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Efficacy of Oral Methylphenidate and Risperidone in Treatment of Attention-Deficit Hyperactivity Disorder: A Randomized Controlled Trial

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Abstract **Original Research Article**

Background: Attention Deficit Hyperactivity Disorder (ADHD) is the most common neurobehavioral disorder of childhood. Worldwide approximately 5-12% of children have ever been diagnosed with ADHD. Dysregulation of frontal-subcortical-cerebellar catecholaminergic circuits and abnormalities of the dopamine transporter are the pathophysiology of ADHD. This site is the main target for medications such as psychostimulants e.g. methylphenidate for ADHD. In addition, to other pharmacological strategies, antipsychotic drugs such as Risperidone have been used for ADHD. The use of antipsychotic medication has been rising significantly for treating DBD in ADHD children. ***Objective*:** This study aimed to compare the effectiveness of oral Methylphenidate and Risperidone in children with ADHD. ***Methods*:** Conducted as a randomized controlled trial (RCT) at the Outpatient Unit of Pediatric Neurology, National Institute of Neurosciences and Hospital in Dhaka, Bangladesh, the study enrolled eighty children aged 3-14 years diagnosed with ADHD based on DSM-V criteria and confirmed by CPRS. Participants were randomly assigned to receive either Risperidone (experimental group, n=40) or Methylphenidate (control group, n=40). The efficacy and side effects of the medications were evaluated at 3-, 6-, and 12-week intervals, with changes in Conner's parent rating subscales and behaviour in school, family, community, and peer groups compared between the groups. Statistical analysis was performed using SPSS version 23. ***Results*:** Both medications demonstrated significant improvements in oppositional, cognitive, hyperactivity, and ADHD index sub-scales by the end of treatment. While the Risperidone group showed early response by 6 weeks, a substantial proportion of the Methylphenidate group required 12 weeks to respond. Academic performance, family dynamics, community engagement, and peer interactions improved in both groups, with a notably significant improvement observed in the Risperidone group at 6 weeks compared to the control group. Reported side effects were generally mild, with insomnia, nervousness, and irritability more common in the Methylphenidate group, and weight gain and sedation more prevalent in the Risperidone group. ***Conclusion*:** Both Risperidone and Methylphenidate are equally effective and well-tolerated in treating children with ADHD. However, Risperidone demonstrated an earlier treatment response compared to Methylphenidate.

Keywords: Attention Deficit Hyperactivity Disorder (ADHD), Methylphenidate, Risperidone, Neurobehavioral disorder.

INTRODUCTION

Attention deficit/hyperactivity disorder (ADHD) is the most common neurobehavioral disorder of childhood and one of the most prevalent chronic health conditions affecting school-age children1. This disorder is characterized by developmentally inappropriate inattention, hyperactivity and impulsivity. The current DSM V criteria state that the behaviour must begin before 12 years, be present for at least 6 months,

and be present in 2 or more settings [1]. Worldwide approximately, 5-12% of children are affected with ADHD [2]. It can cause significant impairment in all areas of functioning in patients of all ages [2]. Preschool ADHD prevalence rates vary from a low of 2% in the primary care office to a high of 59% in a child psychiatry clinic [3]. One in 3 children with ADHD is diagnosed during preschool years and 47% of preschoolers diagnosed with ADHD are treated with medication alone or in combination with behavioural therapy [4, 5].

There are several well-established and evidence-based options for the treatment of children with ADHD that include psychosocial/behavioural therapies, psycho-educational interventions, and pharmacological and combined treatment [1].

In 2000, the USFDA approved the market of Methylphenidate24. Methylphenidate inhibits the reuptake of dopamine and norepinephrine by inhibiting dopamine transporter (DAT) and norepinephrine transporter (NET), which increases dopaminergic and noradrenergic activity in the prefrontal cortex and may explain its efficacy in ADHD23. Methylphenidate enhances cerebral blood flow to the dorsolateral prefrontal cortex, a cortical region believed to be of primary importance in executive control25. MPH reaches peak concentrations between 1 and 3 hours after oral intake. It is rapidly and extensively metabolized by non-microsomal hydrolytic esterases in the liver and other tissues, with an average half-life of 3 hours. Alternative to multiple daily doses are the long-acting formulations of MPH. These formulations reach peak concentration 6-8 hours after oral intake. The entire daily dose is given in the morning when using the long-acting formulations. Another sustained release form of MPH is available as a skin patch that is placed on the skin daily for 9 hours19,20. Appetite suppression, sleep disturbances, mood disturbances, exacerbation of tic disorders, increased risk of substance abuse, growth suppression, behavioural deterioration, seizure, increased heart rate, hypertension, withdrawal effects and rebound phenomenon are the common side effects of MPH [1, 6].

