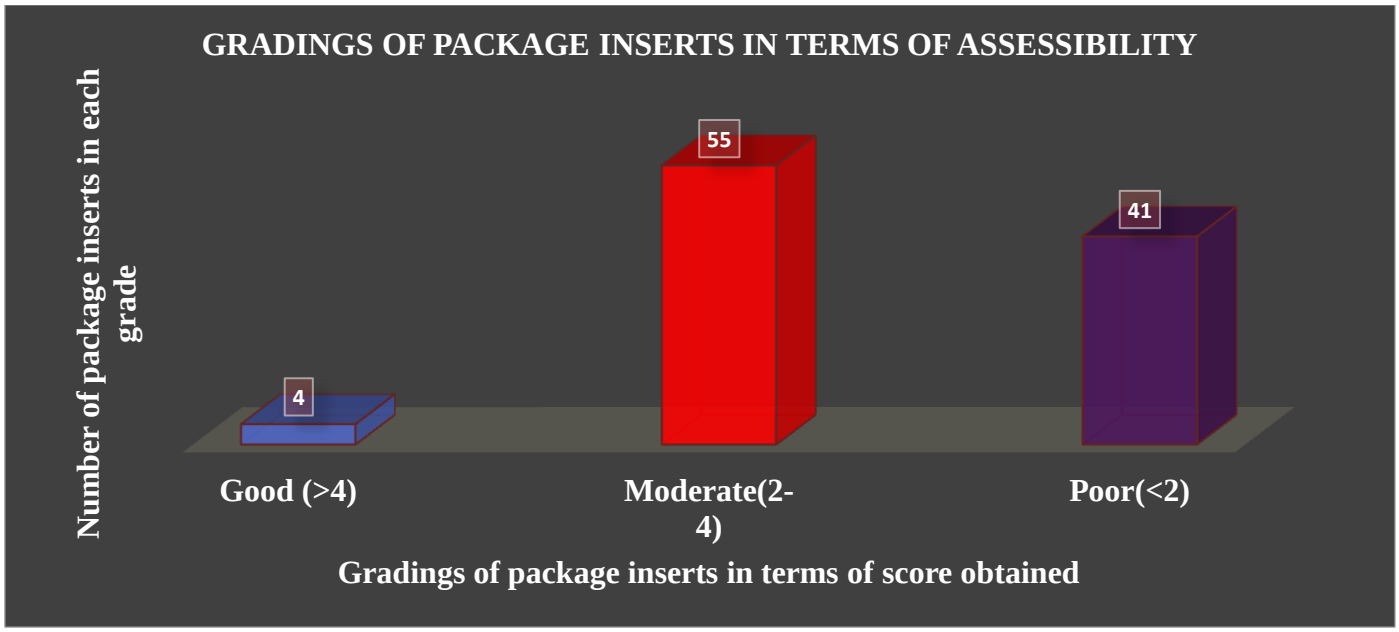

Figure 2: Number of package inserts in each grade amongst the 100 evaluated package inserts

In the 100 evaluated package inserts only 4% of the package inserts have toll free number for the communication of adverse drug reaction,5% had internet address for reporting of adverse drug reaction and postal address of the manufacturing company was present in 30% of the package inserts [Figure 3]

