Original Article

Comparison of Efficacy of Risperidone and Placebo in the Patients Suffering from Schizophrenia in Punjab, Pakistan

Tayyuba Irum, Shabnam Seher and Arooj Iqbal

ABSTRACT

Objective: To examine efficacy of Risperidone for treatment of schizophrenia in comparison with placebo.
Study Design: Randomized clinical study.
Place and Duration of Study: This study was conducted at the Department of Psychiatry, Allied hospital, Faisalabad from May 2016 to May 2017.
Materials and Methods: Approval of the study was taken from Ethical Review Board of the Allied hospital, Faisalabad. Data was collected through universal sampling technique and analyzed by using computer software SPSS version 22, mean and SD was calculated for quantitative variables like age and frequency (percentages) were calculated for qualitative variables like gender, education status and symptoms of disease. Chi square test was applied to see effect modification; p value ≤ 0.05 was taken as significant.
Results: Total 80 respondents were included in this study, 24 (30%) were female and 56 (70%) were males and Placebo and Risperidone groups were equally distributed. Outcome of our study was improvement in symptoms of disease after drug use. From placebo group, almost all study participants were fall in condition not improved group (97.5%) and in Risperidone group more half (80%) study participants fall in condition improved group. Value of Chi square (49.6) at 1 degree of freedom was found statistically significant (0.000) indicating significant relationship of disease status and treatment group.
Conclusion: Significantly greater improvements in relieving the symptoms and improving the quality of life and overall well-being were demonstrated in patients randomized to Risperidone compared to placebo.

Key Words: Risperidone, Schizophrenia, Atypical, Antipsychotics

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INTRODUCTION

Every year about 1% of people of total population suffer from schizophrenia worldwide[1]. Generally symptoms of schizophrenia appear in early age and become worse throughout life. It is not a curable disease yet[2]. In 1950s chlorpromazine has been introduced chemist's start working on treatment of schizophrenia more aggressively and many drugs discovered[3]. After all these efforts and drug invention Schizophrenia still a degenerative disorder and its pathophysiology and causes are unknown[4].

Usually schizophrenia labeled as single disease but it is group of symptoms or set of disorders due to changes in brain neurochemicals[5]. Every group of symptoms demand a different treatment plan consisted of single drug or combination of drugs. After the use of antipsychotic drugs as symptoms improves same time their side effects reduce the quality of life and neurological disorder also becomes poor even permanent functional disorder. Some more side effects include metabolic disorder, weight gain and weak motor response[6].

An antipsychotic drug clozapine was introduced in 1971 and considered a drug of choice in among antipsychotic drugs medicines[7]. Clinical results and pharmacology of clozapine is too much different from 1st generation (haloperidol, chlorpromazine). Clozapine called as atypical antipsychotic because it does not causes extra pyramidal adverse effects[8]. Now in these days a wide range of drugs distribution have been described between 1st and 2nd generation antipsychotics. Drugs in both generations have different mechanism of action and agonist and antagonist properties[9].

Advantages of risperidone over other antipsychotics (haloperidol) are rapid onset of action, less extrapyramidal adverse effects and excellent effectiveness over negative symptoms of schizophrenia. In some reports it was described that risperidone also have short hospital stay in old schizophrenic patients[8,10,11].

This review focuses on the pharmacology and clinical data of risperidone, a novel compound that is currently in Phase III development for the treatment of schizophrenia and other neuropsychiatric and neurodegenerative disorders.

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MATERIALS AND METHODS

It was a randomized clinical trial conducted in the department of Psychiatry, Allied hospital, Faisalabad, from May 2016 to May 2017. Approval of the study was taken from Ethical Review Board of the Allied hospital, Faisalabad. Eighty patients (80) were selected through universal sampling. Patients of Schizophrenia were randomly divided into two equal groups into Risperidone group and Placebo group. Informed consent was taken from the patients after briefing about the study purpose. It was a double blind study so patients and doctors both do not have idea about Risperidone group and Placebo group. Pregnant and lactating women, patients already on neuroleptic disease, drug abusers and who were refused to participate in study were excluded.

