AN EVALUATION OF IMPACT ON QUALITY OF LIFE IN PATIENTS ON ANTIPSYCHOTIC THERAPY AT A TERTIARY CARE CENTRE

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ABSTRACT

BACKGROUND

Antipsychotic drugs utilisation is expanding step by step due to lifestyle changes and increased stress in day-to-day along with psychiatric disorders. Prevalence of Adverse Drug Reactions (ADRs) with antipsychotic drugs is high, which is influencing the quality-of-life of patients more than the underlying disease. Hence, this study was taken up to assess Impact on Quality-of-life in patients using antipsychotics.

MATERIALS AND METHODS

A prospective observational study was carried out in the Department of Psychiatry at Erragadda Hospital, Hyderabad for 6 months. A total of 189 patients on Antipsychotics were enrolled and Baseline Quality-of-life (WHOQOL-BREF) scale was recorded. On a fixed day in a week they were screened for ADRs, 126 adverse drug reactions (ADRs) occurred. ADRs were monitored using causality assessment scale of Naranjo algorithm. The WHOQOL-BREF scale was used to study the quality-of-life.

RESULTS

The physical and psychological domain scores of WHO-QOL BREF decrease in patients with ADRs compared to without ADRs. Of the total 189 patients, 126 ADRs occurred. Adverse drug events were mostly with olanzapine (83) followed by risperidone (71) owing to high usage in the government hospital. Majority of the events were classified as probable (34).

CONCLUSION

The study provides information on the influence of Quality-of-life patients on antipsychotics due to ADRs. Psychiatrists and other health care professionals treating psychiatric patients ought to have information about the possible ADRs and their influence on Quality-of-life following antipsychotic medication and thus should keep an active vigil to prevent, treat and alleviate the adverse health effects due to ADRs.

KEY WORDS

Antipsychotics, Naranjo Scale, WHO-QOL BREF Score.

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BACKGROUND

There are many psychiatric disorders like schizophrenia, bipolar disorder, Tourette's syndrome, etc. Along with these, due to lifestyle changes and increased stress in day-to-day life antipsychotic drugs use is increasing. These drugs are capable of causing several adverse drug reactions (ADR).^[1] Some of which may be fatal ADRs, which can lead to non-compliance and at times discontinuation of therapy.^[2] Monitoring adverse reactions in psychiatry units can play a vital role in early detection of ADRs and alerting physicians to the possibility and circumstances of such events, thereby protecting the user population from avoidable harm and improving quality-of-life. Hence, this study was taken up to assess the impact on Quality-of-life in patients using antipsychotics.

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MATERIALS AND METHODS

A prospective observational study was carried out in outpatient department of psychiatry at Erragadda Hospital, Hyderabad during January 2013 and June 2013 after Institutional Ethics Committee clearance and informed consent. Psychiatric patients of either gender aged 19 to 65 yrs., irrespective of their psychiatric diagnosis were included in the study. Patients with any acute conditions i.e. organ failure, malignancies, immunosuppressive disorders, substance abuse and any other systemic disorder other than psychiatric disorder were excluded from the study. A total of 189 patients on antipsychotics were enrolled and baseline Quality-of-life (WHOQOL-BREF) scales followed by 1-month scores were recorded. On a fixed day in a week, they were screened for suspected ADRs after initiation of antipsychotic medication. Subjects and their accompanying family members were interviewed and patient's detail history along with current and past treatment was taken. Each participant with ADRs were followed up on regular visits till the ADR resolved.

Causality of event was assessed by Naranjo's criteria. Suspected ADRs with causality less than "possible" will not be considered for further analysis. The Naranjo scale is a questionnaire designed for determining the likelihood of whether an ADR is actually due to the drug rather than the result of other factors. Probability is assigned through a score

termed definite, probable, possible or doubtful. Score can range from 0 (doubtful ADR) to ≥ 9 (definite ADR), detailed scoring is described as follows: ≥ 9 = definite ADR, 5 - 8= probable ADR, 1 - 4= possible ADR and 0= doubtful ADR. Adverse drug reaction was reported to CDSCO (central drugs standard control organisation)^[4] suspected ADR drug reporting form.

All of the participants were given the World Health Organisation Quality-of-life-Brief Form (WHOQOL-BREF) to assess their quality-of-life. The WHO Quality-of-life Assessment (WHOQOL) is a generic quality-of-life instrument that was designed to be applicable to people living under different circumstances, conditions and cultures.^[5,6] The WHOQOL is based on a purely subjective evaluation to assess the perceived quality-of-life and in this way differs from many other instruments.^[7] WHOQOL also approaches the quality-of-life as a multidimensional concept.^[8] From total 189 patients screened baseline physical and psychological domain scores of WHO-QOL BREF was compared with 1-month score and was compared with 126 patients with ADRs and 53 without ADRs. If domain scores are scaled in a positive direction (i.e. higher scores denote higher quality-of-life) and vice versa.