Risperidone is a second-generation antipsychotic drug. It is a safe & effective drug for disruptive behavioural disorder & ADHD in children26. The use of this medication started in 1993 when U.S. FDA approved it for irritability for the treatment of schizophrenia in adults. Later in 2006 the FDA also approved the Risperidone use for treating irritability, aggression and hyperactivity related to ASD in adults and children at least 5 years old. This drug is one of the few antipsychotic medications suitable for pediatric patients [7-10]. The mechanism of action of Risperidone is associated with high affinity for D2 and 5HTA2 (dopamine and serotonin) receptors respectively. However, it also has an affinity for other receptors like α1 (adrenergic), α2- (adrenergic) and H1 (histaminergic). It is believed that the dopamine and serotonin receptors antagonism is responsible for the beneficial effect in some ASD symptoms and reduced extrapyramidal symptoms compared with typical antipsychotics [11-13].

Risperidone and Methylphenidate both have been used to treat ADHD for many years. Several RCTs were done like, other study, where these two drugs either independently or combinedly were trialed and compared with each other. 11 But the efficacy and safety of these two drugs were not extensively compared in Bangladesh. So this study was done to compare the safety and efficacy of oral Methylphenidate and Risperidone in children with ADHD.

OBJECTIVE: To compare the efficacy and safety of oral Methylphenidate and Risperidone among ADHD children.

METHODOLOGY

Type of Study:
The present study was a randomized controlled trial.

Place of Study: Outpatient Department of Pediatric Neurology, National Institute of Neurosciences and Hospital, Dhaka.

Duration of Study: January 2022 to December 2022

Study Population:
All 3-14-year-old ADHD cases attending the NINS OPD and requiring medical treatment were the study population. The following enrollment criteria were employed to select the required number of patients

Enrollment Criteria:
Inclusion Criteria:
Children and adolescents aged 3-14 years with a primary diagnosis of ADHD based on DSM V (annexure I) and confirmation by Conner's parent rating scale who required drug treatment.

Exclusion Criteria:

- With comorbid psychiatric disorder, autism spectrum disorder, anxiety disorder, mood disorder, mental retardation, pervasive developmental disorder.
- Taken other psycho stimulant, antiepileptic drugs within 2 weeks
- With serious medical disorders (epilepsy, metabolic disorder, genetic disorder, gastrointestinal disorder). Exclusion was done clinically.

Sample and Sampling
DSM-V was applied to all the consecutive suspected ADHD cases. If the child had features consistent with ADHD according to DSM-V, then Conner's parent rating scale (Revised) short form was filled up by the parents or caregiver with the help of a

clinical psychologist and in the presence of the researcher in the psychological assessment room (6th floor) of the Department of Pediatrics Neurology of National Institute of Neurosciences and Hospital (NINSH) for confirmation of diagnosis and classification of ADHD. The children who were diagnosed with ADHD according to Conner's Parent Rating Scale were included in the study.

Sample Size Calculation:

Sample size calculation is as follows:

$$n = \frac{P1\,(100-P1) + P2\,(100-P2)}{(P1-P2)^2} \times (Z\alpha + Z\beta)^2$$

$P1$ (Treatment group response) = 43% (0.43)
$P2$ (control group response) = 82% (0.82)[1]
$Z\alpha$ (Z value two tail at definite level of significance) = 1.96 at 5% level of significance
$Z\beta$ (Z value one tail at a definite power) = 1.64 at 95% power (β = 0.05)

$$n = \frac{(43 \times 57) + (82 \times 18)}{(43 - 82)^2} \times (1.96 + 1.64)^2$$

= 33 in each group

Considering the 10% dropout sample size was 40 in each group Total sample size-80

Clinical Evaluation:

After enrollment, all the children were evaluated through a detailed history and clinical examination. History related to their parental education level, academic performances in school, relationship between family members, family history of psychiatric illness, developmental history, how difficult to control the child, learning ability, the behaviour of the child in school and market, relationships with peers, socio-economic status were noted. After taking history thorough clinical examination was done before starting treatment.

Randomization

Randomization was done subsequently among ADHD children by computer-generated randomization technique.