In Risperidone group patients were given Risperidone 1mg BD on first day, 2 mg twice on 2nd day, 3 mg twice a day on day three and 3 mg twice was remained continue for seven days. Positive and Negative Syndrome Scale (PANSS) was used to check the symptoms severity of Schizophrenia patients.

Data was collected through questionnaire and entered into SPSS version 23. Analysis was divided in two main parts. First one was descriptive and the second was inferential statistics. Descriptive statistics (percentages and frequency tables) were generated and reported for socio demographic variables and groups. Relationship and efficacy of both groups was also checked. P value ≤ 0.05 was considered as significant.

RESULTS

Total 80 respondents were included in the study and their age distribution was as 24 respondents (30%) were in age category ranging from 19-29 years, 44 (55%) were in range of 30-39 years and 12 (15%) respondents were having 40 years and above age group. Out of total 80 respondents 24 (30%) were females and 56 (70%) were males and Placebo and Risperidone groups were equally distributed.

Their education status revealed that of the total 80 respondents, 25 (31.2%) were illiterate, 37 (46.3%) were primary, 14 (17.5%) were metric, and 4 (5%) of them were having intermediate and above table-1. Frequency of signs and symptoms of schizophrenia were being checked and frequencies are being given in table-2.

Disease status and treatment group were cross tabulated and their findings were statistically significant. From placebo group, almost all study participants were fall in condition not improved group (97.5%) and in Risperidone group more half (80%) study participants fall in condition improved group. Value of Chi square (49.6) at 1 degree of freedom was found statistically significant (0.000) indicating significant relationship of disease status and treatment group given in table-3.

Disease status and age were cross tabulated and their findings were statistically in significant. The highest group among condition improved (40.9%) was from age category 30-39 and condition not improved were from 40 and above age group. Value of Chi square (2.06) at 2 degree of freedom was found statistically in significant (0.356) indicating in significant relationship of disease status and treatment group given in table-4.

Disease status was as our outcome variable and was cross tabulated with gender and findings were statistically significant. From female group majority of participants (70.8%) fell in condition improved and from male group majority of participants fell in condition not improved category. Value of Chi square (12.4) at 1 degree of freedom was found statistically significant (0.000) indicating significant relationship of disease status and gender given in table-5.

Disease status was also cross tabulated with educational status of the participants and findings were statistically significant. There were surprised findings regarding educational status and disease condition. From the primary educational status, more than half (59.5%) of the participants were in condition improved category and all of the participants who from intermediate and above educational category were from condition not improved category. Value of Chi square (14.6) at 3 degree of freedom was found statistically significant (0.002) indicating significant relationship of disease status and education given in table-6.

Table No.1: Demographics

Age Category	Frequency (%)
19-29 Years	24 (30%)
30-39 Years	44 (55%)
40 and above	12 (15%)
Gender	
Female	24 (30%)
Male	56 (70%)
Education Categories	
Illiterate	25 (31.2%)
Primary	37 (46.3%)
Metric	14 (17.5%)
Intermediate and above	4 (5.0%)

Table No.2: Schizophrenia Signs and symptoms in Study Participants

Sr. #	Sign	Positive in Participants
		Yes (%)
1	Hallucination	21 (26.3%)
2	Delusions	35 (43.8%)
3	Disordered Thinking	38 (47.5%)
4	Word Salad	57 (71.3%)
5	Social Withdrawal	62 (76.3%)
6	Loss of Motivation	42 (52.5%)
7	Loss of Judgment	20 (25.0%)
8	Less Response	45 (56.3%)

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Table No.3: Cross Tabulation of Disease Status and Treatment Groups

Group	Disease Status		X^2Results
	Condition Improved (Less than median)	**Condition Not Improved** (Equal to or above median)	
Placebo	1 (2.5%)	39 (97.5%)	X^2= 49.6, df=1, P= 0.000
Risperidone	32 (80.0%)	8 (20%)	