Statistics

Data is represented as mean $\pm$ SD and proportionality and unpaired 't' test was used to compare the quality-of-life in patients on antipsychotic drugs. $P < 0.05$ was considered statistically significant. GraphPad prism version 6 is used.

RESULTS

In our study total of 189 patients on antipsychotics were screened for suspected ADRs, out of which 126 complained with at least one adverse event, thus 66.66% of our study subjects reported ADRs. Among 126 patients, males represented 42.86% ($n = 54$) of cases with mean age 41.4 ± 3.98 yrs. and BMI of 22.4 ± 2.7 kg/m² and females 57.14% ($n = 72$) with mean age of 24.4 ± 2.88 yrs. and BMI of 29.4 ± 2.7 kg/m².

Among the psychiatric disorders treated, Schizophrenia (62%) was the commonest clinical diagnosis among these cases followed by bipolar affective disorder 27%. A few subjects were taking concomitant medicines for other disorders such as dyspepsia and hypertension. The drug history was taken very carefully in such cases before attributing suspected ADRs to the psychotropic medicines concerned-

1. Total Number of Patients for each Drug

Of all the antipsychotic drugs, olanzapine ($n = 83$) followed by risperidone ($n = 71$) were the most common drugs responsible for ADRs, Table I.

2. Adverse Effect Distribution in Study Population

Among the ADRs reported, tremors (26.50%) was the commonest ADR noted followed by weight gain (of 4 kg or more over the baseline weight- 19.60%) and sedation (15.34%) and constipation (14.49%) were the most common ADRs in decreasing order of frequency. All ADRs are tabulated in Table II.

Some interesting ADRs were noted during the course of study. One case of Olanzapine induced diabetes mellitus was noted in a 43-year-old schizophrenic patient. She was on

Olanzapine therapy for last 2 years and developed symptoms of polyuria and polydipsia. She had no history of raised blood sugar prior to starting Olanzapine. Her fasting blood glucose level was 237 mg/dL at the time of study, but returned to normal on substitution of Olanzapine with Risperidone. We also found a rare case of Risperidone induced rabbit syndrome (perioral tremors) in a 34-year-old male Paranoid Schizophrenic patient. One male patient of 42 years developed. Oculogyric crisis immediately within 24 hours after a single dose of parenteral haloperidol.

3. Causality Assessment using Naranjo's Algorithm Scoring

Causality assessment revealed that 61.10% belonged to "Probable" category, whereas 30.16% were of "Possible" type according to Naranjo's scale- Table III. No ADR encountered turned out to be fatal, life-threatening. Some of the events such as tremor were temporarily disabling, but were managed by the clinicians with corrective medication (such as trihexyphenidyl hydrochloride) or dose modification. Drug induced Parkinsonism was countered with Benztropine tablet. Even drug-holidays were being tried.

4. Comparison of World Health Organisation Quality-of-life-BREF Scores on Physical, Psychological Domain

In our study, only physical and psychological domain scores were recorded which are tabulated in Table IV.

Physical Domain Score: It was observed that there was significant improvement in physical domain score taken at 1-month post treatment (14.89 ± 1.61) compared to baseline scores (14.02 ± 2.08) in patients on antipsychotics ($***p < 0.001$).

It showed that there was a significant decrease in physical domain score taken at 1-month post treatment (12.96 ± 2.11) in patients who had ADRs compared to their baseline scores ($***p < 0.001$). Indicating that ADRs in patients is causing great impact on quality-of-life and there was a significant increase in physical domain score taken at 1-month post treatment (15.26 ± 2.74) in patients without ADRs compared to their baseline scores ($***p < 0.001$). There was a significant difference in physical domain score in patients who had ADRs compared to patients without ADRs.

Psychological Domain Scores: It was observed that there was significant improvement in Psychological domain score taken at 1-month post treatment (13.88 ± 1.71) compared to baseline scores (13.28 ± 1.64) in patients on antipsychotics ($***p < 0.001$).

It showed that there was a significant decrease in Psychological domain score taken at 1-month post treatment (12.12 ± 2.13) in patients who had ADRs compared to their baseline scores ($***p < 0.001$). Indicating that ADRs in patients is causing great impact on quality-of-life. And there was a significant increase in Psychological domain score taken at 1-month post treatment (14.17 ± 1.99) in patients without ADRs compared to their baseline scores ($***p < 0.001$).

Psychological domain scores were significantly affected in patients with ADRs (12.12 ± 2.13) compared with patients without ADR (14.17 ± 1.99) ($***p < 0.001$). It was observed that patients with ADRs had significantly lower scores of quality-of-life than patients without ADRs implying that quality-of-life is significantly influenced in patients with ADR compared to patients without ADR.

