PHARMACOVIGILANCE IN INDIA: A BRIEF REVIEW

VARUN ALVES

PharmD Intern, Krupanidhi College of Pharmacy, Karnataka, Bengaluru, India

ABSTRACT

Pharmacovigilance was introduced after a series of events that occurred in the past, with the thalidomide disaster being one of the biggest tragedies in the history of pharmaceutical research. A lot of changes and advancements have been made since the thalidomide incident. Drugs after successfully coming out of clinical trials and being approved for marketing for the general population, were monitored for possible adverse effects. Over the past few decades, pharmacovigilance has shown considerable development around the world, with India still lagging. With more and more drugs being introduced into the market every year, the scope for pharmacovigilance in India is very high. Several initiatives have been taken to ensure proper and frequent Adverse Drug Reaction reporting and to develop a robust pharmacovigilance system in India. Due to the lack of trained professionals, India still hasn't been able to match the global standards of pharmacovigilance. However, several regulatory bodies have been formed with dedicated staff to implement the practice of pharmacovigilance within the country. India still has a long way to go in this regard. Currently, the growth of pharmacovigilance in India is very slow, but with multiple initiatives taken by the regulatory authorities over the past few years, appreciable improvements have been observed, which indicates that pharmacovigilance in India is moving in the right direction. A more serious approach is required to change the current status in the country. Laws need to be implemented to make Adverse Drug Reaction reporting mandatory and consumers need to be educated to report Adverse Drug Reactions to the healthcare professionals. With a proper training, more awareness programs and introduction of pharmacovigilance in the curriculum of medical students and paramedics, the future of pharmacovigilance in India can be improved to a significant extent.

Keywords: - *Adverse Drug Reaction, Pharmacovigilance Program of India, World Health Organization*

INTRODUCTION

The Pharmacovijilance Program of India (PvPI) was initiated in 2010 with the primary objective to safeguard the country with a population of 1.27 billion people. [1] Though most of the western countries have progressed in the field of pharmacovigilance to a significant extent, India is still lagging. Considering the large population in India, there is an urgent need to address the importance of pharmacovigilance. The importance of pharmacovigilance dates to the 19th century with the incident of the 'Thalidomide Disaster', which is considered is one of the darkest episodes in the history of pharmaceutical research. Thalidomide was initially marketed in 1957 as a sedative hypnotic. It was also found to be beneficial in alleviating morning sickness in pregnant women. Within a few years of its widespread use in Europe, Australia and other countries where thalidomide was predominantly prescribed, more than ten thousand children were born with phocomelia, a condition in which the infant is born with deformed limbs. This tragedy ultimately led to the ban of the drug in most countries in 1961. The thalidomide tragedy created global awareness of the importance of pharmacovigilance for the prevention of adverse effects caused by drugs. The discontinuation of thalidomide was followed by the introduction of the Kefauver-Harris amendment, which required scientific evidences of the efficacy and safety of drugs before being tested in humans. The Uppsala Monitoring Centre, which is the global pharmacovigilance center, was started in Sweden, shortly after the thalidomide incident in collaboration with the World Health Organization (WHO) with the primary objective to collect information about the adverse effects of drugs from multiple sources across the world, to ensure that the initial signs of the possible threat from drugs would not be missed. India officially became a part of the WHO Program for International Drug Monitoring in 1997. [2] Although the program was started in 1997, pharmacovigilance in India gained momentum in 2010, when the Ministry of Health and Family Welfare (MoHFW), Government of India, launched the nationwide

PvPI. [3] With the increase in drug development and marketing over the past few decades, the challenge of improving drug safety and maintaining public assurance has become increasingly complex. The main purpose of introducing pharmacovigilance is to receive information about Adverse Drug Reactions (ADR's) from various clinical settings and individual healthcare professionals to understand the severity and impact of a ADR on humans. Based on the severity of the ADR, further investigations are performed. The practice of pharmacovigilance across the globe has significantly helped in decreasing the incidence of ADR's. India being the fourth largest producer of pharmaceutical products in the world and which is also emerging as a clinical trials and health tourism hub, the scope for pharmacovigilance is surplus.

DISCUSSION

The primary intention of PvPI is to expand the practice of reporting ADR's as much as possible in India, so that maximum information can be recorded by the system. [2] Under the PvPI, many Adverse Drug Reaction Monitoring Centers (AMC) were set up across different parts of India. These AMC's were set up in all the medical colleges approved by the Medical Council of India (MCI). Presently, there are more than 170 AMC's in India, with more additions with each passing year. The primary responsibility of these AMC is collection of adverse events in accordance with the standard procedures. The practice of reporting ADR has been established by the PvPI by formulating various steps, including setting up new and reliable AMC's in MCI approved teaching and corporate hospitals throughout the entire country. There has been a significant progress in reporting of ADR's by healthcare professionals over the past 5 years across the country due to the systematic process brought about by the PvPI officials. [2] Various studies conducted across the world have indicated that ADR's significantly reduce the quality of life, increase hospitalizations and increase mortality. Several studies conducted throughout the world also demonstrate ADR's to be one of the leading causes of death and are estimated to cause around 3-7% of all hospital admissions. More than half of these ADR's aren't recognized by physicians during hospital admissions. The financial burden of ADR's to the healthcare system is also huge. With more and more drugs being introduced into the market quickly without long term safety studies by the regulatory authorities and switching of prescription drugs to over-the-counter (OTC) to be used more frequently by patients to medicate themselves, the general population is at a huge risk of exposing itself to ADR's. This scenario will further worsen in India where poverty, illiteracy and corruption are at a high rise. [4] The pharmacovigilance systems are not well organized and do not obtain sufficient funds for a vast country like India to serve the public. The pharmacovigilance system which is handled by the Drug Controller General of India (DCGI) is embedded within the ministry of health and family welfare. Yet, the information shared about ADR's is very little between the regulatory authorities and the healthcare professionals. There is also a lack of qualified and trained professionals to handle the responsibilities related to pharmacovigilance within the DGCI.