Study Procedure

All the ADHD children aged 3-14 years in outpatient department of Pediatric Neurology, National Institute of Neurosciences and Hospital, Sher-e-Bangla Nagar over a period of 12 months were the reference population. Detailed history and clinical examination were done at OPD. From the reference population, patients fulfilling the eligibility criteria (based on DSM-V criteria) were further categorized by Conner's parent rating scale and were enrolled as the study population by consecutive purposive sampling. After taking informed written consent randomization of ADHD children into two study groups (Experimental and Control groups) was done by computer-generated randomization technique. Thereafter thorough evaluation including clinical examination was done. After group allocation, drugs were given according to the following dose schedule. All the patients of control group received oral Methylphenidate named as tablet Methyphen (10 mg) starting from 2.5mg/day and gradually increasing by 2.5-5 mg/day in two divided doses each week based on the therapeutic response and patient's tolerance. The optimal dose of oral Methylphenidate at the end of 6 weeks was 20 mg/day in two divided doses [2, 16]. The experimental group received Risperidone which was prescribed as tablet Risdon (1 mg) at a dose of 0.25 mg/day once daily for children ≤12 years and 0.5 mg/day for children > 12 years. Doses were increased weekly according to response and tolerability to a maximum dose of 2 mg/day for ≤ 12 years and up to 4 mg/day for older youth in two divided doses at the end of 6 week [2, 16]. Follow-up assessment by Conners parent rating scale was done at 3, 6 & 12 weeks respectively after commencement of commencement of treatment.

The primary end-point of the study was after 12 weeks of treatment to determine the efficacy and safety of oral Methylphenidate and Risperidone for core symptoms of ADHD (according to Conner's parent rating scale) in children. Side effects of drugs were also recorded. Benzodiazepine was allowed up to a maximum dose of 2mg/day for extra pyramidal syndrome. Treatment and follow-up were continued as per schedule even after study period at OPD of NINS&H.

Operational Definitions:

ADHD: Neurobehavioral disorder of children characterized by inattention including increased distractibility and difficulty sustaining attention; poor impulse control, motor over activity and motor restlessness which is supported by DSM-V criteria and supplemented by Conner's parent rating scale.

Severe ADHD: ADHD with marked impairment in social or occupational functioning (Annexure I) and in CPRS their percentile is above 98.

Moderate ADHD: Symptoms or functional impairments between "mild" and "severe" are present. In CPRS their percentile is 95-98.

Mild ADHD: mild impairment in social or occupational functioning.

Conner's Parent Rating Scale (CPRS)

The 27-item Conner's' Parent Rating Scale-Revised is a screening instrument that not only assess all of the 12 criteria that are listed in the DSM-V for ADHD but also behaviours that might be indicative of an oppositional defiant disorder. A parent is asked to rate how much each of the 27 symptoms has been a problem

for his or her child during the last month using a 4-point scale ranging from 0 (not true at all) to 3(very much true). The CPRS–R used with children as young as 3 years old and adolescents as old as 17 years old. The ratings are summed to yield 6-item Oppositional, 6-item Cognitive Problems/Inattention, and 6-item Hyperactivity scales (Conner's, 1997). The 12-item Conner's ADHD Index[18]. This scale has been translated into Bangla in Bangladesh.

Total scores of each item then compare to the scores of others in the child's age group to get their standardized scores. These scores, called T-scores, can help people see how the child's symptoms and their severity compare to other children's. It is usually considered normal when T-scores are < 60, while scores > 60 are signs of academic, behavioural, or social issues18

Data Management

The Conner's parent rating scale which were filled up by the parents with the help of a psychologist were then scored and categorized according to the instructions of the scale. Raw scores of oppositional, cognitive, hyperactivity & ADHD indexes were then converted to T score by plotting the raw score into the provided T score chart which is age and gender-specific. The T scores were then converted to percentile according to the guidelines provided with Conner's parent rating scale.

Statistical Analysis

Data were processed and analyzed using SPSS (Statistical Package for Social Sciences), version 23.0. The test statistics used to analyze the data were descriptive statistics, Unpaired t-test, Repeated Measure ANOVA and Chi-square (χ^2) or Fisher's Exact Tests. While data presented on a continuous scale were compared between the two treatment groups using Unpaired t-test and repeated Measure ANOVA, data on a categorical scale were compared between the groups with the help of Chi-square (χ^2) or Fisher's Exact Test. The level of significance was set at 5% and $p < 0.05$ was considered significant.

RESULTS

Majorities of children in both experimental and control groups were 5 – 10 years old. Thirty per cent of children in the experimental group and 20% in the control group were < 5 years old. The age distribution of children in both groups was almost identical (p = 0.419). Boys were predominant in both the group with no significant intergroup difference (p = 0.330).