Drug	No. of Patients with ADRs
Olanzapine	83
Risperidone	71
Haloperidol	17
Quetiapine	13
Amisulpride	7

Table I. Total Number of Patients with ADRs for Each Drug

Side Effect	No. of Patients- ADRs
Tremors	36 (28.7%)
Sedation	27 (21.33%)
Weight gain	23 (18.25%)
Amenorrhoea	17 (13.45%)
Tardive dyskinesia	13 (10.37%)
Constipation, Tachycardia	8 (6.35%) cases for each ADR
Insomnia	7 (5.53%)
Postural hypotension	5 (3.95%)
Dyspepsia	4 (3.16%)
Dryness of mouth, Sexual dysfunction, Parkinsonism	3 (2.73%) cases for each ADR
Anorexia, Hypersalivation	2 (1.58%) cases for each ADR
Perioral tremors, Oculogyric crisis, Impaired glucose tolerance, Frank diabetes, Blurring of vision	1 (0.79%) case for each ADR
Total	126

Table II. Incidence of ADRs in Patients

Category Based on Naranjo's Scale	Patients in each Category
Highly probable/ definite	6.35%
Probable	61.1%
Possible	30.16%
Doubtful/ unlikely	6.24%

Table III. Causality assessment using Naranjo's Algorithm in Patients

Domains	Baseline	1-month	With ADRs	Without ADRs
Physical domain	14.02 ± 2.08	14.89 ± 1.61***	12.96 ± 2.11***	15.26 ± 2.74***
Psychological domain	13.28 ± 1.64	13.88 ± 1.71***	12.12 ± 2.13***	14.17 ± 1.99***

Table IV. Comparison of World Health Organisation Quality-of-life-BREF Scores on Physical, Psychological Domain

***P<0.001

DISCUSSION

The present study has reported the impact on quality-of-life due to antipsychotic drugs in psychiatry department in the south Indian context. In our study, we have observed that quality-of-life improved in patients on antipsychotic drugs compared to baseline score without treatment. But patients with ADRs had significantly lower scores of quality-of-life than patients without ADRs implying that quality-of-life is significantly influenced in patients with ADR compared to patients without ADR. Most common drug which caused ADRs was olanzapine. The central nervous system was among the common organ systems affected by adverse drug events. Majority of ADRs (61.10%) belonged to "Probable" category in Causality assessment. Patients with ADRs had

significantly lower scores of quality-of-life than patients without ADRs implying that quality-of-life is significantly influenced in patients with ADR compared to patients without ADR.

In a study by Genevieve M Hale et al, it was observed that 56 who received antipsychotics 10 suspected ADRs occurred attributed to antipsychotic use. QTc prolongation was the most observed ADR.^[9] In our study, 126 suspected ADRs occurred attributed to antipsychotic drug use. Tremors were the most observed ADR. Finding in our study was not in accordance with the study mentioned above.

In Chawla Shalini et al study, total 224 patients enrolled were followed up for a period of 3 months. Of the total 224 patients, 38 adverse drug events occurred. Adverse drug events were mostly with risperidone (10) followed by olanzapine (8) owing to high usage. Majority of the events were classified as probable (34). The occurrence of adverse drug events decreased the scores on physical and psychological domain scores of WHO-QOL BREF at 3 months compared to baseline.^[10] In our study from a total of 189 patients screened for ADRs, in 126 patients ADR occurred. Adverse drug events were mostly with olanzapine (83) followed by risperidone (71) owing to its high usage in government hospital where it is available free of cost. Majority of the events were classified as probable (61.1%). Occurrence of ADRs had significantly lower scores of quality-of-life than patients without ADRs implying that quality-of-life is significantly influenced in patients with ADR compared to patients without ADR. This is in consistent with the available evidence from the existing studies.

A 6-month prospective observation was conducted at an academic psychiatric hospital in New England. This study reported atypical antipsychotic (37%) to be the most commonly implicated drugs for ADRs. The CNS (66.5%), cardiovascular and dermatological reactions were among the common organ systems affected by adverse drug events.^[11] In our study, the central nervous system was among the common organ systems affected by adverse drug events. The finding in our study is in accordance with the study mentioned above. We could find only one study comparing the association of ADRs with the quality-of-life.^[10] But in our study we compared the quality-of-life with ADRs and without ADRs in south Indian context. With this study, we have tried to determine the influence of ADRs on quality-of-life in patients.

CONCLUSION

The findings from this study confirm that there is an improvement in quality-of-life in psychiatric patients after the treatment is started. But due to high prevalence of ADRs associated with the use of various antipsychotics in our study population, the quality-of-life in psychiatric patients with ADRs significantly decrease compared to patients without ADRs. The presence of an adverse drug reaction compromised the physical and psychological aspect of quality-of-life of patients during the study period. Psychiatrists and other health care professionals treating psychiatric patients ought to have information about the possible ADRs and their seriousness following antipsychotic medication and thus should keep an active vigil to prevent, treat and alleviate the adverse health effects due to ADRs as a result can improve quality-of-life.

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