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REVIEW PAPER

Scope of research in Pharmacovigilance

C. Ramachandra Bhat * , K.M.Sudha , S. Devipriya , K. Kaviya, K. Vijayalakshmi, R. Kiranya
Institute of Pharmacology Madras Medical College, Chennai, Tamil Nadu 600003 India

*Corresponding Author: **Dr C Ramachandra Bhat**

ABSTRACT

Staff, postgraduates, and faculty of adverse drug reactions (ADR) monitoring centers collect data and publish research papers. If they are familiarized about the scope of all research studies possible in pharmacovigilance, their research work would increase. This article is planned to decipher and outline the scope of research in pharmacovigilance. Literature survey was done using online and offline resources on published studies in the pharmacovigilance field to understand and identify the types of research studies conducted in the field of pharmacovigilance. All the different types of research articles in pharmacovigilance were analyzed and categorized into three levels based on the difficulty level. Role of research in pharmacovigilance was found to include pharmacogenetics, personalized medicine, pharmacovigilance in clinical trials, pharmacovigilance work during COVID pandemic, research on safety signals, ADR monitoring in telemedicine, pharmacovigilance in medical education and pharmacovigilance program evaluation. Vaccine vigilance, ecopharmacovigilance and pharmacovigilance of biosimilars were identified as potential areas for future studies.

Keywords: - Medical education, clinical trials, biosimilars, vaccine surveillance, pharmacovigilance

INTRODUCTION

The Pharmacovigilance activities are being done by staff working in Adverse Effects Monitoring Centers across India, with an aim to inculcate “Adverse Drug Reactions reporting” as a regular process by the health care personnel . They strive for collection of ADR reports for further processing before sending them to National Coordinating Centre. Vast number of ADR reports that the staff encounter results in creating a large database of clinical information, which further enables them to conduct research and publish papers. Their research output can be increased if they know the full scope of research activities possible in pharmacovigilance [1-4]. To highlight the latter, this review is planned and designed. Besides the staff involved in ADR monitoring centers, this article will be of immense benefit to all other postgraduates and faculty in many departments. Pharmacovigilance, a critical component of healthcare systems worldwide, plays a pivotal role in monitoring and evaluating the safety of

***CORRESPONDING AUTHOR**
Dr C Ramachandra Bhat
Institute of Pharmacology Madras Medical College, Chennai, Tamil Nadu 600003 India
E.Mail: bhatcr@gmail.com
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pharmaceutical products post-marketing. [5-7] In India, the significance of pharmacovigilance has grown exponentially in recent years, given the burgeoning pharmaceutical industry and the need to safeguard public health [8-11]. This paper explores the landscape of pharmacovigilance in India, highlighting its evolution, current practices, challenges, and future prospects.

Published articles on pharmacovigilance were reviewed to know the type of research activities done in pharmacovigilance area. Based on the observations, broad areas were identified and compiled.

Many research activities were studied and classified into three common categories based on the level of research activity and depth of research work. Apart from original research works, other types of articles published were also included in the compilation enlisted below as these could be useful for junior and senior faculty alike.

Commonly done research activities in Pharmacovigilance

Level one

- Case reports
- Knowledge, attitude and practice studies on pharmacovigilance
- Self-medication
- Medication errors
- Clinical Profile of ADRs
- Studies on patient compliance
- Adverse events following immunisation
- Analysis of drug promotion literature
- ADRs to Medical devices

Level two

- Risk for ADRs
- ADR Preventability studies
- ADR Severity studies
- Comparing different causality methods
- Use of android app for ADR reporting

- Comparing ADRs of diff drugs
- Case series of ADR reports
- Studies on e-prescriptions
- ECG ADRs and prescription pattern studies [to know the potential of polypharmacy in causing ADRs and ADRs through drug interactions]

Level three

- Review articles
- Education forum articles
- "Antibiotic resistance" studies
- Artificial intelligence in Pharmacovigilance
- Pharmacogenetics studies
- Analysis of modern tools used in Pharmacovigilance
- Pharmacovigilance program of India - program aspects
- Drug safety reviews
- Brief communications
- Letters to the Editor

DISCUSSION

According to Albert Szent Gyorgyi, "Research is to see what everybody else has seen, and to think what nobody else has thought". This is more applicable when one identifies ADRs in some individuals due to peculiar genetic factors and pursues further research along the genetic factors. This will also help in the advancement of personalized medicine.

