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Evaluation of Risperidone: A study on selected patients in Peshawar, Pakistan

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Abstract

Risperidone is classified as an atypical antipsychotic and is recognized as an effective treatment for psychotic disorders in adults. However, there is limited knowledge regarding its use in young children. This study aimed to assess the safety profile of risperidone in children under five years old who were receiving treatment for behavioral issues linked to various childhood disorders. The study was conducted in a hospital in Peshawar, Pakistan. Diagnoses of common childhood disorders, particularly those associated with disruptive behavioral problems, were made using the Diagnostic and Statistical Manual (DSM-IV). Symptom severity and improvement were measured using the Clinical Global Impression-Severity (CGI-S) and Clinical Global Impression-Improvement (CGI-I) scales. Informed consent was obtained from the children's parents before initiating risperidone treatment. A total of 10 patients were included in the study, with the following diagnoses: Pervasive Developmental Disorder (PDD) with Attention Deficit Hyperactivity Disorder (ADHD) (n=3), Global Developmental Delay (n=2), and CP with epilepsy (n=5). Baseline CGI scores ranged from 5 to 6, while endpoint scores were between 1 and 2. Initial assessments, including lipid profiles, fasting blood sugar levels, and electrocardiograms (ECGs), were recorded and compared before and after starting risperidone treatment. The prescribed dose ranged from 0.5 to 2 mg per day. The most common side effects observed were sedation and weight gain in a few patients. No life-threatening adverse effects were reported. Based on the findings, risperidone appears to be well tolerated in children under five years of age over a one-year period, demonstrating improvements in target symptoms .

Keywords: Young Children, Risperidone, Safety, Efficacy.

INTRODUCTION

Risperidone is an atypical antipsychotic commonly used to treat conditions such as acute mania in bipolar disorder, schizophrenia, persistent aggression, Alzheimer's disease, and conduct disorder in adults. While it was initially approved for adult use, its application has been extended to younger populations, specifically those aged 5 to 16 years, following approval by the US FDA (Hannah & Sophie, 2009). Research suggests that risperidone is generally safe and effective within this age range. However, there is limited evidence regarding its safety and efficacy in children under the age of 5. Given this gap in literature, in present study, we investigate its effectiveness in this selected age group.

MATERIAL AND METHODS

The study was conducted at a tertiary care hospital in Nairobi, Kenya, focusing on the Department of Psychiatry and Child Neurology. All patients included were referred from the outpatient department. We included children diagnosed with Pervasive Developmental Disorder (PDD), ADHD, Intellectual Disability, and Cerebral Palsy (American Psychiatric Association, 1994). Common symptoms observed in these patients included aggression, irritability, and uncontrollable behavior. Informed consent was obtained from the parents or guardians of all participants. Treatment started with a low dose of risperidone, which was gradually increased. Symptom severity and improvement were assessed using the Clinical Global Impression-Severity (CGI-S) and Clinical Global Impression-Improvement (CGI-I) scales (Guy, 1976). Follow-ups were conducted over a period of four weeks to monitor clinical improvement and side effects, with some patients being observed for up to one year. Additional evaluations, including electrocardiograms (ECG), lipid profiles, fasting blood sugar levels, and baseline body weight, were also recorded and monitored throughout the study.

RESULTS

In the present study, a total of 10 patients were included. Among these, 3 patients were diagnosed with pervasive developmental disorder (PDD) along with attention deficit hyperactive disorder (ADHD), 2 patients had Global development delay with epilepsy, and 5 patients had CP with epilepsy. The baseline Clinical Global Impression-Severity (CGI-S) scores ranged from 5 to 6, while the endpoint scores improved to 1 to 2. Risperidone treatment was initiated at doses between 0.25 mg and 0.5 mg per day. In cases where patients showed minimal or no response to the initial dose, we gradually increased the dosage. Dose adjustments were made for 10 out of the 12 patients. No side effects were observed in 4 patients, while 2 patients experienced abnormal weight gain.