Table No.4: Inferential results of Disease Status and Age Groups

Age Group	Disease Status		X^2Results
	Condition Improved (Less than median)	**Condition Not Improved** (Equal to or above median)	
19-29 Years	12 (50%)	12 (50%)	
30-39 Years	18 (40.9%)	26 (59.1%)	X^2= 2.06, df=2, P= 0.356
40 and above	3 (25%)	9 (75%)	

Table No.5: Inferential results of Disease Status and Gender

Gender	Disease Status		X^2Results
	Condition Improved (Less than median)	**Condition Not Improved** (Equal to or above median)	
Female	17 (70.8%)	7 (29.2%)	X^2= 12.4, df=1, P= 0.000
Male	16 (28.6%)	40 (71.4%)	

Table No.6: Inferential results of Disease Status and Educational Status

Education	Disease Status		X^2 Results
	Condition Improved (Less than median)	**Condition Not Improved** (Equal to or above median)	
Illiterate	10 (40%)	15 (60%)	
Primary	22 (59.5%)	15 (40.5%)	X^2=14.6, df=3, P= 0.002
Metric	1 (7.1%)	13 (92.9%)	
Intermediate and above	0 (0.0%)	4 (100%)	

DISCUSSION

Risperidone become a new competitor in treatment of schizophrenia, and its efficacy confirmed by many comparative studies with haloperidol and antipsychotic drugs. In a study Guy et al[12] concluded that risperidone is more efficient and shows a markable improvement when compared with other drugs global impressions scale. In another study conducted by Kay et al[13] in 1968 reported that risperidone gain a greater decrease in schizophrenia symptoms and clinical outcomes when compared on brief psychiatric scale and positive, negative scale.

A total number of 80 (100%) respondents were included in this study, 24 (30%) were females and 56 (70%) were males. Results of our study shown that, percentage of symptoms improvement with use of placebo was lower as compared risperidone group. In a study Tamara Melink et al[14] compared atypical and typical antipsychotics with placebo and reported that, atypical antipsychotic have better outcomes and more advantages over typical drugs in treatment of reflective schizophrenia. Findings of our study are also comparable with our findings.

Marder et al[15] conducted a study 1994 on risperidone in the treatment of schizophrenia and concluded that risperidone is a effective and safe antipsychotic against schizophrenia (both in positive and negative). In the treatment of schizophrenia role of atypical antipsychotic medicines is well defined and their role in maintenance of schizophrenia is also known, but very few studies available about its role in acute schizophrenia treatment. Here is a study conducted by Raedler TJ et al[16] in 2004 to investigate the role of risperidone in management of acute schizophrenia. In his study he concluded that it is a well tolerated medicine in patients of acute schizophrenia.

Few studies have been conducted in era of 1970s and 1980s for prevention of schizophrenia with long term use of antipsychotics in comparison with placebo[17]. In view of these trials it was reported that continuous use of antipsychotic drugs reduces the chance of hospitalization. In 2012 Lancet[18] conducted a study on relapse prevention of schizophrenia with antipsychotics and concluded that antipsychotic use for long term maintenance of schizophrenia is beneficial for patients.

Rattehalli RD et al[19] conducted a review on role of risperidone as compared to placebo and concluded that risperidone is more effective drug for treatment of schizophrenia when compared with placebo, another advantages of risperidone is that patient compliance is also good and patients level of comfort is also high. Some adverse effects of these drugs limit the use of risperidone. Results of our study are comparable with this review conclusion.

Pajonk FG et al[20] conducted a study on Risperidone: an open-label, observational study of the efficacy,

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tolerability, and prescribing behavior in acutely exacerbated patients with schizophrenia and concluded that in treatment of exacerbated schizophrenia risperidone is very effective and well tolerated. These results are also identical to our results.

CONCLUSION

Significantly greater improvements in relieving the symptoms and improving the quality of life and overall well-being were demonstrated in patients randomized to risperidone compared to placebo. The effect was more pronounced in the risperidone group. Patient satisfaction improved significantly and patient preference for their medicine favored rispiridone120 mg versus placebo.

Author's Contribution:

Concept & Design of Study: Tayyuba Irum
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Conflict of Interest: The study has no conflict of interest to declare by any author.

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