



## COMPARING SAFETY PROFILE OF OLANZAPINE AND RISPERIDONE IN THE TREATMENT OF SCHIZOPHRENIA

**Dr. Sharma  
Supriya**

PG resident (department of pharmacology) Department of Pharmacology, MGM Medical College and Hospital, Kamothe, Navi Mumbai-410209

**Dr. Deshmukh  
Yeshwant A\***

professor and hod(department of pharmacology), mgm medical college and general hospital,navi mumbai,maharashtra,india. \*Corresponding Author

**ABSTRACT** **OBJECTIVE :** To compare the safety profile of olanzapine and risperidone in the treatment of schizophrenia. **METHODS & MATERIALS:** The study was conducted in MGM medical college Navi Mumbai between October 2012 to September 2014. The study included 110 patients of schizophrenia. The extra pyramidal symptoms were assessed with the help of the ESRS (Extra Pyramidal Symptom Rating Scale). **RESULTS :** There was significant increase in the score of ESRS scale for both olanzapine and risperidone but the increase was more in the risperidone group. **CONCLUSION :** Olanzapine produces fewer extrapyramidal side effects as compared to Risperidone.

**KEYWORDS :** olanzapine, risperidone, safety profile

### INTRODUCTION

- Schizophrenia is a clinical syndrome of variable but profoundly disruptive psychopathology that involves cognition, emotion, perception, and other aspects of behavior. The expression of these manifestations varies across patients and over time, but the effect of the illness is always severe and is usually long lasting.
- Schizophrenia is a severe form of mental illness affecting 7 per thousand of the adult population, mostly in the age group of 15-35 years. Though the incidence is low (3 - 10,000), the prevalence is high due to chronicity[1].

The discovery of antipsychotics in the 1950s revolutionized the treatment of schizophrenia and focused on the positive symptoms. The advent of the novel antipsychotics during the last 15 years represents a significant improvement over the effectiveness of conventional antipsychotics. Among the advantages of these second generation antipsychotics over first generation antipsychotics are reduced extrapyramidal side effects[2-3], reduced risk for tardive dyskinesia[4-5] and possibly beneficial effects on cognitive functioning[6] and negative symptomatology.

### Aims and Objectives

• **AIM:**  
"To compare safety profile of olanzapine and risperidone in the treatment of schizophrenia"

- **OBJECTIVES:**
- To study and compare the safety profile of olanzapine and risperidone in the treatment of schizophrenia. This will be done with the help of the ESRS(Extra pyramidal symptom rating scale) SCALE

### MATERIALS AND METHODS

- **STUDY AREA :** The study was performed at the Department of Pharmacology in collaboration with Department of Psychiatry, MGM medical college, Kamothe, Navi-Mumbai. Here patients were offered outpatient consultation and admission when necessary. **SELECTION OF CASES :** The participants were of at least 18 years of age and below 60 years who had provided written informed consent before any study procedure was initiated. **DURATION OF THE STUDY:** October 2012 to September 2014. **SAMPLE SIZE :** 110

### INCLUSION CRITERIA

- 1) Patients fulfilling DSM 4 criteria for schizophrenia, 2) Age of the patients was 18 to 60 yrs, 3) Patients were outpatients or inpatients hospitalised for less than or equal to 4 weeks at the time of treatment, 4) Those patients and their relatives who were willing to give consent for the treatment.

### EXCLUSION CRITERIA

- 1) Patients requiring ECT or hospitalisation. Patients with hypertension, cardiac disorder. 2) Pregnant or nursing females. 3) Patients having any past history or physical disorder that is likely to deteriorate during participation. 4) Patients with suicidal tendencies. 5) Unable to provide informed consent.
- The study was an open label, prospective, randomised comparative clinical trial.
- Ethics approval from Institutional Ethics Review Committee (IERC) was obtained.
- 55 Patients received Olanzapine (5 to 20 mg ) & 55 patients received the drug Risperidone (2 mg to 6mg). The two drugs were given according to the randomization table. The patients were evaluated at: Baseline and were followed up on 7th day (1 week) ,14th day (2 weeks) , 28th day (4weeks) And 42nd day (6 weeks). The patients were evaluated on EXTRAPYRAMIDAL SYMPTOM RATING SCALE(ESRS) scale on baseline and subsequent follow up.
- **STATISTICAL ANALYSIS :** Data is presented using Descriptive statistics, Graphs and Charts. Further analysis was done using ONE WAY ANOVA TEST (The F test) & INDEPENDENT SAMPLE t-test. All means are expressed as mean + standard deviation. The critical levels of significance of the results were considered at 0.05 levels i.e.  $P < 0.05$  was considered significant.