Table 1

Shows Base Line and Final Assessment of Weight and Fasting Blood Sugar Level along With Demographic Details

Gender	Age in Years	Diagnosis Results	Weight – Pre Treatment	Weight- Post Treatment	FBS baseline	FBS after 1 year
Male	3	GDD with Epilepsy	10.5	11.25	84	91
Male	4	GDD with Epilepsy	12.5	12.75	79	91
Male	5	CP with Epilepsy	11.5	13	69	73
Male	3	CP with Epilepsy	13.25	14.25	80	81
Female	4	PDD with AHDD	12.25	13.30	81	83
Male	4	CP with Epilepsy	11.75	12.65	91	93
Male	3	PDD with ADHD	13.5	14.75	85	81
Male	4	CP with Epilepsy	12.75	14.25	89	79
Female	5	CP with Epilepsy	12.25	13.65	81	83
Male	5	PDD with AHDD	14.25	14.55	82	87

None of the patients in our study experienced severe side effects, such as extrapyramidal side effects (EPS). Additional assessments, including lipid profiles and fasting blood sugar levels, revealed no significant increases compared to baseline measurements. Normal fasting blood sugar levels were defined as less than 100 mg/dl, total cholesterol levels as less than 300 mg/dl, and triglyceride levels as less than 150 mg/dl.

Table-2
Shows Base Line and Final Lipid Profile, CGI Scores along with Drug Side Effects

Lipid Profile Baseline		Lipid Profile after 1 Year		Side Effects after 4 Weeks	Side Effects after 6 Months	Side Effects after 1 Year	CGI Score	CGI Score after 1 Year
TC	TG	TC	TG					
114	69	135	68	Sedation	Weight Gain	No Effects	5	1
133	71	163	60	No Effects	No Effects	No Effects	5	1
171	76	171	63	No Effects	No Effects	No Effects	6	2
143	69	174	69	No Effects	No Effects	No Effects	6	1
131	55	143	68	Sedation	Weight Gain	No Effects	5	2
121	63	135	59	Sedation	No Effects	No Effects	6	1
123	78	135	58	No Effects	No Effects	No Effects	5	1
131	69	163	53	No Effects	No Effects	No Effects	5	2
109	63	137	83	Sedation	Weight Gain	No Effects	5	1
118	60	129	79	No Effects	No Effects	No Effects	6	1
113	73	137	78	No Effects	No Effects	No Effects	6	2
139	85	143	85	No Effects	No Effects	No Effects	5	2

Discussion

Behavioral problems can contribute to the development of various disorders and have become a significant concern in recent times. Common behavioral issues include self-injurious behavior, hyperactivity, aggression, and irritability, which are often associated with pervasive developmental disorders (PDD), intellectual disability, and ADHD (Valsamma & Gururaj, 2005). It is estimated that these behavioral problems affect approximately 4% to 9% of all children (Campbell, Gonzalez, & Silva, 1992; Scott, 1998). Such behaviors not only interfere with rehabilitative efforts but also present serious challenges for parents, caregivers, educators, and society at large (James, James, Bhavik, Pegeen, Daniel, & Michael, 2002). When behavioral issues disrupt daily functioning, it is recommended that parents or guardians consider pharmacological interventions. Typical antipsychotics, such as haloperidol, are commonly used for this purpose but are associated with a high risk of extrapyramidal symptoms (EPS). In contrast, atypical antipsychotics, including risperidone, are preferred due to their lower likelihood of causing such side effects. Although risperidone has been shown to effectively manage behavioral symptoms in adults, limited data is available on its use in children under five years of age (Roberto & Valeria, 2008). However, studies indicate that risperidone may be effective in addressing behavioral problems in children (Kewley, 1999). It is important to note that psychosocial interventions should be prioritized when treating behavioral issues in children (Murat, Suleyman, & Mucahit, 2011). Nevertheless, psychopharmacological treatment is necessary when the symptoms cause significant distress to parents and other caregivers (Gleason, Egger, Emsile, Greenhill, & Kowatch, 2008). Our study supports the use of risperidone in managing disruptive behaviors in preschool-aged children, aligning with previous research. For instance, studies have demonstrated the effectiveness of risperidone in treating aggressive behavior in this age group (Cesena, Gonzalez-Heydrich, Szigethy, Kohlenberg, & DeMaso, 2002). Risperidone is commonly prescribed for conditions such as disruptive behavior disorder, ADHD, intellectual disability, and PDD (Murat, Suleyman, & Mucahit, 2011). In our study, risperidone was administered to children under five years of age, with weight gain and sedation being the most frequently observed side effects. Overall, our findings indicate that risperidone, combined with

appropriate psychosocial support, is an effective treatment option for managing behavioral problems in young children.

FINAL THOUGHTS AND LIMITATIONS

Based on the findings of our study, we conclude that risperidone is well tolerated in children under five years of age. Significant improvement in targeted symptoms was observed by both the research team and the children's parents. This improvement was also linked to a reduced family burden and an enhanced quality of life. The limitations of this study include a small sample size, which may affect the generalizability of the findings. Therefore, we recommend future research with a larger sample size, utilizing a placebo-controlled or double-blind design to provide more robust and reliable results.

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