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THE ADVERSE DRUG REACTIONS REPORTED IN PSYCHIATRY IN A USING NARANJO'S ASSESSMENT

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AUTHORS' CONTRIBUTIONS

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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ABSTRACT

The present study analyzes the adverse events caused by the psychotropic drugs during their prevalence. In our study the most commonly prescribed was atypical antipsychotics followed by benzodiazepines, SSRI and others. In the category of antipsychotic drugs the most commonly prescribed was quitiapine and olanzapine which contributed a major part of ADR. Drugs in the atypical antipsychotics like aripiprazole, ziprasidone were prescribed among the 120 patients and proved to have very minimal or no ADR. The drug adverse effects such as cardiotoxicity, particularly arrhythmia could be prevented or minimized by following preventive measures. The usage of safer agents like aripiprazole would help in minimizing the drug adverse interactions. The newly discovered second generation antipsychotic drugs have reduced the incidence of Extra Pyramidal Symptoms (EPS) to the maximum limitation. These results showed that the patients with EPS should be treated with second generation drugs.

Keywords: Adverse drug reaction; pharmacovigilance; reporting causality.

1. INTRODUCTION

Pharmacovigilance is a discipline of science concerned with the detection, assessment, comprehension, and prevention of adverse effects or other drug-related issues. [1]. The adverse drug reactions could be a minute, small or severe in their nature. Any events that are occurred by means of 'unexpected, unintended, undesired or excessive response on drug usage and considered to be even after a time period following the drugging tenure [2]. The side effect raised by unintentional or un known reaction of the drug on the metabolic processes and few drugs intentionally used for their principle drug effects over the others, example, anti-histaminergic agents (such as promethazine) [3]. The thalidomide tragedy was the one well known for its side effects and used for the treatment as hypnotic and anti-

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emetic for nausea and vomiting in early pregnancy. Its teratogenic effects were increase the need of regulatory monitoring about the drug effects even after marketing. Meanwhile, many well known drugs also cause a number of side effects that varies with minute to lesser rare adverse drug reactions (ADRs) even if these are serious [3-6]. Many obstacles found in analyzing the rare side effects arising from the metabolically variations between the registered volunteers and the patients. Those effects mostly related with the skin, haematopoietic system and lining of the gut and the effects may different such as type B illnesses, such as toxic epidermal necrolysis, aplastic anaemia, pseudomembranous colitis, drug induced hepatitis or nephritis [7-9]. The pharmacoepidemiology especially analyze the side effects of the registered or marketed drugs on the epidermal tissues and their drug- drug interaction events. Usually, the public health surveillance helps on finding the possibilities ADRs [10]. These studies mostly based on the 'hypothesis-generating' or 'hypothesis-testing' method for ADR identification [11, 12].

2. MATERIALS AND METHODS

The study was conducted in Department of Psychiatry, Bharath Institute of Higher Education and Research during 2011-2012, with clearance of human and institutional ethics committee. The patients were from different residential area spread in sub urban and rural of Chennai, Kanchipuram, Villupuram, Cuddalore districts. Patients were selected after making the clinical diagnosis after confirmation of any psychiatric disorders. The patients were then selected in accordance with the exclusion and inclusion criteria noted below. All patients with psychiatric disorder or diagnosed within six months and discontinued / continuing the treatment from all ages and both sex. The patients were excluded with typical and atypical antipsychotics treatment together at the time. The patients were excluded with pregnancy, uncontrolled mind and without attenders, lactation and renal failure/ hepatic failure. This is a type of longitudinal prospective observational study with 150 cases of different psychiatric disorder based on following questioner, causality of adverse events was algorithm assessed by the Naranjo' s Naranjo adverse drug reaction probability scale;

- Are there any earlier reports on this response that are conclusive?
- Did the adverse event happen after you took the suspicious drug?
- When the medicine was stopped or a particular antagonist was given, did the adverse response improve?
- When the medicine was re-administered, did the adverse response reappear?
- Are there any other factors (besides the medicine) that might have triggered the reaction?
- When a placebo was administered, did the response return?
- Was the drug found in dangerous amounts in the blood (or other bodily fluids)?
- Was the response more severe or even less severe when the dosage was raised or reduced?
- Is there a history of the patient having a similar reaction to the same or comparable medications in the past?
- Was there any objective proof that the bad event occurred?

3. RESULTS AND DISCUSSION

The result of the present study inferred that ADRs of the psychotropic drugs in the enrolled patients. As indicated by the previous studies, our results also showed that depression as the commonest ADR during the antipsychotics tenure [13]. A study conducted in Bulgaria showed that the lesser than 1% papteints treated with antipsychotics suffering from such ADRs. A Norwayan study showed that the ADRs could be used to calculate and finalize the frequency of the risk factors during the treatment tenure [14].

Quitiapine was the most commonly used drug in the study site followed by Olanzapine and other atypical antipsychotics. Aripiprazole, reboxetine, venlafaxine, ziprasidone are among the few drugs that were not frequently prescribed for the patients in Indian subcontinent. The present study showed that 94 ADRs (96.90%) classified as "probable" category and only, 3.09% were belonged to the "possible" type based on the naranjo s algorithm [Table 1]. Whilst, no single "certain" label was found and no known rechallenge was recorded once after the withdrawal of the drug. A case of Phenytoin induced rashes was noted after two days of initiation of therapy. One case of quetiapine induced photosensitivity rash was noted.

Table 1. Causality of ADR by naranjo's scale

Category of ADR*	Instances of event n=97(%)	Adverse drug events	Drug(s)
Probable (97)	24 (24.74)	Weight gain	Olanzepine(9),quitiapine(8), risperidone(5), aripiprazole(2)
	14 (14.43)	Constipation	Olanzapine(4),quitiapine(2), trihexyphenidy1(8)
	8 (8.24)	Tremor	Olanzapine(2),risperidone(4), haloperidol(2)
	6(6.18)	Sedation	Lorazepam(2),sertraline(2), escita1opram(2)
	5(5.15)	Increased appetite	Olanzapine(5)
	5(5.15)	Headache	Clonazepam(2),quitiapine(3)
	5(5.15)	Dry mouth	Risperidone plus(5)
	4(4.12)	Dyspepsia	Quitiapine(4)
	3(3.09)	Decreased ap te	Quitiapine (3)
	3(3.09)	Urinary retention	Imipramine(2),risperidone plus(1)
	2(2.06)	rashes	Phenytoin(l),quitiapine(I)
	2(2.06)	Lack of co ordination	Trihexyphenidyl(2)
	2(2.06)	metabolic syndrome	Olanzapine(1),quitiapine(1)
	2(2.06)	Impaired glucose tolerance	Quitiapine(2)
	2(2.06)	akathisia	Haloperidol(2)
	2(2.06)	bradykinesia	Haloperidol(2)
	2(2.06)	fatigue	Risperidone(2)
	1(1.03)	Dyskinesia	Sertra1ine(1)
	1(1.0.3)	Impaired accomodation of vision	Clonazepam(1)
	I(1.03)	Swelling of lips	Quitiapine(1)
Possible(3)	1(1.03)	Mouth ulcer	Risperidone(1)
	1(1.03)	Palpitation	Olanzapine(1)
	1(1.03)	Leg muscle cramp	Risperidone(1)
Total	97		

4. CONCLUSION

Adverse medication effects such as cardiotoxicity, particularly arrhythmia, can be avoided or reduced by taking precautions. The current study showed that milder ADRs were common among the psychiatry patients and reduced by taking certain precautions.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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