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REVIEW OPEN ACCESS

Adverse Drug Reactions in Psychiatry: An Alarming Scenario

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ABSTRACT

In the world, India is the largest producer of pharmaceuticals. It is very much essential that the treatment with these drugs should be efficacious, safe and cost effective. Every year, introduction of newer drugs and the production of various pharmaceutical products were increasing. World Health Organization (WHO) realized the need for a responsible surveillance system in order to ban the noxious drugs in the market. Both in hospitalized and ambulatory patients, ADRs are the significant cause of morbidity and mortality. Around 6-15% of the hospitalized patients may experience a serious ADR and nearly 6.5% of the hospital admissions are admission due to ADR. Some of the new ADRs that can be seen with psychotropic drugs are Risperidone associated with an increased risk of stroke in elderly patients with dementia and dopamine receptor agonists (Cabergoline and Pergolide) associated with cardiac valve fibrosis. So many drugs act at more than one receptor type. Tricyclic antidepressants shows their therapeutic effect by the stimulation of monoaminergic pathways by a reduction in monoamine reuptake, but tricyclic antidepressants also show the antimuscaranic activity and this is responsible for adverse effects like retention of urine, drymouth and constipation. To avoid the noxious reactions of psychotropic drugs, pharmacovigilance plays a pivotal role in detecting the adverse drug reactions that alert the psychiatrist in their management. In developing countries like India, pharmacovigilance activities are still in initial stage and especially in case of psychotropic drugs only few reports are available on this concern. A wide range of surveillance programs on adverse drug reactions of psychotropic drugs should be emphasized, in our Indian scenario to strengthen the database.

Introduction

The most common medical interventions are the drugs which are mainly administered to relieve disease condition. In the last decades highly effective drugs were developed, from which the patients got remarkable benefits [1]. In the world, India is the largest producer of pharmaceuticals. It is very much essential that the treatment with the drugs should be efficacious, safe and cost effective [2].

Every year, introduction of newer drugs and the production of various pharmaceutical products were increasing. World Health Organization (WHO) realized the need for a responsible surveillance system in order to ban the noxious drugs in the market. This became a platform for initiating the International Drug Monitoring Program. On 1st January 2005, the Ministry of Health and Family Welfare had started the National Pharmacovigilance Program. This program was further revised in July 2010 which can be overseen by the Central Drugs Standard Control Organization (CDSCO) at New Delhi.

Both in hospitalized and ambulatory patients, ADRs are the significant cause of morbidity and mortality. Around 6-15% of the hospitalized patients may experience a serious ADR and nearly 6.5% of the hospital admissions are admission due to ADR [3,4]. An ADR can be simply defined as "any undesirable effect of a drug beyond its anticipated therapeutics occurring during clinical use". But according to World Health Organization an ADR can be defined as "any response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of a disease or for modification of physiologic function". Drug abuse, overdose (either accidental or intentional), drug administration errors and treatment failure are excluded from this definition. The usage of different definitions of ADRs and different methodologies such as retrospective chart screening or prospective intensive surveillance to identify the ADRs and the sample size of the studies shows diversity in the incidence of ADRs in different parts of the world. ADRs were found to be 4th to 6th leading cause of death which was suggested by a meta-analysis in the United States [5,6]. In general population, the percentage of ADRs which leads to hospital admission varies from a maximum of 12.8% in Greece, 8.4% in Denmark, 6.5% in Britain, 3.6% in Italy, 3.2% in France and 1.8% in Netherlands. These percentages are even higher in case of elderly patients, ranging from 8.4% to 24% [7].

Psychotropic drugs use require the weighing of benefits and risks, coupled with careful monitoring because of their potential adverse effects [8]. Psychotropic drugs affect the central nervous system which influences a dramatic change in the perception and behaviour of a patient [9,10]. For classifying psychotropic drugs there is no consistent basis. Psychotropic medication was limited to barbiturates chloral hydrate and amphetamine in 1940s. But, nowadays almost 100 psychotropic drugs with effective treatment are available for a wide range of psychiatric diagnosis. Any class of drugs may involve in precipitating Adverse Drug Reactions.

Some of the new ADRs that can be seen with psychotropic drugs are Risperidone associated with an increased risk of stroke in elderly patients with dementia and dopamine receptor agonists (Cabergoline and Pergolide) associated with cardiac valve fibrosis [11, 12]. So many drugs act at more than one receptor type. Tricyclic antidepressants shows their therapeutic effect by the stimulation of monoaminergic pathways by a reduction in monoamine reuptake, but tricyclic antidepressants also show the antimuscaranic activity and this is responsible for adverse effects like retention of urine, dry-mouth and constipation [13].

Adverse drug reactions are often difficult to diagnose and they should be considered in the differential diagnosis of a wide range of conditions [14]. The psychiatrist should be aware of differences among patients in terms of doses causing adverse effects. Dose related depression of the central nervous system is the most common adverse effects of sedatives and hypnotics [15,16]. Significant dose related anterograde amnesia may be caused due to the usage of benzodiazepines [17]. Patients with cardiovascular disease, hepatic impairment, respiratory disease and also in geriatrics an increased sensitivity to hypnotics is very common [18]. In case of patients with chronic pulmonary disease and in those with symptomatic sleep apnea, sedatives-hypnotics can exacerbate breathing problems. For the drugs which precipitate rare and unknown adverse drug reactions, spontaneous reporting system is the most significant warning system currently [19].

Both on health and healthcare cost ADRs have a great negative impact. In order to improve the public health and reduce the patient harm early detection, evaluation and monitoring of ADRs are very much essential, but in our country ADR monitoring and reporting are still in infancy stage [20].

The major significant component of monitoring and evaluation activities performed in hospitals is the spontaneous reporting program of the adverse drug reactions [21]. This is the most common method of drug surveillance which is more capable of recognizing ADRs in the daily medical practice [22]. ADR reporting programs not only influences the increase in the reporting of ADRs but also they create the awareness among the health care professionals about potential ADRs and their management in the clinical set up [23]. Every individual hospital based reporting program will contributes to the national and international data bases on ADRs that ultimately plays a key role in drug safety decisions. This information may serve in designing various patient education strategies and also for product labeling revision. This information disseminates the health care professionals that helps in ensuring drug safety in the clinical set up. The main disadvantages involved in this system are lacking of information on number of people actually exposed to the drug and also under reporting due to various reasons [24].

In case of hospitals where under reporting was noticed, clinical pharmacist active involvement must be essential to create awareness among healthcare professionals about the detection, evaluation and management of Adverse Drug Reactions [25]. Pharmacist should be good in decision making for assessing the risk-benefit ratio the drugs to provide better health care which should be in a cost effective manner. Pharmacists should actively participate in health education, counseling and reconciliation [26].

Conclusion

To avoid the noxious reactions of psychotropic drugs, pharmacovigilance plays a pivotal role in detecting the adverse drug reactions that alert the psychiatrist in their management. In developing countries like India, pharmacovigilance activities are still in initial stage and especially in case of psychotropic drugs only few reports are available on this concern. A wide range of surveillance programs on adverse drug reactions of psychotropic drugs should be emphasized, in our Indian scenario to strengthen the database.

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