### RESULTS

#### EFFECT ON THE EXTRA PYRAMIDAL SYMPTOM RATING SCALE (ESRS)

#### EFFECT OF OLANZAPINE AND RISPERIDONE ON THE QUESTIONNAIRE SCALE OF ESRS

**Table 1: Effect of Risperidone on Questionnaire**

Week	N	Mean	SD	SEM	F-stat	p-value
Baseline	55	1.436	1.450	0.196	93.043	< 0.001**
First	55	1.436	1.450	0.196		
Second	55	2.255	1.554	0.210		
Fourth	55	3.382	1.929	0.260		
Sixth	55	5.145	2.844	0.384		

The result indicates that there is significant increase in the score according to duration ( $p < 0.001$ ). One - way ANNOVA test was used. The score at baseline was 1.436 which increased to 5.145 at the end of 6th week. The mean change in the score was 3.709.

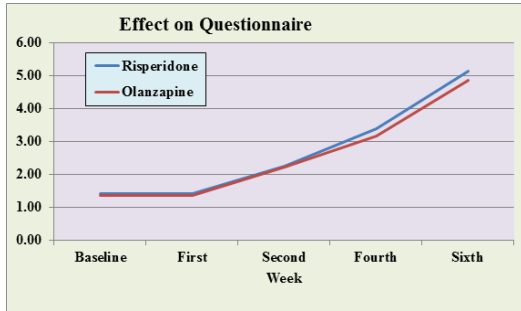
**Table 2: Effect of Olanzapine on Questionnaire**

Week	N	Mean	SD	SEM	F-stat	p-value
Baseline	55	1.364	1.406	0.190	77.033	< 0.001**
First	55	1.364	1.406	0.190		

Second	55	2.236	1.465	0.198		
Fourth	55	3.164	1.903	0.257		
Sixth	55	4.855	3.009	0.406		

The result indicates that there is significant increase in the score according to duration ( $p < 0.001$ ). One - way ANNOVA test was used. The score at baseline was 1.364 which increased to 4.855 at the end of 6th week. The mean change in the score was 3.491. In the questionnaire scale the scores increased exhibiting symptoms of mild severity in both the groups.

**FIG 1. : Effect of Olanzapine and risperidone on Questionnaire**



**EFFECT OF OLANZAPINE AND RISPERIDONE ON THE PARKINSON'S SCALE**

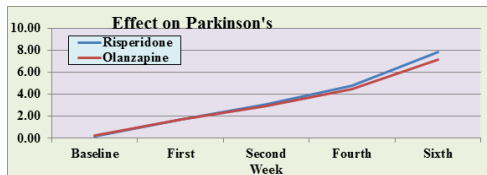
Week	N	Mean	SD	SEM	F-stat	p-value
Baseline	55	.182	.512	.069	200.804	< 0.001**
First	55	1.673	1.019	.137		
Second	55	3.055	1.177	.159		
Fourth	55	4.800	2.181	.294		
Sixth	54	7.870	3.732	.508		

The result indicates that there is significant increase in the score according to duration ( $p < 0.001$ ). One - way ANNOVA test was used. The mean change in the Parkinsonism scale was 7.688.

Week	N	Mean	SD	SEM	F-stat	p-value
Baseline	55	.236	.576	.078	124.413	< 0.001**
First	55	1.709	1.031	.139		
Second	55	2.909	1.266	.171		
Fourth	55	4.473	2.372	.320		
Sixth	54	7.148	4.324	.588		

The result indicates that there is significant increase in the score according to duration ( $p < 0.001$ ). One - way ANNOVA test was used. The mean change in the Parkinsonism scale was 7.182. On parkinsonism examination the scores in both the groups increased significantly ( $p < 0.001$ ).

