The International Journal of Psychosocial Rehabilitation
Volume 18, Number 2
July 2013– June 2014

Risperidone and Social Outcome in Schizophrenia: A One Year Follow-up Study

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Citation:
Shrivastava A, Shah N, Sonavane S, & DeSousa A (2014) Risperidone and Social Outcome in Schizophrenia: A One Year Follow-up Study. International Journal of Psychosocial Rehabilitation. Vol 18(2) 67-71

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Abstract

Risperidone has been found to be effective in the management of schizophrenia across various studies. Most of these studies have looked at the clinical outcomes in patients with schizophrenia. The emphasis has always been on improvement in clinical features is usually primarily assessed by various rating scales. Most of these studies are of 8-12 weeks duration and report short-term outcomes. One should also assess the improvement on various psychosocial measures as clinical improvement may not give the clear picture of recovery. It is also important to look at the long-term outcome in schizoprenia. So the present study was envisaged with the intention to study the clinical as well psychosocial outcome at the end of one year in patients of schizophrenia on Risperidone. 50 consecutive patients of schizophrenia, diagnosed as per the DSM-IV criteria, fulfilling the selection criteria were followed-up and treated with Risperidone over a period of one year. Improvement was assessed using Positive and Negative Symptom Scale (PANSS), Clinical Global Improvement – Severity (CGI-S) and seven psychosocial parameters viz. social functioning, productivity, economic independence, education, suicidality, re-hospitalization and exacerbation. Predefined operational criteria were used to rate the patients on these seven psychosocial parameters. A statistically significant improvement was noticed with Risperidone therapy on PANSS and CGIS at the end of study period of one year. This was associated with a clinically significant improvement on all the various psychosocial parameters. A significant improvement was observed on clinical as well as psychosocial parameters in the patients of schizophrenia over a period of one year with Risperidone therapy.

Key words – Risperidone, social outcome, psychosocial, outcome.

Introduction

Many patients of schizophrenia may continue to have impairment in psychosocial and occupational functioning in spite of significant improvement in clinical features like delusions and hallucinations (Lin, Wood, & Young, 2013). Therefore, it has been emphasized that in order to get a comprehensive idea about improvement, one has to assess improvement in psychosocial and occupational functioning as well, along with clinical improvement, not only after a couple of months but over a long-term period (Fiszdon, & Reddy, 2012).

Risperidone is an atypical antipsychotic that has been widely in the management of patients with schizophrenia (Emsley, & Oosthuizen, 2004). Majority of the studies with Risperidone have looked at the short-term clinical outcome (Eberhard, Levander, & Lindstrom, 2009). Very few studies have evaluated the psychosocial outcome over long-term with Risperidone therapy in schizophrenia (Haro, & Salvador-Carulla, 2006). Hence, the present study was envisaged to study the psychosocial outcome along with clinical outcome in patients of schizophrenia at the end of 1 year with Risperidone treatment.

Methodology

The study was carried out in a tertiary centre for schizophrenia management. The potential candidates and their accompanying relatives attending the outpatient department of the center were explained the nature and purpose of this study. Those who expressed their willingness to participate in the study by signing the informed consent form were screened as per the following selection criteria. The following inclusion and exclusion criteria were used for the study.

Inclusion criteria :

1. Patients of schizophrenia who fulfilled the DSM-IV criteria.

2. Patients who were either drug naïve or those who were on a single antipsychotic medication other than Risperidone but were unable to tolerate it.

Exclusion Criteria :

1. Patients who have received Risperidone anytime in the past and have discontinued it due to lack of efficacy or side-effects.

2. Patients who had any other concomitant psychiatric disorder like substance use disorder which was likely to interfere with the study.

3. Patients who had any other concomitant medical disorder like seizure disorder which was likely to interfere with the study.

3. Patients who were pregnant, lactating or who were unwilling to use contraceptive measures during the study period.

5. Patient who required intensive psychiatric intervention as they were either harmful to self or others.

6. Patients who had received electroconvulsive therapy (ECT) in the past 3 months.

A total of 50 patients meeting the inclusion and exclusion criteria were selected for the study.

Patients who fulfilled the selection criteria were rated on the Positive and Negative Symptom Scale for Schizophrenia (PANSS) and on seven psychosocial outcome parameters (Social functioning, Productivity, Economic independence, Education, Suicidality, Rehospitalization, Exacerbation) using operational criteria and a lickert type rating from 0 to 4 as shown in Table 1. Please note that in the first 4 psychosocial parameters higher the score better the functioning, while in the last 3 parameters lower the score better the functioning.

