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Research Article

Evaluating the Efficacy and Safety of Risperidone in the Management of Pediatric Autism Spectrum Disorder

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Keywords
Autism Spectrum Disorder; risperidone; children; behavioral symptoms; efficacy; safety; irritability.

Abstract

Background: Risperidone is an atypical antipsychotic commonly used to manage severe behavioral symptoms associated with autism spectrum disorder (ASD) in children.

Objective: To evaluate the efficacy and safety of risperidone in children with ASD and associated behavioral symptoms.

Methodology: A prospective, hospital-based clinical study was conducted from March 2024 to February 2025 at four tertiary-care teaching hospitals in Pakistan: Pakistan Institute of Medical Sciences (PIMS), Islamabad; DHQ Teaching Hospital, Dera Ismail Khan; Mufti Mehmood Memorial Teaching Hospital, Dera Ismail Khan; and Sir Ganga Ram Hospital, Lahore. The study included 120 children aged 5–16 years who had been diagnosed with ASD and presented with associated behavioral symptoms. Participants received risperidone and were assessed using the Aberrant Behavior Checklist at baseline and at 4, 8, and 12 weeks. Treatment-related adverse effects, body weight, and BMI were also monitored. Data were analyzed using IBM SPSS Statistics version 27. Continuous variables were analyzed using paired-samples t-test and repeated-measures ANOVA, while categorical variables were assessed using the Chi-square test. A p-value <0.05 was considered statistically significant.

Results: Among 120 participants, 111 (92.50%) completed 12 weeks, of whom 81 (72.97%) achieved a clinically meaningful response. Marked response occurred in 34 (30.63%) and moderate response in 47 (42.34%) participants. Adverse effects were reported in 61 (50.83%), most commonly increased appetite in 38 (31.67%), weight gain in 34 (28.33%), and sedation in 27 (22.50%).

Conclusion: Risperidone demonstrated beneficial behavioral effects but requires

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careful monitoring for adverse effects.

Introduction

Autism spectrum disorder (ASD) is a complex, neurodevelopmental condition that involves ongoing problems with social communication and interaction, along with repetitive, restricted patterns of behavior, interests or activities [1,2]. They tend to appear in early childhood and can greatly impact learning, family life and daily functioning [3]. Many children suffer from a range of additional behavioral complications such as irritability, aggression, intense tantrums, self-injurious behaviors, hyperactivity, and emotional dysregulation (disinhibition) in addition to ASD. These additional symptoms can present significant difficulties for children, parents and teachers and can impact learning and behavior interventions [5].

Treatment of ASD is multidisciplinary covering behavioral, educational, psychological and supportive treatment [6]. When the child's behavior poses a threat to safety, or negatively impacts the child's functioning and/or ability to engage with non-pharmacological treatments, however, pharmacologic treatment may be warranted [7]. Irritability/disruptive behaviours in children and adolescents with ASD have been extensively studied with an atypical antipsychotic, risperidone, which is mainly antagonistic to dopamine D2 and serotonin 5-HT2A receptors [8]. A number of clinical studies have already shown an improvement in the aggression, tantrums and self-injurious behaviors of appropriately selected pediatric patients [9].

Though risperidone carries with it some beneficial-effects, it also has a number of adverse-effects that need to be monitored. Some of the most frequent concerns include weight gain, increased appetite, sedation, fatigue, and metabolic abnormalities. Some extrapyramidal symptoms and higher levels of prolactin can also result, especially from prolonged use [10,11]. Hence, the assessment of treatment related adverse effects, along with therapeutic response should be mandatory when considering risperidone in children.

Research Objective

The objective of this study was to evaluate the efficacy and safety of risperidone in the management of behavioral symptoms associated with autism spectrum disorder in children, with particular emphasis on clinical improvement and the occurrence of treatment-related adverse effects.

Materials and Methods

Study Design and Setting

The efficacy and safety of risperidone were evaluated in a hospital-based, prospective clinical study conducted among children diagnosed with autism spectrum disorder (ASD) presenting with behavioral symptoms. The study was conducted at four tertiary-care teaching hospitals in Pakistan: Pakistan Institute of Medical Sciences (PIMS), Islamabad; DHQ Teaching Hospital, Dera Ismail Khan; Mufti Mehmood Memorial Teaching Hospital, Dera Ismail Khan; and Sir Ganga Ram Hospital, Lahore. The study was carried out over a period of one year, from March 2024 to February 2025.