Table 1: Distribution of demographic characteristics of children between study groups

Demographics	Group		p-value
	Experimental (n = 40)	Control (n = 40)	
Age# (years)			
< 5	12(30.0)	8(20.0)	
5 – 10	27(67.5)	30(75.0)	
> 10	1(2.5)	2(5.0)	
Mean ± SD	5.8 ± 1.6	6.1 ± 1.7	0.419
Sex*			
Male	36(90.0)	33(82.5)	0.330
Female	4(10.0)	7(17.5)	

Academic performance of the children between experimental and control groups were no different with poor and average performance being predominant in either group (p = 0.567).

Table 2: Distribution of patients by academic performance at baseline

Academic performance baseline	Group		p-value
	Experimental (n = 40)	Control (n = 40)	
Poor	21(52.5)	22(55.0)	
Average	19(47.5)	17(42.5)	0.567
Good	0(0.0)	1(2.5)	

Conners parents rating subscale scores of the two study groups are shown in this table. The mean values of oppositional, cognitive, hyperactivity and ADHD index scores were almost identically distributed between the two study groups (p > 0.05 in each case).

Table 3: Distribution of children by Conner's parents rating subscale score at baseline

Conners parents rating subscale	Group		p-value
	Experimental (n = 40)	Control (n = 40)	
Oppositional subscale score	79.1 ± 8.4	79.9 ± 8.3	0.797
Cognitive subscale score	80.2 ± 7.7	80.2 ± 12.6	0.983
Hyperactivity subscale score	81.2 ± 8.6	80.2 ±7.1	0.602
ADHD Index score	76.3 ± 7.2	78.0 ± 6.5	0.182

This table illustrates ADHD severity in terms of Conners parents' rating subscale score. Seventy percent of the children in the experimental group and almost 77% in the control group were markedly atypical by Conners parents oppositional subscale score. In terms of the cognition subscale, the majority (more than 90%) of either group were markedly atypical. Hyperactivity subscale also revealed > 90% of the children in each group with marked abnormality. ADHD Index shows that 95% in the experimental and 92.3% in the control group were markedly abnormal.

Table 4: ADHD severity at baseline based on Conner's parents' rating subscale score

ADHD severity	Group		p-value
	Experimental (n = 40)	Control (n = 40)	
Baseline Oppositional			
Mildly atypical	3(7.5)	2(5.1)	0.849
Moderate atypical	9(22.5)	8(20.0)	
Markedly atypical	28(70.0)	30(76.9)	
Baseline Cognition			
Mildly atypical	1(2.5)	0(0.0)	0.549
Moderate atypical	2(5.0)	3(7.5)	
Markedly atypical	37(92.5)	37(92.5)	
Baseline Hyperactivity			
Mildly atypical	2(5.0)	0(0.0)	0.094
Moderate atypical	1(2.5)	5(12.5)	
Markedly atypical	37(92.5)	35(87.5)	
Baseline ADHD Index			
Moderate atypical	2(5.0)	3(7.5)	0.644
Markedly atypical	38(95.0)	37(92.5)	

*Data were analyzed using **Chi-square Test (χ^2)** and were presented asn(%). Figures in the parenthesis denote corresponding percentage

The mean oppositional subscale score in both experimental and control groups at baseline was approximately 80, which, after the intervention, reduced to 70.0 and 76.3 in experimental and control groups at the end of 6 weeks and further reduced to 66.3 and 71.1 respectively at the end-point of the study. The reduction of oppositional subscale scores within each group from baseline to the end-point of the study was statistically significant ($p < 0.001$). The reduction of the oppositional subscale score was also significantly greater in the experimental group than in the control group at all the levels of evaluation (3, 6 and 12 weeks) ($p = 0.018$, $p < 0.001$ and $p = 0.018$ respectively).