The national pharmacovigilance program is presently being funded by the World Bank. However, there is absolutely no funding obtained from the budget of the Health Ministry whatsoever. Apart from funding, a focused vision and effective strategy are the two key factors lacking within the Indian pharmacovigilance system which leads to the lack of knowledge of the exact incidence of an ADR. There are multiple local teaching hospitals in India that incorporate some work on pharmacovigilance as a part of postgraduate program, but these are seldom shared with the regulatory authorities within the country, nor does the practice of these teaching hospitals informing the pharmaceutical manufacturer regarding a product and ADR exist. Another major drawback which has been encountered is that, there are discrepancies in the reporting form used by various people involved in some pharmacovigilance work than that used by the PvPI. This makes is extremely difficult to transfer date into the national database, even though the information is shared by various parties. [4] PvPI has undertaken certain initiatives which include, provision of a toll-free number and introduction of Adverse Event reporting forms in six regional languages to encourage consumers to report ADR's. It is necessary to incorporate pharmacovigilance culture in schools to ensure an effective pharmacovigilance system. The MCI mandate for all medical colleges within the country to have a pharmacovigilance department has been one of the primary reasons for the success achieved by PvPI. Despite these achievements, the pace of growth in pharmacovigilance is insufficient for a country with a population with over a billion people. A more serious approach is required by the regulatory authorities and the practicing healthcare professionals for the proper and effective functioning of the pharmacovigilance system. Global pharmaceutical giants and pharmacovigilance outsourcing industry have joined hands with PvPI which was evident in the symposium "Comprehensive Pharmacovigilance for India- The Road Ahead", which was organized by the Pharmacovigilance Working Group (PVWG) of the Indian Society for Clinical Research (ISCR) which was held in Mumbai in December 2014. [5] Every medicine is associated with beneficial as well as undesirable effects. ADR's are a common clinical problem which need to be minimized to reduce economic burden. In this regard, the launch of PvPI marks and important milestone towards safeguarding public health. Multiple conferences and seminars are being conducted by PvPI to extend pharmacovigilance in India. Multiple recent steps have been initiated by PvPI to ensure that pharmacovigilance moves in the right direction. Pharmacovigilance is moving at a slow but steady pace with more and more advances with each passing year. With more drugs being introduced into the market

every year, the need for an effective pharmacovigilance is essential. The primary purpose of PvPI is to improve patient safety and welfare in Indian population by monitoring the safety of drugs and thereby reducing the risk associated with the use of medicines and to collate data, analyze it and use the inferences to recommend informed regulatory interventions, besides communicating risks to healthcare professionals and the public. [1] Pharmacovigilance in India relies primarily upon the spontaneous reporting of adverse drug events. The major challenge for pharmacovigilance in India is under-reporting. Although, there has been a significant improvement in the number of reports submitted after regular trainings and awareness programs conducted by The Indian Pharmacopoeia Commission. (IPC) The IPC is a national coordinating center under PvPI. A proper functioning of pharmacovigilance system is required if medicines are to be used safely. This will in turn benefit all parties including healthcare professionals, regulatory authorities, pharmaceutical companies and the consumers. [4] With several clinical trials and other clinical research activities being conducted in India very frequently, there is an urgent need to understand the importance of pharmacovigilance and the way is impacts the life cycle of a product. Considerable effort has been made by DCGI to develop an effective robust pharmacovigilance system. However, this is not sufficient as more effort and strategic planning is required to meet the challenges of the growing population and ensuring that all data is captured and analyzed. The DCGI can go a step forward and hire private firms to train and set up an effective pharmacovigilance system to overcome the problems of inexperience and shortage of trained staff.

Due to the complexity associated with new drugs entering the market, every health care professional must be updated and have the knowledge about the possible ADR's and the importance of adverse drug reaction reporting, monitoring and pharmacovigilance. Making pharmacovigilance reporting mandatory can be one of the effective steps in developing a robust pharmacovigilance system. The Government of India's Health Ministry must pass a law and make pharmacovigilance reporting mandatory throughout the country. Education and additional training of medical students, pharmacists, nurses and other paramedics in the area of pharmacovigilance must be incorporated. Continuous medical education programs need to be conducted, especially for those healthcare professionals in rural areas where the need to recognize ADR's is more important. Incorporating pharmacovigilance in academic syllabus will not only train young minds but also impart a sense of responsibility and discipline in the future healthcare professionals.

CONCLUSION

Pharmacovigilance is a complex process and a robust system is necessary for its smooth functioning. The growth of pharmacovigilance in India is slow but not stagnant. However, the system needs to be refined under the guidance of trained professionals and information technology. The practice of pharmacovigilance must start early in the professional training of healthcare students. This is the first and the most important step to ensure, the proper reporting of ADR's and development of an effective pharmacovigilance system in the future. The authorities of PvPI are continuously working towards increasing its reach in India and to serve the purpose for which the committee was formed, i.e. to develop and spread the practice of Pharmacovigilance in India. Multiple attempts have been made and several recent steps have been implemented by PvPI which prove that pharmacovigilance is moving in the right direction. With a more serious approach, proper training and with the collaboration of healthcare professionals and regulatory authorities, a robust pharmacovigilance system can be developed in India in par with global standard procedures.

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