Study Population

Children ages 5–16 who had a confirmed clinical diagnosis of ASD and clinically significant behavioral symptoms, such as irritability, aggression, tantrums or disruptive behaviors, were included in the study. Children who had hypersensitivity to risperidone, serious uncontrolled medical conditions, were being treated with an antipsychotic at the same time or did not have adequate follow-up were excluded. Parents/legal guardians gave informed consent in writing.

Sample Size

The number of pediatric patients in the study was 120. The sample size was determined to allow for an adequate number of participants to assess the changes in behavioral symptoms and adverse effects of treatment that occurred over the course of the study.

Sampling Technique

Consecutive sampling was used to recruit participants. All the children who presented at the study site were evaluated and recruited

consecutively for the required sample size of 120 children.

Risperidone Treatment Protocol

Risperidone was administered in line with FDA approved pediatric recommendations for the use of risperidone in irritability associated with autistic disorder. Children that weighed less than 20 kg were given the starting dose of 0.25 mg per day and children more than 20 kg were given 0.5 mg per day. The dose was adjusted incrementally based upon clinical response and tolerability. The total daily dose was given as a single dose or in divided doses as per clinical discretion [12].

Assessment of Efficacy and Safety

The participants were evaluated at baseline, and at 4, 8 and 12 weeks after treatment. The Aberrant Behavior Checklist (ABC) was used to assess efficacy, especially with regards to irritability, aggression, tantrums and other disruptive behaviors. Safety was evaluated by treatment-emergent adverse events such as sedation, appetite, weight gain, fatigue and extrapyramidal symptoms. All the relevant clinical parameters and body weight were followed up.

Outcome Measures

Change in severity of behavioral symptoms (ABC score) from baseline to week 12 was the primary outcome. Secondary outcomes were individual ABC subscale score changes, body weight and BMI changes, treatment tolerability, and occurrence and severity of AE's.

Statistical Analysis

IBM SPSS Statistics software (version 27) SPSS 27 was used for data analysis. Data are presented as mean ± SD for continuous variables and as frequencies and percentages for categorical variables. If continuous clinical or behavioral data were normally distributed, the paired-samples t-test was used to compare data from baseline and follow-up assessments. The Chi-square test was used to compare categorical variables, including the frequency of adverse events. Where appropriate, repeated-measures analysis of variance (ANOVA) was used for comparisons across baseline, 4-week, 8-week and 12-week assessments. A p-value <0.05 was considered statistically significant.

Ethical Considerations

Institutional Review Committee (IRC) approval was obtained before initiation of the study. Written informed consent was obtained from the parents or legally authorized guardians of all participants before enrollment. The confidentiality and privacy of participants were maintained throughout the study. Participants were monitored for adverse effects and other clinically significant events during follow-up, and any such events were appropriately evaluated and managed by the treating clinical care team as required.

Results

A total of 120 children with ASD were included in the study, with a mean age of 9.8 ± 3.1 years (Table 1). The majority were male (91, 75.83%) compared with females (29, 24.17%). The mean body weight was 34.7 ± 13.2 kg, while the mean BMI was 18.4 ± 3.5 kg/m². Among behavioral problems, irritability was the most common (103, 85.83%), followed by severe tantrums (84, 70.00%), emotional dysregulation (79, 65.83%), aggression (76, 63.33%), and hyperactivity (72, 60.00%). The mean baseline ABC total score was 72.6 ± 14.8, indicating substantial behavioral symptom severity at study entry.

Table 1: Baseline demographic and clinical characteristics of pediatric patients with ASD

Category	Characteristic	Number of Patients (n)	Frequency (%) / Mean ± SD
Age	5–8 years	39	32.50
	9–12 years	48	40.00
	13–16 years	33	27.50
	Mean age (years)	9.8 ± 3.1	
Gender	Male	91	75.83
	Female	29	24.17

Anthropometric characteristics	Body weight (kg)	34.7 ± 13.2	
	BMI (kg/m²)	18.4 ± 3.5	
Behavioral problems	Irritability	103	85.83
	Severe tantrums	84	70.00
	Aggression	76	63.33
	Hyperactivity	72	60.00
	Disruptive behavior	69	57.50
	Emotional dysregulation	79	65.83
	Self-injurious behavior	31	25.83
Behavioral severity	Baseline ABC total score	72.6 ± 14.8	