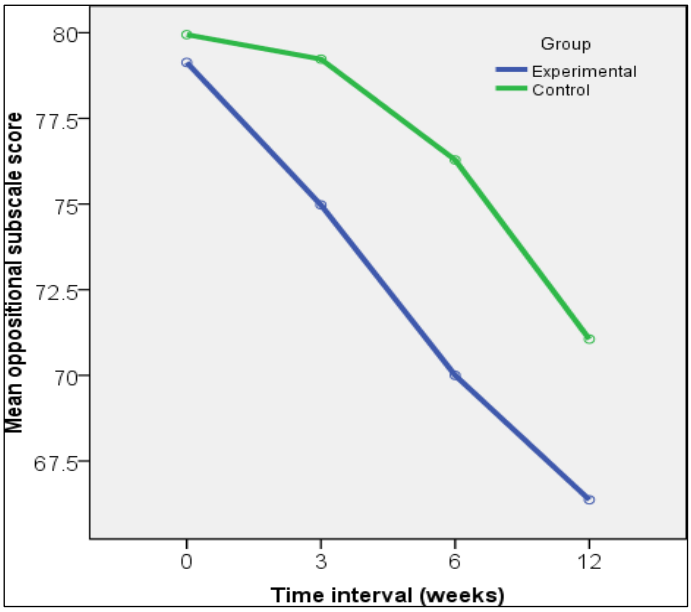

Fig 1: Changes in oppositional subscale score following intervention

Table 5: Comparison of changes in Conner's oppositional subscale between group

Conners oppositional subscale score	Group		p-value[#]
	Experimental (n = 40)	Control (n = 40)	
Baseline	79.1 ± 8.4	79.9 ± 8.3	0.797
Week 3	74.9 ± 8.3	79.2 ± 7.7	0.018
Week 6	70.0 ± 7.0	76.3 ± 6.9	< 0.001
Week 12	66.3 ± 9.2	71.1 ± 7.1	0.018
p-value*	< 0.001	< 0.001	

The mean cognitive subscale scores in both experimental and control groups at baseline was over 80, which, after the intervention, reduced to < 75 and < 74 in experimental and control groups respectively at the end-point of the study. The reduction of cognitive score within each group from baseline to end-point of the study was statistically significant, although no significant difference was observed between the groups at 3, 6 and 12 weeks of intervention (p = 0.334 and p = 0.271 and p = 0.601 respectively).

Table 6: Comparison of changes in Conner's cognitive subscale score between groups

Conners cognitive subscale score	Group		p-value[#]
	Experimental (n = 40)	Control (n = 40)	
Baseline	80.2 ± 7.7	80.2 ± 12.6	0.983
Week 3	78.4 ± 7.7	80.7 ± 12.4	0.334
Week 6	75.2 ± 7.6	77.8 ± 11.9	0.271
Week 12	74.3 ± 8.2	73.1 ± 11.5	0.601
p-value*	0.019	0.007	

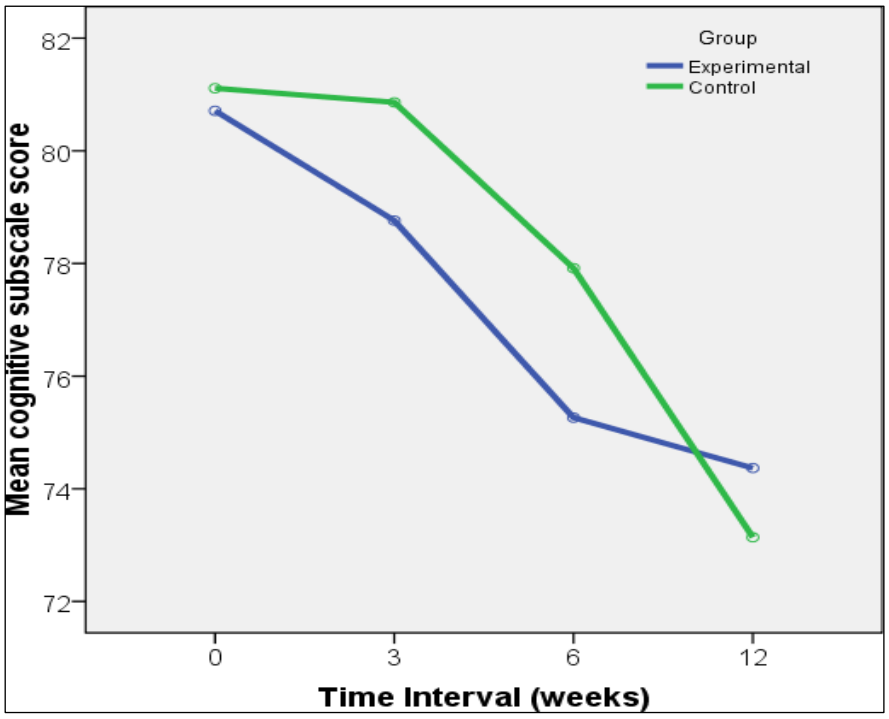

Fig 2: Changes in cognitive subscale score following intervention

At baseline, there was no significant difference between the study groups in terms of Conners hyperactivity subscale score (81.2 ± 8.6 vs. 80.2 ±7.1, p = 0.602). The Conners hyperactivity score responded in both the study groups after intervention. However, the response was significantly earlier in the experimental group than that in the control group. At the end of 6 weeks, the hyperactivity score in the experimental group decreased to 74.6 and that in the control group to only 79.3 (p = 0.020). At the end of 12 weeks, the scores of both groups reduced significantly from their baseline figures (p < 0.001 and p =< 0.024).

