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Original Research Article

Comparison of drug information in package inserts with standard medical textbook of pharmacology

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ABSTRACT

Background: Accurate and reliable drug product information is important for the safe and effective use of medicines. But there are variations in the quantity and quality of information mentioned in different drug information sources and a single credible benchmark is lacking. This study was carried out to compare the presentation and completeness of clinical information in package inserts (PIs) marketed by pharmaceutical companies in India with standard medical textbook of pharmacology.
Methods: Out of eighty five PIs of different drugs, only 55 were found eligible to be included in this study after applying inclusion and exclusion criteria. These PIs and medical textbook were analysed for quantitative and qualitative drug information and were compared using Chi square test of two proportions. The p value of 0.05 was used as cut off to evaluate statistical significance.
Results: Quantitatively medical textbook was significantly better statistically in context of treatment of overdose and references. No statistically significant difference was observed in relation to information related to mechanism of action (MOA) and pharmacokinetics (Pk). After qualitative analysis, medical textbook was significantly better statistically in context of size and readability, references related to adverse drug reactions (ADRs) and indications and pictures. No statistically significant difference was observed in context of dosing interval, frequency of doses and pharmacokinetic parameters.
Conclusions: PIs can be used as a reliable source of drug information by health care professionals in addition to other sources like medical textbooks.

Keywords: Drug information sources, Package inserts, Standard medical textbook

INTRODUCTION

Accurate and reliable drug product information is important for the safe and effective use of medicines. It has been observed that there are variations in the quantity and quality of information mentioned in different drug information sources and a single credible benchmark is lacking. Such variation do not provide the medical fraternity reliable drug information and can also promote off label and irrational drug use leading to increased incidence of adverse reactions and possible treatment failure.[1-2] In India, healthcare professionals depend on a variety of sources, including textbooks for information on drugs.[3] Standard medical textbooks are convenient and accessible. Out of these Goodman and Gillman's pharmacological basis of therapeutics is considered to be a "gold standard" pharmacology textbook. Drug information contained in this is generally well accepted by one and all and also approved and accepted by Regulatory Agencies.

Package Insert is considered to be the another source of drug information. It is a printed leaflet provided by pharmaceutical companies that contains information based on regulatory guidelines for the safe and effective use of a drug. It is also known as prescription drug label. A good PI contains the approved, essential, and accurate information about a drug. It is written in a language that is

not promotional, false, or misleading. It is evidence-based and should be updated from time to time as per the relevant pre-clinical and clinical data availability.[4] Various studies have concluded that PIs because of their easy availability can produce an important impact on patients compliance and thus on the ultimate effectiveness of drug use.[5,6] However, product information provided by pharmaceutical companies in India has been determined to be far from adequate and not conforming with the WHO recommendations.[7,8] Physicians quite often prescribe off-labeled indications simply because the package inserts did not contain sufficient information about all the labeled indications. It has also been observed in another study that physician utilization of package inserts which contained incomplete or absent information, with regard to side effects, drug interactions, warnings and precautions, use in lactation and pregnancy, may contribute to an increase in emergency room visits.[9]

Various researchers have analysed drug information in PIs in comparison to 'Section 6.2' of Schedule D of Drugs and Cosmetics Rules, 1945.[10,11] After extensive literature search, there was no study found which compared this drug information with standard medical textbook. Hence, this study was carried out to compare the presentation and completeness of clinical information on package inserts of drug products marketed by pharmaceutical companies in India with standard medical textbook of pharmacology i.e. Goodman and Gillman's pharmacological basis of therapeutics (12th edition).

Aims and objectives

- To find out the quantitative difference of drug information between Package Inserts and standard medical textbook of pharmacology.
- To find out the qualitative difference of drug information between Package Inserts and standard medical textbook of pharmacology.

METHODS

Package inserts of different drugs were collected from pharmacies in and around tertiary care hospital in North India during a period of one year (January 2016 to January 2017). Only those package inserts were included in the study which fulfilled the following inclusion and exclusion criterias.

Inclusion criteria

- PIs with single active ingredient.
- PIs from drugs dispensed recently.
- PIs in English language only.

Exclusion criteria

- PIs with more than one active ingredient.
- PIs indicating only directions for use.
- PIs indicating information only about disease.
- Leaflets of drug information.
- Duplicates (same drug formulation and company)
- PIs in languages other than English.

These PIs were then analysed for quantitative and qualitative data of drug information.

The difference of proportions between the two groups (PIs and MT) was explored using chi square test of two proportions. The p value of 0.05 was used as cut off value to evaluate statistical significance.

No consent form was required because this study didn't include any patient or physician or any living being. The study was approved by Institutional Human Ethics Committee.

RESULTS

Total 85 package inserts were collected from pharmacies in and around tertiary care hospital in North India, out of which only 55 package inserts fulfilled the inclusion and exclusion criteria and were included in the study.

Rest of the package inserts were excluded from the study as 11 were drug duplicates, 14 were giving information about drug combinations and 5 package inserts were giving no information about drugs.