Significant improvements in behavioral symptoms were observed following risperidone treatment over the 12-week follow-up period (Table 2). The mean ABC total score decreased progressively from 72.6 ± 14.8 at baseline to 62.3 ± 13.7 at 4 weeks, 54.4 ± 12.8 at 8 weeks, and 48.3 ± 11.9 at 12 weeks, corresponding to a 33.47% overall reduction ($F=61.37$, $p<0.001$). Irritability showed the largest improvement, decreasing by 44.74%, followed by hyperactivity/ noncompliance (39.80%). Lethargy/social withdrawal, stereotypic behavior, and inappropriate speech also improved significantly, with all domains demonstrating statistically significant changes ($p\leq0.002$).

Table 2: Changes in Aberrant Behavior Checklist scores during 12 weeks of risperidone treatment

ABC domain	Baseline Mean ± SD	4 weeks Mean ± SD	8 weeks Mean ± SD	12 weeks Mean ± SD	Mean Change	Reduction (%)	F-value	p-value
Irritability	22.8 ± 5.4	18.1 ± 5.0	14.9 ± 4.7	12.6 ± 4.4	−10.2	44.74	52.84	<0.001
Lethargy/social withdrawal	9.7 ± 4.1	8.8 ± 3.9	7.9 ± 3.7	7.2 ± 3.5	−2.5	25.77	18.62	<0.001
Stereotypic behavior	8.9 ± 3.8	8.4 ± 3.6	7.8 ± 3.5	7.4 ± 3.3	−1.5	16.85	5.27	0.002
Hyperactivity/noncompliance	19.6 ± 5.7	16.1 ± 5.2	13.7 ± 4.9	11.8 ± 4.6	−7.8	39.80	43.76	<0.001
Inappropriate speech	11.6 ± 4.3	10.9 ± 4.1	10.1 ± 3.9	9.3 ± 3.7	−2.3	19.83	14.93	<0.001
ABC total score	72.6 ± 14.8	62.3 ± 13.7	54.4 ± 12.8	48.3 ± 11.9	−24.3	33.47	61.37	<0.001

Among the 111 children who completed the 12-week assessment, 81 (72.97%) achieved an overall treatment response, defined as at least a 25% reduction in ABC total score (figure 1). A marked response of ≥50% reduction was observed in 34 patients (30.63%), while 47 (42.34%) demonstrated a moderate response of 25–49%. In contrast, 22 (19.82%) showed minimal response and 8 (7.21%) showed no improvement or worsening. The distribution of treatment responses was statistically significant ($\chi^2=39.08$, $df=3$, $p<0.001$), indicating an overall favorable clinical response to risperidone.

