International Journal of Current Advanced Research
ISSN: O: 2319-6475, ISSN: P: 2319-6505, Impact Factor: SJIF: 5.995
Available Online at www.journalijcar.org
Volume 6; Issue 10; October 2017; Page No. 6525-6528
DOI: http://dx.doi.org/10.24327/ijcar.2017.6528.0958

Research Article

ADVERSE DRUG REACTION STATUS AND RELATIONSHIP OF ADRs WITH AGE AND SEX OF THE PATIENTS ON ANTI-PSYCHOTIC DRUGS IN OUT-PATIENT DEPARTMENT OF A PSYCHIATRY HOSPITAL IN KASHMIR; A PROSPECTIVE OBSERVATIONAL STUDY

Afkat Ahmad [1]., Sabahat Farooq[1]., Mehwish Majeed[2]., Samina Farhat[1]., Mohd Younis Rather[1]., Peerzada Anis[1] and Zorawar Singh[1]

[1]Department of Pharmacology, Government Medical Collage Srinagar, Jammu and Kashmir, India
[2]Sheri Kashmir Institute of Medical Sciences Soura Srinagar, Jammu and Kashmir, India

A R T I C L E I N F O

Article History:

Received 15th July, 2017
Received in revised form 19th
August, 2017 Accepted 25th September, 2017
Published online 28th October, 2017

Key words:

Adverse drug reactions, Antipsychotic drugs, ADRs and ADR Status.

A B S T R A C T

Adverse effects are usually dose dependent and can be influenced by patient characteristics including age and gender and these confounding factors should be considered in clinical practice and in the interpretation of research data .Antipsychotic drugs are a great benefit in treatment of various psychiatric disorders. Selection of an antipsychotic drug should be an individual patient basis. Their use is increasing day by day, but all of them are capable of causing a wide range of potential adverse effects. Current study was carried out with the aim to look into the ADR status in patients according to antipsychotic drugs used and their relationship with age and sex of the patients. It was a prospective observational study conducted over a period of one year in Out-Patient department of Institute of Mental Health and Neurosciences (IMHNS), Government Medical College Srinagar. Causality assessment was done using WHO-UMC scale and Naranjo's Scale while severity by using modified Hartwig and Siegel scale. Chi-square test was used to test for the independence of two categorical variables. Psychiatrists and other health care professionals treating psychiatric patients should have a good knowledge about possible ADRs following antipsychotic medication and thus keep an active vigil to prevent and treat such ADRs so as to improve patients quality of life. The establishment of an active pharmacovigilance programme is hence an essential requirement to any health institute.

INTRODUCTION

Adverse effects are usually dose dependent and can be influenced by patient characteristics including age and gender. These confounding factors should be considered in clinical practice and in interpretation of research data. Selection of an antipsychotic drug should be on individual patient basis. Patients should be involved in prescribing decisions and this should involve discussion about adverse drug reactions.[1] The antipsychotic drugs are chemically diverse but possess the common property of alleviating the symptoms of both functional and organic psychosis.[2] These drugs can be of great benefit in a range of psychiatric disorders including bipolar affective disorders and schizophrenia and their use is increasing day by day, but all are capable of causing a wide range of potential adverse reactions that can lead to non compliance ,can impair quality of life, cause stigma, physical morbidity leading to discontinuation of medication and in extreme cases be fatal.[1] Pharmacovigilance in psychiatry units can play a vital role in detecting adverse drug reactions (ADRs) and alerting physicians to the possibility and of circumstances of such events, thereby protecting the population from avoidable harm.[3]

Corresponding author:* **Afkat Ahmad
Department of Pharmacology, Government Medical Collage Srinagar, Jammu and Kashmir, India

MATERIAL AND METHODS

It was a prospective observational study conducted by the department of pharmacology in collaboration with Department of Institute of Mental Health and Neurosciences (IHMNS), Government Medical College Srinagar for a period of 1 year. The study aimed at aimed analyzing the clinical spectrum of ADRs in psychiatric patients. All the diagnosed patients (old and new) of various psychiatric disorders who were receiving different anti-psychotic drugs were included in our study. The ADRs were reported either spontaneously by the treating consultant or by patients being treated or their guardians. A questionnaire was also used to ask the patient specific questions related to likely ADRs and the patient responses were recorded in Case Record Form. Causality assessment was done using WHO-UMC scale and Naranjo's Scale while severity by using modified Hartwig and Siegel scale. Chi-square test was used to test for the independence of two categorical variables.