**Fig 2. effect of olanzaine and risperidone on parkinson's scale**



**EFFECT OF OLANZAPINE AND RISPERIDONE ON DYSTONIASCALE**

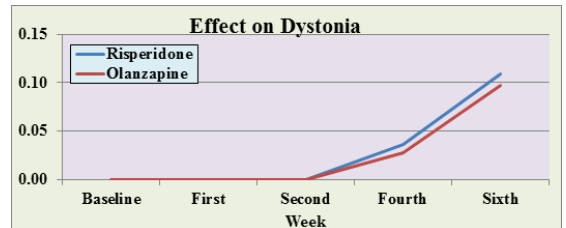
Week	N	Mean	SD	SEM	F-stat	p-value
Baseline	55	0.00	0.00	0.00	62.035	< 0.001**
First	55	0.000	0.000	0.000		
Second	55	0.000	0.000	0.000		
Fourth	55	0.036	0.189	0.025		
Sixth	55	0.109	0.369	0.050		

The result indicates that there is significant increase in the score according to duration ( $p < 0.001$ ). One - way ANNOVA test was used.

Week	N	Mean	SD	SEM	F-stat	p-value
Baseline	55	0.00	0.00	0.00	61.327	< 0.001**
First	55	0.000	0.000	0.000		
Second	55	0.000	0.000	0.000		
Fourth	55	.027	.189	.025		
Sixth	55	.097	.369	.050		

The result indicates that there is significant increase in the score according to duration ( $p < 0.001$ ). One - way ANNOVA test was used. There was not a single patient of acute torsion dystonia in either of the two groups. In the risperidone group 2 patients presented with mild (2) score and 1 patient presented with very mild (1) score on the 7 point ESRS SCALE. In the olanzapine group 2 patients presented with very mild (1) score on the 7 point ESRS scale.

**Fig 2. effect of olanzaine and risperidone on parkinson's scale**



**EFFECT OF OLANZAPINE AND RISPERIDONE ON DYSKINESIASCALE**

Week	N	Mean	SD	SEM	F-stat	p-value
Baseline	55	0.00	0.00	0.00	54.315	< 0.001**
First	55	.018	.135	.018		
Second	55	.018	.135	.018		
Fourth	55	.109	.416	.056		
Sixth	55	.145	.558	.075		

The result indicates that there is significant increase in the score according to duration ( $p < 0.001$ ). One - way ANNOVA test was used. The mean change in the score at the end of the study was 0.145

Week	N	Mean	SD	SEM	F-stat	p-value
Baseline	55	0.00	0.00	0.00	71.274	< 0.001**
First	55	0.000	0.000	0.000		
Second	55	0.018	0.135	0.018		
Fourth	55	0.091	0.348	0.047		
Sixth	55	0.109	0.416	0.056		

The above table indicates the effect of Olanzapine on Dyskinesia score. The result indicates that there is significant increase in the score according to duration ( $p < 0.001$ ). One - way ANNOVA test was used. The mean change in the score at the end of the study was 0.109.

**DISCUSSION :**

**EFFECT ON EXTRAPYRAMIDAL SYMPTOMS:**

In the questionnaire scale the mean change in score (i.e. increase) in the risperidone group was 3.709 and in the olanzapine group was 3.491. In the parkinsonism score the mean change was 7.182 in the olanzapine group and was 7.688 in the risperidone group. Not a single patient from either of the group presented with acute torsion dystonia. But in the risperidone group 2 patients presented with mild (2) score and 1 patient presented with very mild score (1) on the 7 point ESRS scale. In the olanzapine group 2 patients presented with very mild (1) score on the ESRS scale. The mean change in dyskinesia scores in the risperidone group and olanzapine group was 0.145 and 0.109 respectively.

Tran P V et al (1997) did a Double blind comparison of olanzapine versus risperidone in the treatment of schizophrenia and other psychotic disorders. Statistically significantly fewer adverse events were reported by olanzapine-treated patients than by their risperidone-treated counterparts.

Saeed Shoja Shafti and Mahsa Gilanipoor in 2014 conducted A Comparative Study between Olanzapine and Risperidone in the Management of Schizophrenia. Conclusion of the study is that

olanzapine showed superior efficacy with respect to negative symptoms, along with lesser extrapyramidal side effects, in comparison with risperidone.

**CONCLUSION:**

Olanzapine produced fewer extrapyramidal side-effects as compared to Risperidone on the 7-point EPRS Scale. Thus, the conclusion of our study is that Olanzapine still remains the treatment of choice for schizophrenia.

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