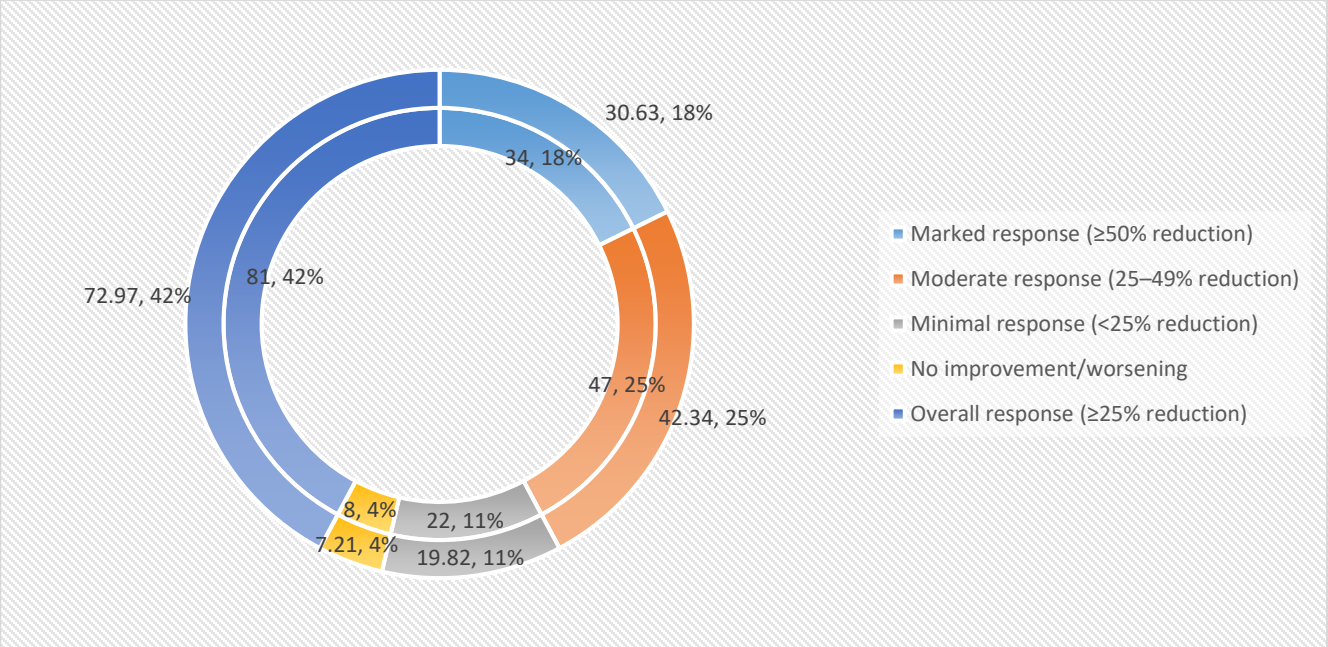

Figure 1: Clinical response to risperidone at 12 weeks.
Note: Chi-square goodness-of-fit test: $\chi^2 = 39.08$, $df = 3$, $p < 0.001$. Percentages are based on participants completing the 12-week assessment (n=111).

A significant increase in body weight and BMI was observed during the 12 weeks of risperidone treatment (table 3). Mean body weight increased from 34.7 ± 13.2 kg at baseline to 35.8 ± 13.4 kg at 4 weeks, 37.0 ± 13.7 kg at 8 weeks, and 38.1 ± 14.0 kg at 12 weeks (F=24.67, p<0.001). Similarly, mean BMI increased from 18.4 ± 3.5 to 19.5 ± 3.8 kg/m² over the study period (F=13.84, p<0.001). These findings demonstrate significant anthropometric changes during risperidone therapy and are relevant to its safety profile.

Table 3: Changes in body weight and BMI during risperidone treatment

Parameter	Baseline	4 weeks	8 weeks	12 weeks	Repeated-measures ANOVA F	df	p-value
Body weight (kg)	34.7 ± 13.2	35.8 ± 13.4	37.0 ± 13.7	38.1 ± 14.0	24.67	3, 330	<0.001
BMI (kg/m²)	18.4 ± 3.5	18.8 ± 3.6	19.1 ± 3.7	19.5 ± 3.8	13.84	3, 330	<0.001

Treatment-emergent adverse effects were reported in 61 (50.83%) of the 120 participants (Figure 2). The most frequently reported adverse effects were increased appetite (38, 31.67%), weight gain (34, 28.33%), and sedation/drowsiness (27, 22.50%). Fatigue occurred in 19 (15.83%), while constipation was reported in 15 (12.50%). Less frequent events included headache (11, 9.17%), extrapyramidal symptoms (7, 5.83%), and prolactin-related symptoms (5, 4.17%). Because participants could experience more than one adverse effect, the reported percentages were not expected to total 100%.