Statistical analysis: Data was entered in Microsoft Excel. Continuous data was summarized as mean (±) standard deviation. Categorical variables were summarized as percentages. Chi-square test was used to test for the independence of two categorical variables. An exact p-value (two sided) was reported when chi-square was not valid (as per Cochran criteria).

RESULTS

Out of total 177 patients who were enrolled for study, 54.2% were constituted by males and 45.8% of the study population were females with average age of the patients being 32.9 years ± SD of 13.42 years.

Table 1 Distribution of the study population according to age

Age (years)	Frequency	Percent
≤10	3	1.7
11-20	31	17.5
21-30	56	31.6
31-40	48	27.1
41-50	25	14.1
51-60	7	4.0
61-70	7	4.0
Total	177	100.0

Table 2 Distribution of the study population according to sex

Sex	Frequency	Percent
Male	96	54.2
Female	81	45.8
Total	177	100.0

Table 3 Antipsychotic drugs used in study population

Name of drug	Frequency	Percent
Olanzapine	60	33.9
Risperidone	40	22.6
Quetapine	31	17.5
Aripiprazole	10	5.6
Haloperidol	7	3.9
Amisulpride	7	3.9
Trifluperazine	6	3.4
Olanzapine+Amisulpride	7	3.9
Clozapine	3	1.7
Flupenthixole	1	0.6
Amisulpride +Aripiprazole	1	0.6
Aripiprazole+ Flupenthixol	1	0.6
Quetapine+Fluphenazine	1	0.6
Risperidone+ Amisulpride	1	0.6
Trifluperazine+Olanzapine	1	0.6
Total	177	100.0

Table 4 Distribution of study population according to ADR

ADR	Frequency	Percent
Present	77	43.5
Absent	100	56.5
Total	177	100.0

Out of the total study population, 77 patients reported at least one or more ADRs out of which 37 were females and 40 were males. Most of the ADRs had a probable causal relationship with the prescribed antipsychotics while both Naranjo's and WHO-UMC monitoring scales and most (83%) of the ADRs were mild in severity according to modified Hartwig and Siegel scale. Maximum proportion of patients with ADRs were reported with either clozapine or combination like 'amisulpride and aripipazole', 'aripipazole and flupenthixol', quetiapine and flupenthixol', 'risperidone and amisulpride', 'trifluperazine and olanzapine' (all 100%). Their was no statistically significant relationship between development of ADRs with age (p=0.8) and sex (p=0.6) of the patients included in the study.

Table 5 Adverse drug reactions in the study population

Type of ADR		Frequency (N=100)	Percent
Neurological	Sedation	10	5.6
	Akathasia	9	5.1
	Increased sleep	6	3.4
	Tremor	6	3.4
	Insomnia	3	1.7
	Acute dystonia	2	1.1
	Dizziness	2	1.1
	Rigidity	2	1.1
	Auditory hallucinations	1	0.6
	Somnolence	1	0.6
	Slurring of speech	1	0.6
	Tightness in head	1	0.6
Metabolic/ Endocrine	Increase in weight	19	10.7
	Amenorrhea	2	1.1
	Raised liver enzymes	1	0.6
	Raised serum triglycerides	1	0.6
	Agranulocytosis	1	0.6
	Glactorrhea/hyperprolactenemia	1	0.6
Gastrointestina	Increased appetite	12	6.8
	Epigastric discomfort	1	0.6
	Loss of appetite	1	0.6
Psychiatric/ Behavioural	Irritability	2	1.1
	Restlessness	1	0.6
Sexual	Diminished libido	2	1.1
	Erectile/ejaculatory dysfunction	1	0.6
Autonomic	Dryness of mouth/throat	2	1.1
	Hyper salivation	2	1.1
	Postural hypotension	2	1.1
Others	Photosensitivity	1	0.6
	Excessive sweating	1	0.6
	Difficulty in swallowing	1	0.6
	Shivering	1	0.6
	Pain in legs	1	0.6