Table 7: Comparison of changes in Conner's hyperactivity subscale between group

Conners hyperactivity subscale score	Group		p-value[#]
	Experimental (n = 40)	Control (n = 40)	
Baseline	81.2 ± 8.6	80.2 ±7.1	0.602
Week 3	78.3 ± 9.2	80.4 ± 6.8	0.250
Week 6	74.6 ± 9.2	79.3 ± 7.9	0.020
Week 12	71.4 ± 9.5	75.0 ± 7.7	0.079
p-value*	< 0.001	<0.024	

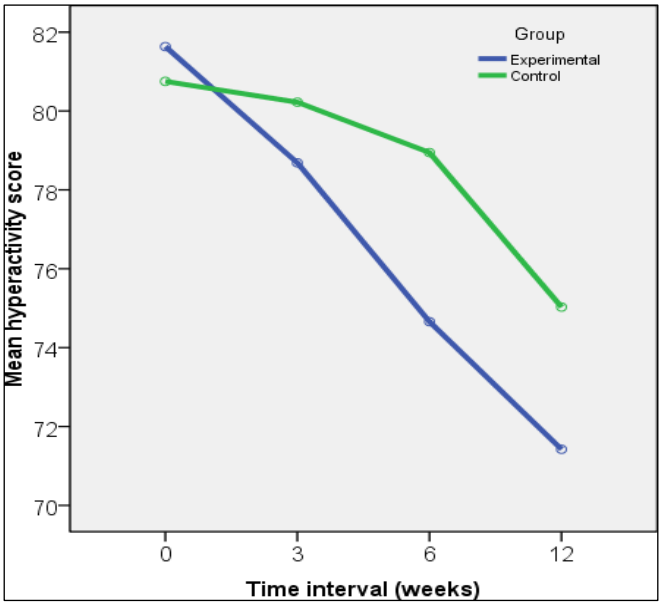

Fig 3: Changes in hyperactivity subscale score following intervention

The mean ADHD index score in experimental and control groups at baseline were 76.3 and 78.0 respectively, which, declined to < 68 and nearer to 70 in experimental and control groups respectively at the end-point of the study. Both groups experienced a significant reduction in ADHD index scores from their baseline figures ($p < 0.001$). However, at each level of evaluation (3, 6 and 12 weeks) the reduction was significantly greater in the experimental group than that in the control group ($p = 0.001$, $p = 0.011$ and $p = 0.037$ respectively).

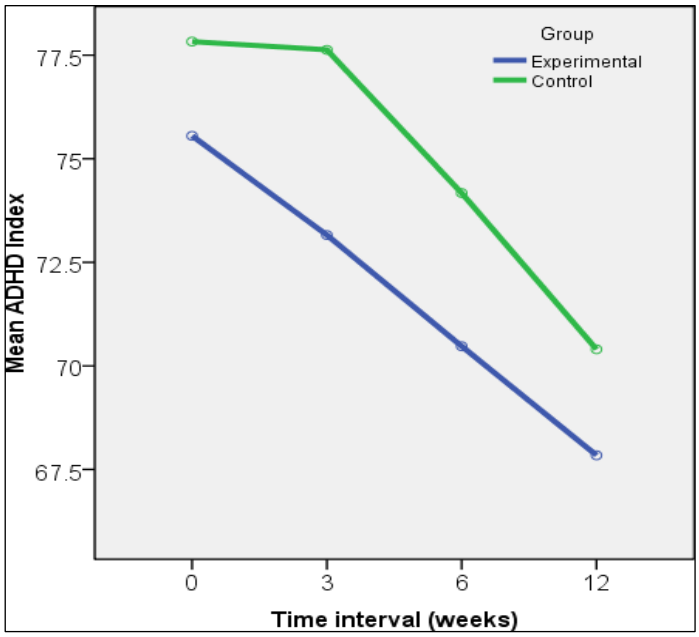

Fig 4: Changes in ADHD index subscale score following intervention

Table 8: Comparison of changes in Conner's ADHD index score between groups

Conners ADHD index score	Group		p-value[#]
	Experimental (n = 40)	Control (n = 40)	
Baseline	76.3 ± 7.2	78.0 ± 6.5	0.182
Week 3	72.9 ± 5.5	78.0 ± 6.5	0.001
Week 6	70.4 ± 6.3	74.5 ±7.1	0.011
Week 12	67.8 ± 3.3	70.4 ± 6.5	0.037
p-value*	< 0.001	< 0.001	

As school performance following treatment was evaluated and compared between the two study groups, it was evident that a substantial proportion (61.5%) of children in the experimental group at 3 weeks of intervention demonstrated improvement in their academic activities compared to only 2.6% in the control group ($p < 0.001$). The school performance in the former group further improved to 71.1% at the end of 6 weeks; meanwhile, approximately 40% of the control group showed improved performance in their academic activities ($p = 0.008$). However, over three-quarters of the children in both groups (76.3% in the experimental and 77.1% in the control group) demonstrated improved performance in their academic affairs at the end of 12 weeks, and there was no significant difference between the groups concerning their performance ($p = 0.933$).