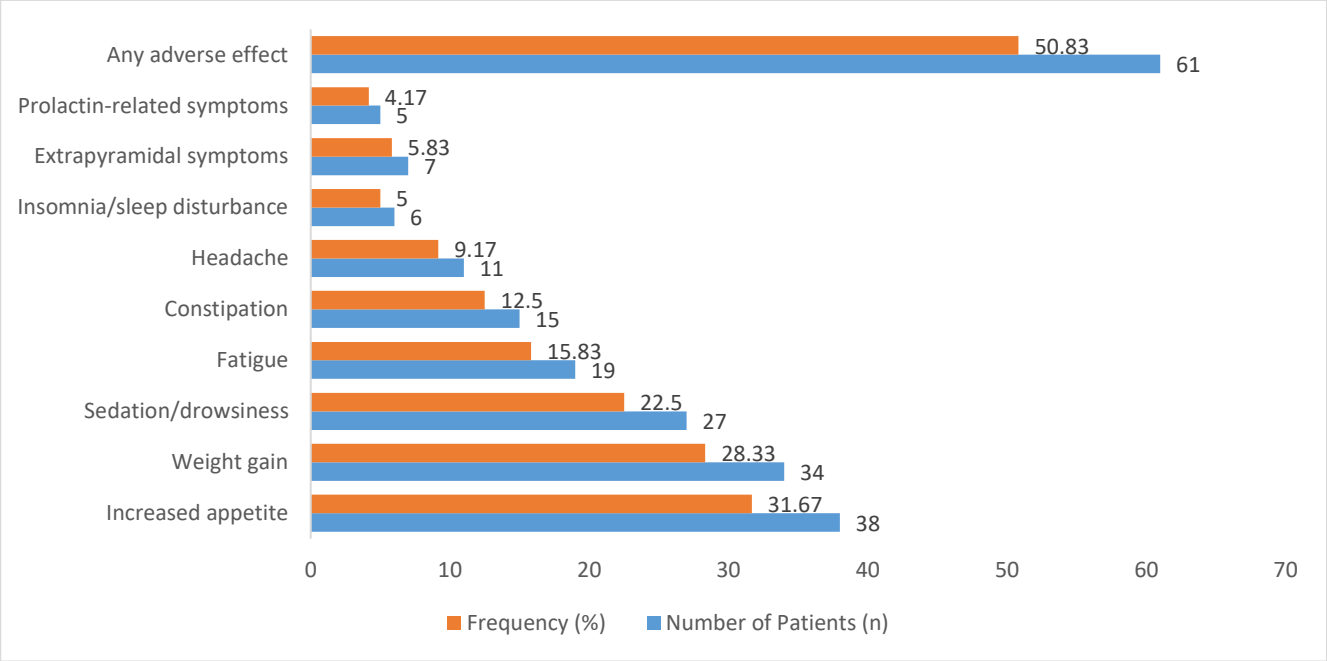

Figure 2: Treatment-Emergent Adverse Effects.
Note: Percentages are based on the total study population (N=120). Participants could experience more than one adverse effect; therefore, percentages do not sum to 100%.

Treatment response was significantly associated with the presence of baseline aggression and severe tantrums (Table 4). Among children with baseline aggression, 58 (76.32%) were responders compared with 18 (23.68%) non-responders (χ^2=5.91, p=0.015). Similarly, among those with severe tantrums, 62 (73.81%) were responders and 22 (26.19%) were non-responders (χ^2=4.68, p=0.030). In contrast, treatment response was not significantly associated with sex (p=0.359) or age group (p=0.156). These findings suggest that baseline behavioral characteristics, particularly aggression and severe tantrums, were associated with treatment response.

Table 4: Association between treatment response and baseline characteristics

Variable	Category	Responders n=81; (%)	Non-responders n=30; (%)	χ^2	df	p-value
Sex	Male	63 (69.23)	28 (30.77)	0.84	1	0.359
	Female	18 (62.07)	11 (37.93)			
Age group	5–8 years	29 (74.36)	10 (25.64)	3.72	2	0.156
	9–12 years	33 (68.75)	15 (31.25)			
	13–16 years	19 (57.58)	14 (42.42)			
Baseline aggression	Present	58 (76.32)	18 (23.68)	5.91	1	0.015
	Absent	23 (52.27)	21 (47.73)			
Severe tantrums	Present	62 (73.81)	22 (26.19)	4.68	1	0.030
	Absent	19 (65.52)	10 (34.48)			

Note: Response was defined as ≥25% reduction in ABC total score at 12 weeks. Chi-square test was used.

Study completion and treatment adherence remained relatively high throughout the 12-week follow-up (Figure 3). A total of 117 (97.50%) participants completed the 4-week assessment, 114 (95.00%) completed the 8-week assessment, and 111 (92.50%) completed the 12-week assessment.

Premature treatment discontinuation occurred in 9 (7.50%) participants, including 4 (3.33%) due to adverse effects, 2 (1.67%) due to inadequate response, and 3 (2.50%) lost to follow-up. Overall, 103 (85.83%) participants demonstrated good treatment adherence, whereas 17 (14.17%) had suboptimal adherence.