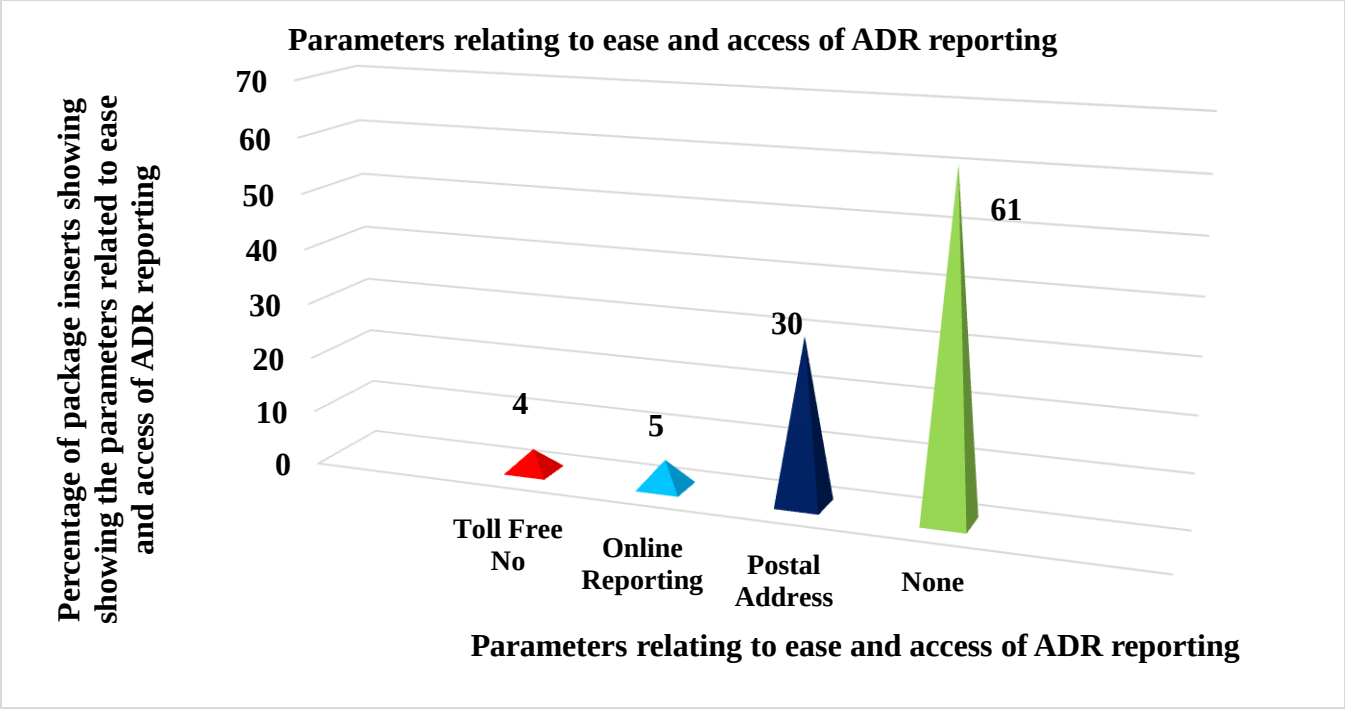

Figure 3: Percentage of package inserts showing the parameters related to ease and access of reporting

DISCUSSION:

Package inserts forms a reliable source of information which after approval from the respective administrative authority acts as an effective tool for the minimization of medication errors along with safe and efficient drug use[10].The date of updating of information and date of approval for marketing of the

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drug provides a better idea since when the drug is there in the market giving a better glimpse of its safety and efficacy[11]. In the present study the date of update of information is present in 20% which is more as compared to study conducted by Shruti et al[9] where it was present only in 18.7% of the evaluated package inserts.

In the present study as well study conducted by Shruti et al [9]and Kalma et al [12] there was no uniformity in the length and breadth of the paper size used .

As far as quality and texture of the paper was concerned it was found appropriate in all the evaluated package inserts which was better compared to only 80.2% of the evaluated package inserts in the study conducted by Shruti et al.[9]

In the present study as well as the study conducted by Sudha et al [4]date of approval for marketing the drug was not present.

In the present study of 100 evaluated package inserts use of special font or colour for accessibility of important information was present in 19% [Figure 1] which is more then that of a study conducted by Sudha et al [5]were it was present in only 6%.Information on the front sheet was present in 4% table of contents were present in 6% in present study while it was absent in the study conducted by Sudha et al[4]. Though in a study conducted by Shruti et al [9]font size problem was seen in the present study 10% of the evaluated package insert used bigger font size for better accessibility of important information. In the present study though improvement has occurred in terms of accessibility of important information still as compared to studies conducted by Sudha et al [4]and Shruti et al [9]further improvement is needed.

In terms of grades for accessibility though most of the package inserts fell under poor grades in a study conducted by Sudha et al [4], Kalma et al,[12] Sudhamadhuri et al [13]however in the present study among the 100 evaluated package inserts 55 of the package inserts were under moderate grade, 41 of the evaluated package inserts were under poor grade and 4 of the package inserts were under good grade[Figure 2]

Toll free numbers as well as internet web portals will help not only in solving doubts related to new medication but also help in Adverse drug reaction reporting and also keeping a watch on the frequency of adverse drug reactions as adverse drug reactions are costly. In the present study toll free no for communication was present in 4% among the 100 evaluated package inserts, internet address for reporting of Adverse drug reaction was present in 5% of the evaluated package inserts as compared to a study conducted by Sudha et al [4] where toll free number was present only in 2% of the evaluated package inserts,1% had the internet address for adverse drug reaction reporting. In a study conducted by Gupta et al [14] it was proposed that address of manufacturer should be present, in the present study 30% of the evaluated package inserts had the mention of postal address of the manufacturer [Figure 3]

Limitation of the present study was that it was conducted with the package inserts available local pharmacy and medical store of a tertiary care hospital hence more wide scale study covering different pharmacy as well as hospitals in a region should be done for more better evaluation.National and International as well as government and nongovernment company wise distribution was not done in the present study however it should be done to evaluate in terms of accessibility of information, adverse drug reaction reporting facilities, quality and texture of the paper used, uniformity of length and breadth and also whether it has whether information regarding last update of information as well as date of approval for different brand of same drug to enhance the safety efficacy as well as efficient use of drugs along with minimizing adverse drug reactions.

CONCLUSION:

Though present study showed improvement compared to previous studies like Lal sethi et al[15] , Shivkar et al [16]and Mahatma et al[3] still further improvement is required. Proper evaluation of package inserts by expert authorities before being released into the market and frequent and timely watch on the contents of package insert will increase its effectiveness to serve as a tool of enhancing safety and efficacy of drug use and guiding tool for patient as well as increase their compliance reducing the costly unwanted adverse drug reactions.

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