Quantitative analysis of drug information

MT was found significantly better statistically in context of treatment of overdose and references. No statistically significant difference was observed in relation to MOA and Pk. There was statistically significant difference in context of generic name, chemical composition, indications, contraindications, warnings and precautions, drug interactions, information for special population, adverse drug effects, overdose, dosage and administration in which PIs were found better (Table 1).

Qualitative analysis of drug information

MT was found significantly better statistically in context of size and readability, references related to ADRs and indications and pictures. No statistically significant difference was observed in context of dosing interval, frequency of doses and pharmacokinetic parameters.

There was statistically significant difference in context of uniformity of information and categorization of ADRs in which PIs were found better.

DISCUSSION

Author undertook this study to assess and compare the quantity and quality of drug information available in package inserts and Goodman and Gillman's textbook of pharmacology.

Table 1: Comparison of contents of quantitative data in the package inserts and medical textbook.

Quantitative criteria	Package inserts		Medical textbook		p value
	Number of drugs	Proportion of drugs	Number of drugs	Proportion of drugs	
Generic name	55	1.0	49	0.89	0.027 (FET)
Chemical composition	53	0.96	31	0.56	0.000 (PCS)
Mechanism of action	50	0.90	44	0.80	0.105 (PCS)
Pharmacokinetics	48	0.87	41	0.74	0.089 (PCS)
Indications	55	1.0	49	0.89	0.027 (FET)
Contraindications	51	0.92	4	0.07	0.000 (PCS)
Warnings	49	0.89	1	0.02	0.000 (PCS)
Precautions	52	0.94	3	0.05	0.000 (PCS)
Drug interactions	48	0.87	12	0.22	0.000 (PCS)
Information for special population	47	0.85	5	0.09	0.000 (PCS)
Adverse effects	54	0.98	30	0.54	0.000 (PCS)
Dosage and administration	55	1.0	39	0.71	0.000 (PCS)
Overdose	46	0.83	33	0.6	0.006 (PCS)
Treatment of overdose	7	0.12	27	0.49	0.000 (PCS)
References	6	0.1	28	0.51	0.000 (PCS)

FET: Fischer's exact test
PCS: Pearson chi square test

In medical textbook, although all of the drugs were written in generic names and their indications were mentioned but some of the drugs were absent in the textbook as these drugs came after the publication of the textbook. So, while doing analysis of the study, proportion of drugs for generic name and drug indications were not considered in case of medical textbook. Although all the PIs had mentioned drug indications but average number of indications per drug were written more in medical textbook as compared to PIs.

In package inserts, references related to drug information were most frequently missing as compared to medical textbook. So, information in MT is more authentic and reliable as one can validate the drug information from the given references. One more point that go in favour of MT is that the textbook represented majority of drug information with pictorial diagrams, tables and graphs. So, details of any drug are easy to understand from textbook than PIs. Although caution of overdose was given in package inserts, but their treatment was not mentioned in majority of the PIs, so providing incomplete information regarding overdose in comparison to MT. Some PIs were not readable at all. Small font size was a common problem.

In medical textbook, drug information was not given uniformly. It was scattered in different chapters. It was difficult to locate and find the necessary information easily due to variable layout and heading, making it inconvenient for the users to use it as quick reference. Moreover, Categorization of ADRs was missing in MT whereas it was written for most of the times in PIs .Providing such information could be useful, as a study from southern India revealed that of a total of 2340 hospital admissions, 6.4% were drug related of which 50% were due to ADRs, with a majority being reported as preventable.[12] In MTs contraindications, warnings and precautions were not given for majority of drugs. In the special warnings and precautions section, many a time, information on pediatric and geriatric use was missing. This could be of concern as a study from northern India has shown that more than 56% of hospital admissions, due to adverse drug events, occurred in people aged over sixty years.[13]

ADRs were written in majority of the package inserts but their references were missing. Although ADRs were not mentioned for all of the drugs in MT but references were given for majority. This proves the validity of medical textbook.

There is a need to further refine the quality of package inserts to make them more reliable. PIs must be optimized and tested by selected groups of experts prior to the approval of the drug. This will ensure the avoidance of the lack of information and will guide towards informed and better treatment outcomes. The supply of the PIs should be made mandatory in the package along with the drugs. The government should make strict rules to ensure that the pharmaceutical companies comply with the regulatory guidelines.

A limitation of this study could be that only 55 package inserts were analyzed. Another limitation was the difficulty in finding a gold standard to compare the accuracy of the information present in the package inserts with medical textbook. As the drug information given in Goodman and Gillman is basically medical student oriented and it is given in respective topics where the drug is used. So while doing analysis, some information might

be missed, as it was very difficult to gather such kind of drug information.

Various authors had conducted studies on completeness of package inserts, but none had compared this data with standard medical textbook. So, while doing this study, we could only compare the data of package inserts with other studies. As the new edition of Goodman and Gillman has not come yet, so we compared the PIs with its 12th edition, which came in 2011 in which the latest drug information was missing.

CONCLUSION

Package Inserts can be used as a source of drug information by health care professionals in addition to other sources like medical textbooks.

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