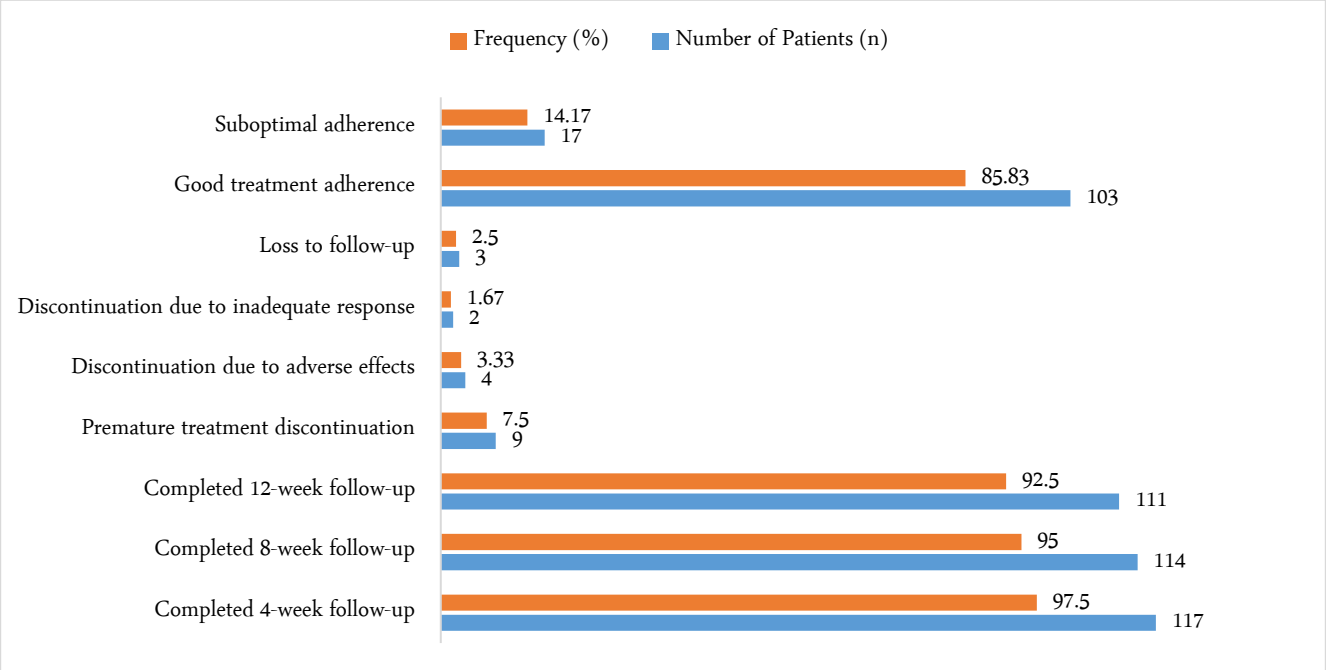

Figure 3: Treatment Adherence and Study Completion

Discussion

In the present study, 12 weeks of risperidone treatment resulted in significant improvement in behavioral symptoms. The mean ABC total score decreased from 72.6 ± 14.8 at baseline to 48.3 ± 11.9 at 12 weeks, representing a 33.47% reduction ($F=61.37$, $p<0.001$). Hyperactivity/noncompliance (39.80%) and irritability (44.74%) were the two other areas that improved the most. These results are similar to those of a randomized controlled study conducted by Kent et al. (2013), which found that the ABC-Irritability score was significantly lower in risperidone-treated patients than in placebo-treated patients: the mean change in the ABC-Irritability score in the high-dose risperidone group was −12.4, whereas the corresponding score in the placebo group was −3.5 ($p<0.001$). A systematic review of seven randomized trials with 372 patients also found risperidone to be effective for treating ABC-Irritability in patients compared to placebo [13].

The overall decrease seen in our cohort further reinforces the effectiveness of risperidone. In 111 children who completed the 12-week assessment, 81 (72.97%) had ≥25% reduction in ABC total score, of which 34 (30.63%) had a marked response and 47 (42.34%) had a moderate response. In addition, the children with baseline aggression had a significantly higher response rate (76.32%, $p=0.015$) whereas those with severe tantrums had a response rate of 73.81% ($p=0.030$). The results support the data indicating that risperidone is especially effective for the disruptive symptoms of behavior, including aggression, tantrums and irritability. In a systematic review of RCTs, Maneeton et al. (2018) reported a significant pooled difference between risperidone and placebo in favour of risperidone in the areas of ABC-Irritability and treatment response. The relatively high response rate in our study could therefore be due to children who had obvious disruptive behaviours being included [14].