Pharmacovigilance in clinical trials

ADR reports collected in any clinical trial can be a good database for research work. This is also a very important pharmacovigilance work done across countries, especially in clinical trials involving many centers in different countries. Routine clinical trials do not pick up rare and late ADRs. Hence, specially designed surveillance or research studies are needed to pick up rare and late ADRs [1].

Pharmacovigilance research activities during covid pandemic

Different drugs were used during COVID-19 after repurposing studies. They needed to be monitored for ADRs when used urgently on a massive scale. Hence, simultaneous and intensive pharmacovigilance monitoring was carried out. Similar approach was also adopted for surveillance of vaccines deployed during the COVID-19 pandemic. Such continued monitoring ensured patient safety besides generating clinical data for further research studies. Any new information identified regarding patient safety is shared with the review committees. Studies on the impact of such communications are warranted [2].

Special pharmacovigilance tools

Following tools aid data mining research work

- Italian VALORE is a coordinated analysis of collection of data from across the world
- Opensafely, is another platform for analysis of data based on electronic health records
- Large data collected, as noticed during the COVID-19 pandemic, requires new tools like Artificial Intelligence [AI] and Machine Learning [ML] for fast processing.AI can be used for case report entry and processing and identification of clusters of adverse events [1].

Research on safety signals

Using different statistical methods, signals are detected for further action by regulatory authorities. This process of signal detection gives scope for further research [3].

Exploratory trials and regulatory trials

Exploratory trials and regulatory trials were also done during COVID. They lead to new modifications and adaptations. Thus, adaptive trial designs and decentralization of clinical trials became popular. These studies also generated a lot of ADR data for further analysis.

Follow up in digital therapeutics

- Telemedicine as a new mode of clinical care is beneficial for many situations. ADRs occurring during telemedicine therapy, besides medication errors, must be watched for closely [1].

Pharmacovigilance activity based on social media

Decoding the terms used in social media discussions must be taken up besides developing novel statistical concepts. Validation of this kind of research in relation to existing research methods must be done[4].

Advance therapy medicinal products

These are drugs based on genes,cells, and tissue engineering. ADRs caused by these products have be monitored. These ADRs could be delayed in nature and appear unrelated to the causative agent. These ADRs must be actively managed and well-documented for in-depth research work [1].

Emerging fields in pharmacovigilance

Ecopharmacovigilance is developing fast while studies are done to know the impact of pharmaceuticals on environment. Environmental pollution by pharmaceuticals must be continuously monitored through routine activities and additional research activities [1].Environmental contamination can occur through households, medical outlets, transit points or manufacturing facilities. This can be a good area for research [5].There are many journals which are dedicated to publishing articles on drug safety and other articles as outlined above.

Pharmacovigilance of antimicrobial use

Continuous monitoring of efficacy of antimicrobial agents, their resistance development and identification of factors responsible for the resistance is needed. Such studies will decipher steps to be taken to prevent resistance to antimicrobial agents [6].

Extension of ADR monitoring

Materiovigilance is a program to monitor ADRs to medical devices. This is an area where a lot of research is waiting to be done. Recently, many research articles in materiovigilance are getting published [7].

Program evaluation research

Research studies are needed in pharmacovigilance program, vaccine pharmacovigilance and other such programs. Such studies can include research on quality control methods in the program[8]. Underreporting of ADRs is a common issue encountered in many places. Causes for this can be taken up as a research study [9, 10]. Different methods of ADR reporting used can be compared through research studies [11,12].

Pharmacovigilance in medical education

Steps are being taken to improve ADR reporting by physicians. In this regard, pharmacovigilance is included in the curricula in undergraduate and postgraduate medical courses. Such curricula need continuous research for improvement and evaluation [12-14].

SUMMARY

Different types of research articles in pharmacovigilance were classified and detailed based on the difficulty level. Apart from ADRs, researchers can also consider publishing new articles in related fields like pharmacogenetics, medication errors, telemedicine safety, clinical trials ADRs, ADRs from social media discussions, ecopharmacovigilance and biovigilance which includes new biological products and biosimilars. Faculty can take up research in curriculum and program evaluation aspects.

CONCLUSIONS

Pharmacovigilance is indispensable for ensuring the safety and efficacy of pharmaceutical products in India. With a rapidly evolving healthcare landscape and growing pharmaceutical market, robust pharmacovigilance mechanisms are essential to mitigate risks associated with medication use and protect public health. While challenges persist, concerted efforts from all stakeholders can pave the way for a more effective and responsive pharmacovigilance system in India.

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