Table 6 Frequency of ADRs according to organ system involved

System involved	Frequency	Percentage
Neurological	44	44.0
Metabolic/Endocrine	25	25.0
Gastrointestinal	14	14.0
Autonomic	6	6.0
Psychiatric/Behavioural	3	3.0
Sexual	3	3.0
Others	5	5.0
Total	100	100.0

Table 7 ADR status in patients according to drugs used

Drugs used	ADR		Total
	Present N (%)	Absent N (%)	
Olanzapine	26 (43.3)	34 (56.7)	60
Risperidone	13 (32.5)	27 (67.5)	40
Quetiapine	12 (38.7)	19 (61.3)	31
Aripiporazole	3 (30.0)	7 (70.0)	10
Haloperidol	6 (85.7)	1 (14.3)	7
Amisulpride	2 (28.6)	5 (71.4)	7
Olanzapine +Amisulpride	3 (42.9)	4 (57.1)	7
Trifluoperazine	4 (66.7)	2 (33.3)	6
Clozapine	3 (100.0)	0 (0.0)	3
Flupenthixol	0 (0.0)	1 (100.0)	1
Amisulpride +Aripiprazole	1 (100.0)	0 (0.0)	1
Aripiprazole+Flupenthixol	1 (100.0)	0 (0.0)	1
Quetiapine+Fluphenazine	1 (100.0)	0 (0)	1
Risperidone+Amisulpride	1 (100.0)	0 (0)	1
Trifluperazine+Olanzapine	1 (100.0)	0 (0)	1
Total	77 (43.5)	100 (56.5)	177

Table 8 Distribution of study population according to age and ADR

Age (years)		ADR		Total
		Present	Absent	
≤10	Count	1	2	3
	%	33.3%	66.7	100.0%
11-20	Count	14	17	31
	%	45.2%	54.8%	100.0%
21-30	Count	25	31	56
	%	44.6%	55.4%	100.0%
31-40	Count	24	24	48
	%	50.0%	50.0%	100.0%
41-50	Count	8	17	25
	%	32.0%	68.0%	100.0%
51-60	Count	3	4	7
	%	42.9%	57.1%	100.0%
61-70	Count	2	5	7
	%	28.6%	71.4%	100.0%
Total	Count	77	100	177
	%	43.5%	56.5%	100.0%
p= 0.825, chi square test (Exact p)				

Table 9 Distribution of study population according to sex and ADR

SEX		ADR		Total
		Present	Absent	
Female	count	37	44	81
	%	45.7%	54.3%	100.0%
Male	Count	40	56	96
	%	41.7%	58.3%	100.0%
Total	Count	77	100	177
	%	43.5%	56.5%	100.0%

P= 0.649, chi-square test

DISCUSSION

Knowledge about the association of various ADRs with various antipsychotics can prevent their frequency as well as the severity when various factors influencing the same are taken into consideration. So the present study was conducted and the results were compared with the studies conducted earlier. In the present study, the participants were in the middle and young age groups and the male female ratio was 1.2 and the results were similar to those reported by Haddad PM *et al* [1] and Wallace M *et al*[4] . The proportion of ADRs with at least one ADR was found to be 43.5% and most of them (83.0%) being mild in severity according to modified Hartwig and Siegel scale.

Though the number of females showing adverse drug reactions was less as compared to the males but the prevalence of the same was more in them as the number of female patients under study were less 81 as compared to males which were 96 and thus percentage of females showing the ADRs is 45.7% (37/81) and in males, the same is 41.75% (40/96). It is well reported fact that the prevalence of ADRs is more in case of females than the males[5,6].

There was no significant relationship of ADR with age (p=0.83). Also there was no statistically significant relationship of ADR with sex (p=0.65) of the enrolled patients. These results are similar to those reported by many others [7, 8,9,10]. However a male female ratio of < 1 was present in their studies.

Olanzapine was the most common drug prescribed in our study followed by risperidone and quetiapine. Similar observations have been reported by Lucca JM *et al* [5]. Also olanzapine has been reported to be most commonly drug prescribed drug by other studies [8,9,10,11]. This shows that the pattern of pharmacological therapy for psychiatric diseases in these studies was similar to our study.