Table 1 – Assessment of various psychosocial domains

Scores Areas	0	1	2	3	4
Social Functioning	Withdrawn behavior	Expressed desire of interaction	. Definitive evidence of improved functioning	Improvement in functioning and relationship	Functioning with satisfaction
Productivity	Unproductive	Expression of productivity	Occasional Productivity	Productive with support	Productive without support
Economic Independence	Complete dependence	Desire to earn	Attempt with failure	Attempt with success	Satisfactorily independent
Education	Unable to resume	Feels confident but unable to start	Attempt but not sustained	Sustained without satisfaction	Sustained with satisfaction
Suicidality	No intent	Occasional death wish	Contemplating suicide	Experiencing suicidal crisis	Attempted suicide
Rehospitalization	Not required	Required unrelated to current illness	Required due to side effects	Required due to additional stress	Required due to relapse
Exacerbation	No exacerbation	Mild behavioral exacerbation	Moderate exacerbation	Severe exacerbation	Severe exacerbation with hospitalization

After the baseline rating on PANSS and on the above mentioned seven psychosocial parameters, patients were started on Risperidone (2 mg) at bed-time. Patients were asked to follow-up, initially every week for a period of 4 weeks during which dose of the medication was titrated up to 6-8 mg/day. Concomitant medication such as Trihexiphenydyl (4-6 mg/day) and Clonazepam (0.5 -2 mg/day) were added as and when required. Subsequently patients were followed-up on the monthly basis till the end of the study period of 1 year. During each follow-up visit, patients were asked to report any adverse event experienced by them. At the end of the study period of 1 year, patients were again rated on PANSS and above mentioned seven psychosocial parameters using same operational criteria.

Results

There were an almost equal number of male and female subjects in the study. There were 34 males and 26 female patients. All 50 patients enrolled in the study completed the study with no drop outs. This was due to the fact the patient was paid a transport allowance for each visit to ensure compliance and a telephonic reminder of the visit was made. As is evident from Table 2, a statistically significant reduction was observed in the scores on all the four parameters on the PANSS scale suggesting a substantial clinical improvement in patients of schizophrenia with Risperidone over one year of treatment. On assessing the scores on the seven psychosocial parameters (Table 3), it was noted that Risperidone helped in improved in all areas of psychosocial functioning with over 62% of patients reporting improvement in social functioning, productivity, economic independence and education while over 82% patients showed an improvement in suicidality, risk of rehospitalization and acute exacerbation of symptoms. The adverse effect profile when monitored for Risperidone therapy was also favorable with weight gain (6%) and extrapyramidal symptoms (16%) being the commonest side effects reported. Sexual side effects were reported with 12% patients while amenorrhea was reported by 6 of the female subjects.

Table 2 – Improvement on the PANSS scores over a one year period

PANSS	Mean (SD) Baseline score	Mean (SD) Score at 1 year	t value	p value
Positive symptoms score	30.4 (6.9)	17.5 (4.1)	11.3649	< 0.0001*
Negative symptoms score	24.5 (6.8)	13.7 (4.1)	10.776	< 0.0001*
General psychopathology score	49.5 (13.3)	32.1 (12.2)	6.8172	0.0001*
Total PANSS Score	104.6 (12.6)	64.3 (12.2)	16.2882	< 0.0001*

* significant

Table 3 – Improvement on various domains of psychosocial functioning

Psychosocial parameters	Number of patients rated as 0 or 1	Number of patients rated as 2, 3, or 4
Social Functioning	16 (32%)	34 (68%)
Productivity	15 (30%)	35 (70%)
Economic Independence	19 (38%)	31 (62%)
Education	10 (20%)	40 (80%)
Suicidality	45 (90%)	05 (10%)
Rehospitalization	44 (88%)	06 (12%)
Exacerbation	43 (86%)	07 (14%)

* In the first 4 psychosocial parameters higher the score better the functioning, while in the last 3 parameters lower the score better the functioning.

Discussion

Risperidone has been shown in research studies to have a good efficacy in the management of schizophrenia. The reduction in PANSS scores were in keeping with previous efficacy and clinical improvement studies of Risperidone (Ristner, Gibel, Perelroyzen, Kurs, Jabarin, & Ratner, 2004). A study that compared Risperidone to Olanzapine head on has also found that Risperidone has better efficacy that Olnazapine on psychosocial parameters (McGrath &

Tempier, 2005). In another large study of 1029 subjects with schizophrenia and related disorders it was noted that most antipsychotics help in improving psychosocial outcome in schizophrenia though in early stage psychosis with results in chronic schizophrenia being unknown (Guo, Zhang, Zai, & Early Stage Schizophrenia Outcome Study Investigators, 2012).

It is also well known that no medication can alone improvement psychosocial functioning but needs to be coupled with social skills training, psychotherapy and family psychoeducation (Awad & Voruganti, 2004). Our study was a small circumscribed study limited to just 50 patients with schizophrenia and cannot be generalized to all settings. We need further studies that compare chronic and early stage schizophrenia, studies that compare various atypical antipsychotics and studies that combine various pharmacological and non pharmacological treatments to assess psychosocial function improvement in detail. This is however one of the few studies that looked at psychosocial functioning in seven domains and further longitudinal studies in larger number of subjects in various settings are warranted.

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