Table 9: Comparison of school performance following treatment between groups

School performance	Group		p-value
	Experimental	Control	
Week 3			
Unchanged	15(38.5)	37(97.4)	< 0.001
Improved	24(61.5)	1(2.6)	
Week 6			
Deteriorated	1(2.6)	0(0.0)	
Unchanged	10(26.3)	23(60.5)	0.008
Improved	27(71.1)	15(39.5)	
Week 12			
Unchanged	9(23.7)	8(22.9)	0.933
Improved	29(76.3)	27(77.1)	

Two-thirds (66.7%) of children in the experimental group showed improved performance in their family affairs as opposed to 7.9% in the control group ($p < 0.001$) at 3 weeks of evaluation. At the end of week 6, nearly 80% in the experimental group and 52.6% in the control group exhibited improved performance ($p = 0.038$). At the end-point of the study, the control group excelled the experimental group in the performance of their family activities, although the difference in performances between the two groups was not statistically significant ($p = 0.090$).

Table 10: Comparison of family performance following treatment between groups

Family performance	Group		p-value
	Experimental	Control	
Week 3			
Unchanged	13(33.3)	35(92.1)	< 0.001
Improved	26(66.7)	3(7.9)	
Week 6			
Deteriorated	1(2.6)	1(2.6)	0.038
Unchanged	7(17.9)	17(44.7)	
Improved	31(79.5)	20(52.6)	
Week 12			
Deteriorated	0(0.0)	1(2.9)	0.090
Unchanged	10(26.3)	3(8.6)	
Improved	28(73.7)	31(88.6)	

*Data were analyzed using **Chi-square Test (χ^2)** and were presented as **n(%).** Figures in the parenthesis denote the corresponding percentage.

Children of the experimental group demonstrated significant improvement in community performance after 3 weeks of evaluation compared to their control counterparts (56.4% vs. 10.5%, $p < 0.001$).

After 6 weeks the improved performance in experimental group reached to almost 70% compared to 34.2% in the control group (p = 0.007). However, no significant difference between children of the two groups was noted with respect to their community performance at the end-point of the study (p = 0.432).

Table-11: Comparison of community performance following treatment between groups

Community performance	Group		p-value
	Experimental	Control	
Week 3			
Unchanged	17(43.6)	34(89.5)	
Improved	22(56.4)	4(10.5)	< 0.001
Week 6			
Deteriorated	0(0.0)	1(2.6)	0.007
Unchanged	12(30.8)	24(63.2)	
Improved	27(69.2)	13(34.2)	
Week 12			
Deteriorated	0(0.0)	1(2.9)	0.432
Unchanged	12(31.6)	8(22.9)	
Improved	26(68.4)	26(74.3)	

*Data were analyzed using **Chi-square Test (χ^2)** and were presented as **n(%).** Figures in the parenthesis denote corresponding percentage.

Analysis of peer groups performance revealed that over 30% of children in the experimental group had improved interaction with peer groups as compared to only 2.6% of those in the control group (p = 0.001) at the end of 3week intervention. While the experimental group further improved to 38.5% at the end of 6 weeks, the control group remained static. At the end-point of the study, over half (52.6%) of the experimental group had improved peer group performance compared to only 22.9% of the control group (p = 0.009).

Table-12: Comparison of peer groups' performance between groups

Peer groups performance	Group		p-value
	Experimental	Control	
Week 3			
Deteriorated	0(0.0)	0(0.0)	0.001
Unchanged	27(69.2)	37(97.4)	
Improved	12(30.8)	1(2.6)	
Week 6			
Deteriorated	0(0.0)	1(2.6)	< 0.001
Unchanged	24(61.5)	36(94.7)	
Improved	15(38.5)	1(2.6)	
Week 12			
Deteriorated	0(0.0)	0(0.0)	0.009
Unchanged	18(47.4)	27(77.1)	
Improved	20(52.6)	8(22.9)	

*Data were analyzed using **Chi-square Test (χ^2)** and were presented as **n (%).** Figures in the parenthesis denote corresponding percentage

Very few children in either group encountered side effects. While insomnia and nervousness in the control group deserve mention followed by anorexia and headache, weight gain was significantly present in experimental group (p = 0.003) followed by sedation and anorexia.