Olanzapine was responsible for most number of the ADRs in our study population followed by risperidone and quetapine which may be explained by the fact that these drugs were being most commonly prescribed in the study population. Olanzapine being responsible for most of the ADRs has been reported by Lucca JM *et al*[5]. The proportion of patients with ADRs varied following the use of various antipsychotic drugs. The antipsychotic drugs that were associated the maximum proportion of patients with ADRs in our study population included either clozapine alone or combination of drugs like amisulpride+aripiprazole and risperidone+ amisulpride. This may be explained on the basis of the fact that the number of patients who were receiving the above mentioned antipsychotic drugs was too less and all of them has shown at least one ADR as compared to the patients who were on other antipsychotic drugs in our study population

CONCLUSION

The present study adds to the existing information on the frequency and pattern of ADRs following antipsychotic medication from the other centers where such studies have already been conducted and also create awareness among our own health care professionals about importance of carrying out active surveillance studies regarding association of ADRs with various antipsychotic drugs. Psychiatrists and other health care professionals treating psychiatric patients should have a good knowledge about possible ADRs following antipsychotic medication and thus keep an active vigil to prevent and treat these ADRs. The establishment of an active pharmacovigilance programme (centre) is hence an essential requirement to any health institution. This will pave way to improve the quality of patient care by ensuring safer use of drugs.

References

1. Haddad, PM., Sharma, SG. 2007. Adverse effects of atypical antipsychotics: Differential risk and clinical implications. CNS. *Drugs*., 21: 911-936.
2. Bradley, PB., Hirsch, SR.1986. Pharmacology of antipsychotic drugs. The psychopharmacology and treatment of schizophrenia. Oxford Medical Publications, Chapter 2: pp 27.
3. Faich, GA., 1996. US adverse drug reaction surveillance 1984-1994. *Pharmacoepidemiol Drug. Saf.,* 5: 393-398.
4. Wallace, M. 2001. Real progress-the patient's perspective. *Int. Clin. Psychopharmacol*., 16(suppl 1): 21-24.
5. Lucca, JM., Madhan, R., Parthasarathi, G *et al*. 2014. Identification and management of adverse effects of antipsychotics in a tertiary care teaching hospital. *J. Res. Pharm. Pract.*, 3: 46-50.
6. Yonkers, KA., Kando, JC., Cole, JO, *et al*. 1992. Gender differences in pharmacokinetics and pharmacodynamics of psychotropic medication. *Am. J. Psychiatry*. 149(5): 587-595.
7. Ho, YF., Huang, HS., Lin, HN. 2002. Detecting drug-drug interactions in medication profile of psychiatric

inpatients: a two stage approach. J. *Formos. Med. Assoc* . 101: 294-297.
8. Sengupta, G., Bhowmick, S., Hazra, A *et al*. 2011. Adverse drug reaction monitoring in psychiatry out-patient department of an Indian teaching hospital. *Ind. J. Pharma* . 43 (1): 36-39.
9. Lahon, K., Shetty, HM., Paramel, A *et al*. 2012. Adverse drug reaction monitoring of antipsychotics, antidepressants and mood stabilizers in the psychiatric outpatient unit of a teaching hospital-A retrospective study. *Int. J.Pharma. Bio. Sci* . 3(1): 470-478.
10. Prajapati, HK., Joshi, ND., Trivedi, HR *et al*. 2013. Adverse Drug Reaction Monitoring In Psychiatry Outpatient Department Of A Tertiary Care Hospital. NJIRM. 4(2): 102-106.
11. Jayanthi, CR., Divyashree, M., Sushma, M. 2013. Adverse drug reactions in psychiatry outpatients: Clinical spectrum, causality and avoidability. *J. Chemical and Pharmaceutical Res*. 5 (8): 128-135.

How to cite this article:

Afkat Ahmad *et al* (2017) 'Adverse Drug Reaction Status And Relationship of ADRs With Age And Sex of The Patients on Anti-Psychotic Drugs In Out-Patient Department of A Psychiatry Hospital In Kashmir; A Prospective Observational Study ', *International Journal of Current Advanced Research,* 06(10), pp. 6525-6528.
DOI: http://dx.doi.org/10.24327/ijcar.2017.6528.0958

****