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Mini Review

Pharmacovigilance in India: A Need of the Hour

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Abstract

Medicines in the current health system hold an indispensable role not only for curing a disease but also for prophylaxis or diagnosis of a medical condition. Medicines are supposed to be harmless but contrary to the belief they do come with adverse effects called as adverse drug reactions (ADRs). ADRs accounts for increase in morbidity, sufferings and in the worst case can culminate into mortality. Apart from them they also lead to hospitalization of patients and tend to increase the economic burden on them. In view of such undesirable consequences, regular monitoring and reporting of ADRs play a crucial role in the prevention of further ADRs. In India, National Coordinating Centre (NCC) at Indian pharmacopeia commission is running a nationwide Pharmacovigilance program of India (PvPI) which suggests monitoring and report the suspected ADRs to them. Healthcare professionals (HCPs) forms a key element in the detection, monitoring and reporting of ADRs. Present scenario in India doesn't seem to be good enough with regards to ADRs reporting. There are multiple reasons for underreporting of ADR but most crucial is the lack of knowledge and awareness among the HCPs. NCC-PvPI have taken multiple steps to tackle the situation and there has been improvement in the last few years. We can hope a changed scenario and conducive environment in future for reporting of ADRs and help the patients to have a safe and effective use of medicines.

Keywords: Adverse Drug Reactions; Pharmacovigilance; Healthcare Professionals; PvPI, ADR Reporting

Introduction

It is a well-known fact that excess of anything is not favorable in this ecosystem and the same holds true for the medicines. We can call the drugs as a dual-edged sword as it cures the diseases on the contrary it also has adverse effects at higher doses and even therapeutically viable doses. With hastening use of medicines in the present scenario it has become extremely important to monitor the adverse drug reactions (ADRs) associated with them. ADRs by definition is "a response to a drug which is noxious and unintended, and which occurs at doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function [1]. The science of monitoring the ADRs is called Pharmacovigilance (Pv). WHO officially defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problem, particularly long-term and short-term adverse effects of medicines [2]. Pv not only monitors medicines but also the biological products, blood products, herbals, vaccines, medical device, traditional and complementary medicines in view of identifying new adverse effects associated with products and safeguard the patients. It also deals with polypharmacy, iatrogenesis, paradoxical reaction and serious adverse event associated with a drug.

The ADRs not only morbidity in the patients but there is also increased rate of hospitalization. Literature reveals that ADRs are one of the chief causes of hospitalization and astonishingly they constitute a significant burden on economic status of the patients in India [3,4]. Study done in south India revealed that hospital ad-

missions due to ADRs was about 0.7% of total admissions into the hospital and deaths resulted due to serious ADRs were about 1.8% of total admissions in a territory referral center [5].

During the development phase of a particular drug, medicine or product only a few thousands of humans are tested with the product, so the adverse effects noted are lesser. The scenario post marketing of the product is completely different. During the development phase of a drug, it is monitored closely but post-marketing it is being used in uncontrolled population without a controlled environment so the chances of encountering ADRs proportionately rise [6]. Pv is crucial for clinical trials safety and post-marketing surveillance. With a rise in new ADRs there are increased drug alerts and drug withdrawals, the pharmaceutical industry and regulatory authorities have now geared up to change the scenario in relation to Pv.

Aims of Pharmacovigilance: [7]

1. To improve patient health, well-being and safety of the patients with regards to the use of medicines and all medical and paramedical interventions.
2. To improve public health and safety in relation to the use of medicines.
3. To contribute to the assessment of benefit, sufferings, effectiveness and risks associated with medicines and further encouraging their safe, rational and more cost-effective use.
4. To promote understanding, educate and clinical train the public regarding pharmacovigilance.
5. To detect problems related to the use of medicines and communicate the findings in a timely manner.

Pharmacovigilance program of India (PvPI)

ADRs due to pharmacotherapy are usually daily encountered in hospital wards but due to various reasons they are not being reported. The various reasons can be a lack of knowledge among the healthcare professionals (HCPs), apart from that there is a lack of awareness and attitude in the HCPs. Lack of motivation and facilities are one of the prime causes of underreporting of ADRs. Lack of organization, funding, shortage of qualified trained people are few other causes [8]. literature reveals that study conducted on knowledge, attitude and practice (KAP) of HCPs regarding Pv shows lack of knowledge among HCPs which would then hamper the attitude and practice subsequently [9-14]. Looking at such a deficiency in pharmacovigilance system Government of India along with the Ministry of Health and Family Welfare launched the national Pharmacovigilance Programme of India (PvPI) to encourage ADR reporting culture and to ensure patient safety in India, was initiated in 2010. With the improved functioning of the PvPI, there has been huge improvement and progress in reporting of ADRs by the HCPs in the past 5 years [15].

Steps to further strengthen the pharmacovigilance system in India

To strengthen the Pv system first we need to develop awareness among the HCPs. It is the most crucial part of the whole process as HCPs are the cornerstone for ADR reporting since they are the one who is with the patients most of the time. We should organize advance level training for the concerned persons of all ADR monitoring centers (AMC) in their respective regions. Increase the number of CME in pharmacovigilance at all AMC to increase the awareness of HCPs about the ADR reporting. All approved medical colleges, hospitals, private and corporate hospitals as well as other concerned organizations should have their own pharmacovigilance monitoring system [15]. Increase awareness and dissemination of information to the general public regarding adverse drug reactions, their importance, when to report, what to report, how to report and where to report through public lectures, media communications, pamphlets, roleplay etc. which would reinforce the information to be passed to them. The HCPs should be continuously kept in touch regarding the proceedings and advancements by sending them newsletters and emails. They should be positively greeted and acknowledged when they send proper ADR reports which would boost the morale and build confidence in them. National Coordinating Centre (NCC) at Indian pharmacopeia commission, Ghaziabad has taken few steps to further ease the process of ADR reporting by introduction of toll-free helpline number, ADR reporting mobile application, availability of ADR reporting form in vernacular languages, set up of ADR monitoring centers with a dedicated pharmacovigilance safety associate to monitor, collect, assess and report the ADRs.

Conclusion

Pharmacovigilance in the current scenario is an indispensable tool to monitor the ADRs. ADRs, not only increases morbidity but also the economic burden on the patient and society and sometimes can get worse leading to mortality in few cases. Dying of a treatment is really unacceptable but most of the ADRs are prevent-

able by proper monitoring and precautions. So, it is high time to bring about a culture of reporting every ADR we come across in our practice. It will not only help to build a national data on various unknown drug adverse effects but also prevent the future ADRs. We can hope in near future with the effective implementation of Pv and constructive efforts, we can ensure the availability of safe and effective medicines to the public.

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