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CASE REPORT

Pharmacovigilance in psychiatry: time to take notice

Arghya Pal, Atul Ambekar, Sagar Chandra Bera

All India Institute of Medical Sciences, New Delhi, India.

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INTRODUCTION:

The term 'Pharmacovigilance' is used to describe the activities that are related to monitoring adverse drug reactions (ADRs). The World Health Organization (WHO) defines it as "the science and activities relating to the Detection, Assessment, Understanding and Prevention of adverse drug reactions or any other possible drug related problems".

Johnson and Bootman's decision-analytic model shows three types of incorrect or inappropriate attention by physicians; viz., ADR, Drug interactions, Drug use without indication. This represents a serious medical problem, evidenced by the fact that the cost of drug-related morbidity and mortality exceeded $177.4 billion in 2000, which brought pharmacovigilance into focus. (1)

ADRs have been defined by WHO as "a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function". The word "noxious" in the definition lent itself to ambiguity and vagueness (2) and hence a refined definition was proposed "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product".

Pharmacovigilance assumes special significance in psychiatric practice in the backdrop of increasing trend of psychotropic use both by physicians and mental health specialists. (3) Most of the initial work on pharmacovigilance in psychiatry in developed countries comprised of observational studies looking into the incidences of ADRs (4, 5). Few studies further progressed to the next step to look into the differences associated with the age groups (6). However inspite of these endeavors the literature underscored the fact that the lower ranked descriptive case reports/spontaneous reports provided better information about new and previously undetected ADRs over more refined and evolved descriptive and analytical research designs (7). To circumvent the substantial under reporting from the health care professionals (HCPs) (8), patients reporting is being encouraged though its impact is yet to be systematically studied.(8).

Psychiatrists in general remain not sufficiently aware of harm caused by errors and methodological issues regarding error detection (9). Surveys reveal that about 39-50% of psychiatrists had never reported any ADRs and had little idea about types of reactions to be preferentially reported and purposes of ADR reporting systems (10). The main reason identified behind this was the lack of teaching on pharmacovigilance for most professionals. Customized training programs - available from International Society of Pharmacovigilance (WHO), - remain under-utilized (11).

Indian research on pharmacovigilance has been mostly constituted of observational studies looking into the incidences of ADRs (12, 13). A questionnaire based survey from WHO involving 55 low and middle income countries to assess pharmacovigilance activities revealed inadequate funding of the authorities with no defined role which also has been hindering progress of research in this field.

India launched the National Pharmacovigilance Program in 2004 which aimed to contribute to regulatory assessment of benefit, harm, effectiveness and risk of medicines, encouraging safe, rational and more effective use; with focus to improve patient care and safety, improve public health and safety in relation to use of medicines and promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public. As a part of the program the HCPs are expected to report any ADR they encounter in their clinical practice. The program has been recently revamped generating guarded optimism. (14)

*Corresponding author: Arghya Pal|| E-mail: drarghyamb@gmail.com

In recent years, Indian pharmaceutical companies have been investing in research and development of new drugs with their own research efforts. Clinical research has also increased in India due to its large population, high enrolment rate, and low cost. Since most of the products launched in India are already launched products in other countries, the assessment of the benefit-risk profile of a drug are also dependent on the experiences gained from these markets where the drug was being used for several years before introduction in India. To take appropriate corrective actions, the Indian pharmaceutical companies as well as the regulators need to establish a strong pharmacovigilance system of their own. Thus under reporting remains an important barrier in the battle against ADRs. Some innovative strategies which can be proposed are: (a) providing research credits for reporting of ADRs (this may encourage clinicians to be vigilant in detecting and reporting ADRs); (b) focus on reporting ADRs can be incorporated in the pharmacology syllabi; (c) developing user-friendly and hassle-free reporting mechanisms and (d) encouraging consumer groups to incorporate patients‟ reporting in their awareness and advocacy activities. Research has also shown the viability of using clinical notes for the purpose of pharmacovigilance[15].

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