Table-13: Comparison side-effects encountered by the children of the two groups

Side Effects	Group		p-value
	Experimental	Control	
At 3 Weeks			
Sedation*	1(2.6)	0(0.0)	0.506
At 6 Weeks			
Sedation*	1(2.6)	0(0.0)	0.506
Insomnia*	0(0.0)	4(10.5)	0.055
Anorexia / loss of appetite*	2(5.1)	2(5.3)	0.683

Side Effects	Group		p-value
	Experimental	Control	
Nervousness*	0(0.0)	4(10.5)	0.055
Headache*	0(0.0)	2(5.3)	0.240
At 12 Weeks			
Sedation*	4(10.3)	0(0.0)	0.061
Insomnia*	1(2.6)	4(10.5)	0.171
Anorexia / loss of appetite*	1(2.6)	3(7.9)	0.298
Weight gain*	8(20.5)	0(0.0)	0.003
Nervousness*	0(0.0)	3(7.9)	0.115
Headache*	0(0.0)	2(5.3)	0.240

*Data were analyzed using **Fisher's Exact Test** and were presented as **n (%).** Figures in the parenthesis denote corresponding percentage.

DISCUSSION

When the data were compared, both the groups improved in the scores of Conner's parent rating scale (CPRS). Following intervention, the reduction of oppositional subscale score was also significantly greater in experimental group than that in control group at all the levels of evaluation (3, 6 and 12 weeks). While the reduction of cognitive score within each group from baseline to end-point of the study was statistically significant, no significant difference was evident between the groups at 3, 6 and 12 weeks of intervention. The Conners hyperactivity score responded in both the study groups with substantially greater response in the experimental group than that in the control group. Both groups experienced a significant reduction of ADHD index score from their baseline figures with reduction being significantly greater in the experimental group than that in the control group.

The above findings obtained from this study need to be compared and contrasted with similar studies conducted at home and abroad to arrive at a conclusion. However, after extensive online search only one head-to-head study, conducted by other study [2]. The study demonstrated that both Risperidone and Methylphenidate experienced a significant improvement in ADHD symptoms over the 6 weeks of treatment for parent ADHD Rating Scale and Parent Conners Rating Scale. But there were no significant differences between the two groups. The study concluded that both treatments were well-tolerated and equally effective. Another study comparing treatment outcome of Methylphenidate alone and combined Methylphenidate and Risperidone [13]. The study showed that the total and subscale scores of Conners' Rating Scale were significantly reduced in both groups, but there was no significant difference between the groups. Both protocols were well- tolerated.

Other study showed that adding Risperidone to Methylphenidate results in significant improvement in antisocial behaviors in school aged children with ADHD [13].

Regarding follow up findings on 3,6,12 weeks after intervention, children in both groups exhibited academic performance, family and peer relationship. Among them attention level in academic activity was improved much earlier in experimental group then controlled group. All these improvements were noticed by mother. Teachers were not involved and no other scales were used to assess the improvement. Other studies individually showed their study attention span and family behavior improved after Methylphenidate and Risperidone treatment. The reason behind this condition are improvement of impulsivity and behavioral activity [14, 15].

Initially majority of the children was markedly atypical with respect to all the CPRS. In this study after treatment with Risperidone significant improvement was found in T scores of oppositional, cognitive, hyperactivity and ADHD index domain of CPRS within 3 weeks continue up to the end of the study at 12 weeks. This result is similar to the other studies [16-18].

Similarly, MPH showed statistically significant improvement in T score of oppositional cognitive and ADHD index domain of CPRS after 3 weeks of treatment and after 6 weeks of treatment there were improvement in all domains of the CPRS, continued upto 12 weeks. This result is similar to the result done by other study [19]. Where improvement was found in ADHD children in attention after treatment with psycho-stimulants namely methylphenidate. Other study found improvement in cognition, impulsivity and attention after treatment with MPH which was assessed by conners' rating scale and this is similar to the present study [14].

In the present study very few patients had shown side effects following treatment. Insomnia and nervousness were common in control group followed by anorexia and headache. Three patient discontinued treatment due to severe nervousness, and insomnia. It is similar to other study [2].

CONCLUSION

The study concluded that although majority of the children with ADHD at baseline was markedly atypical with respect to all the Conner's parent rating

subscales, they improved after 12 weeks of treatment with either Methylphenidate or Risperidone. Academic (76% & 77%), family affairs (73% & 88%), community performance (68% & 72%) and peer relationship (52% & 22%) improved after 12 weeks of treatment with Risperidone and Methylphenidate respectively. Both the drugs are equally effective and well tolerated in ADHD children. In Risperidone group response was earlier than Methylphenidate group. In this period few side effects were developed in both groups.

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