Our study also showed positive gains in each individual area of behavior. All measures showed significant decreases in irritation (44.74%), lethargy/social withdrawal (25.77%), stereotypic behavior (16.85%), and hyperactivity/noncompliance (39.80%), and inappropriate speech (19.83%). The results are consistent with the systematic review and meta-

analysis published by Sousa et al. (2021) who found risperidone to have beneficial effects on several ABC domains, including lethargy and inappropriate speech, as well as weight gain being an important limitation [15]. Therefore, our results support the notion that risperidone first alleviates associated behavioral problems and not the core social communication disabilities of ASD.

However, there were important anthropometric changes noted. Mean body weight increased from 34.7 ± 13.2 kg to 38.1 ± 14.0 kg, while BMI increased from 18.4 ± 3.5 to 19.5 ± 3.8 kg/m² over 12 weeks ($p<0.001$). 38 (31.67%) experienced increased appetite and 34 (28.33%) weight gain. Our results are similar to those reported in a randomized trial of Scahill et al. (2016) in which children treated with risperidone gained 5.4 ± 3.4 kg over 24 weeks ($p<0.0001$), along with a significant BMI increase and increase in metabolic parameters. The authors noted that frequent weight gain can be a risk factor for insulin resistance and metabolic syndrome, thus highlighting the importance of regular assessment of weight and metabolic parameters during the treatment with risperidone [16].

Other adverse effects in our study were: sedation/drowsiness (22.50%), fatigue (15.83%), constipation (12.50%), extrapyramidal symptoms (5.83%) and prolactin-related symptoms (4.17%), with 61 (50.83%) of the participants reporting at least one adverse effect. These results are corroborated by Kent et al. (2013), who identified increased appetite, somnolence and sedation as some of the most common AEs, especially at higher doses of risperidone [13]. Likewise, in a 21-month follow-up study by Aman et al. (2015), there were no increases in neurological side effects in children receiving long-term risperidone treatment, but there was increased appetite and weight gain. Hence, the results of the present study confirmed the known safety profile of risperidone, where metabolic and sedative adverse events are of greater concern than severe neurological events [17].

Finally, the treatment retention and adherence in our study was good, with 117 (97.50%) completing 4 weeks, 114 (95.00%) completing 8 weeks, and 111 (92.50%) completing 12 weeks. Adherence to treatment was good with 103 (85.83%) and only 9 (7.50%) individuals terminated the treatment prematurely including 4 (3.33%) due to adverse effects. The results are broadly consistent with the systematic review conducted by Maneeton et al. that concluded risperidone showed good efficacy, and similar overall acceptability when compared to placebo in pediatric ASD [17]. But the substantial decrease of ABC score in our study was accompanied by significantly increased weight and BMI (Body Mass Index), making it vital to consider metabolic risks along with efficacy. Our results overall support the use of risperidone as an effective treatment for severe behavioral symptoms in pediatric ASD provided there is individualized dosing and frequent monitoring for weight, BMI, appetite, sedation, and other side effects.

Strengths and Limitations

The prospective design, multicenter hospital-based setting, standardized 12-week follow-up, objective assessment of behavioral changes using the Aberrant Behavior Checklist (ABC), and systematic monitoring of treatment-related adverse effects are major strengths of this study. The study also provided a balanced assessment of both the efficacy and safety of risperidone in children with ASD and associated behavioral symptoms. However, several limitations should be considered. The relatively small sample size of 120 children and the hospital-based recruitment may limit the generalizability of the findings to children with ASD in other clinical or community settings. The absence of a placebo or untreated comparator group limits the ability to attribute observed behavioral improvements exclusively to risperidone, as changes may partly reflect natural variation, concurrent interventions, or other factors. Furthermore, the relatively short 12-week follow-up limits assessment of long-term treatment efficacy and metabolic or other delayed adverse effects. Consecutive sampling may also have introduced selection bias, and the lack of adjustment for potential confounding variables may have influenced the observed treatment response. Therefore, the findings should be interpreted in the context of these methodological limitations and should be confirmed through larger, controlled studies with longer follow-up periods.

Conclusion

Risperidone was found to be effective in reducing behavioral symptoms of ASD in children, especially those of irritability, hyperactivity, aggression, and severe tantrums, in conclusion. Treatment was overall well tolerated and demonstrated a good clinical response, with some treatment-related side effects such as increased appetite, weight gain, sedation, lack of energy, and others. Risperidone, therefore, should be considered a potentially useful pharmacologic tool in the treatment of children with severe behavioral issues related to ASD when used in an individualized fashion, with periodic monitoring for weight gain, neurological and other adverse effects.

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