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EFFICACY OF ARIPIPRAZOLE AND RISPERIDONE IN TREATMENT OF CHILDREN WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER: A DOUBLE-BLIND CLINICAL TRIAL STUDY

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Attention-deficit hyperactivity disorder (ADHD) is one of the most common psychiatric disorders in children. Poor academic readiness for school entry, fine motor skills, and social impairment are more common in preschoolers than healthy controls. Since dopaminergic system dysfunction is connected with numerous neuropsychological diseases, including ADHD, antipsychotic drugs are used for the treatment of ADHD. Considering the importance of ADHD treatment in preschoolers and the fact that psychostimulant drugs are less effective in preschoolers and have more adverse effects, this study is conducted to compare the safety and efficacy of risperidone and aripiprazole in the treatment of ADHD. Fifty-five 3-6-year-old children diagnosed with ADHD were randomized to a 12-week trial of treatment with risperidone or aripiprazole[1]. The assessment was performed by Parent ADHD-RS, Strengths and Difficulties Questionnaire (SDQ), Children's Global Assessment Scale (CGAS) before treatment, and weeks 2, 4, 6, and 12 of treatment. The study showed that the ADHD-RS score of both groups was significantly reduced after starting the treatment. After the 12th week, the score of aripiprazole's group was significantly less than the score of risperidone's group (p-value = 0.019). In addition, the CGAS scores and the total SDQ score improved for both groups without any statistically significant difference between them. Both risperidone and aripiprazole are effective in the treatment of ADHD among preschool-aged children. Both drugs are well-tolerated, significantly reduce the ADHD-RS score and the total SDQ score and improve the CGAS score.

Keywords: *Attention-deficit hyperactivity disorder, Aripiprazole, Risperidone, clinical trial*

INTRODUCTION

Attention-deficit hyperactivity disorder (ADHD) is one of the most common developmental or neurobehavioral disorders, and its worldwide prevalence is currently estimated between 5.9 to 7.1%[2-4]. The disorder is typically presented with symptoms of inattention and hyperactivity in early childhood, but it is mainly diagnosed in the school-age years[5]. Although many ADHD-related problems may regress in puberty, secondary problems such as antisocial behaviors, academic problems, and substance abuse could persist throughout adolescence and adulthood[2-4].

Preschoolers with ADHD have the same social and academic dysfunction level as do school-age children with ADHD[6]. Poor academic readiness for school entry, poor fine motor skills, and social impairment is more common in preschoolers compared to healthy controls[6-8].

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Behavioral and social dysfunction caused by ADHD and the continuation of its problems throughout adulthood necessitates immediate treatment of ADHD in preschool-age children[6]. Although systematic research and practice guidelines regarding psychopharmacology in very young children are limited[6&9], adrenergic drugs are considered the first-line medications for treating ADHD[3]. Methylphenidate is the most frequently used drug of this class for treating preschool children with ADHD in the Preschool Psychopharmacology Working Group (PPWG) algorithm[9&10]. Methylphenidate has more side effects and is less effective in preschoolers than older children[11&12]. Loss of appetite and reduction in growth rate is more prominent in preschoolers. However, emotional side-effects such as nervousness, insomnia, irritability, and crying are frequent reasons for discontinuing the dru [9,12&13].

Since dopaminergic system dysfunction is connected with numerous neuropsychological diseases, including attention deficit hyperactivity disorder (ADHD), antipsychotic drugs, especially risperidone, are used to treat ADHD[14]. Risperidone was found to be an effective and tolerable drug in preschool children[15-17]. In a double-blind, placebo-controlled clinical trial, Aman et al. demonstrated that risperidone could significantly reduce the symptoms of ADHD in children. Moreover, they found that a combination of risperidone and a psychostimulant drug significantly better control of hyperactivity than that achieved by stimulant treatment alone [18]. Studies have also shown that risperidone produces as good or even better results for the treatment of ADHD compared to what is achieved by administering methylphenidate[3&16].

Aripiprazole is a third-generation atypical antipsychotic drug with a mechanism of action that differs from other atypical antipsychotics[19&20]. It is a partial agonist at dopamine D2 and serotonin 5HT1A receptors and an antagonist at the serotonin 5HT2A receptor[21]. Aripiprazole has a higher affinity for dopamine D2 receptors compared to endogenous dopamine. Therefore, it is less likely to induce extrapyramidal symptoms (EPS) and elevate serum prolactin levels than other antipsychotics and is considered a dopaminergic system stabilizer[19-21]. Aripiprazole is indicated in the USA to treat schizophrenia, bipolar mood disorder, and irritability associated with autistic disorder in adults and pediatric patients[19]. The efficacy and tolerability of aripiprazole in children and adolescents have been well-demonstrated in numerous clinical studies[19].

Considering the importance of ADHD treatment in preschoolers and that psychostimulant drugs are less effective in preschoolers and have more adverse effects [11, 12], this study is conducted to compare the Efficacy of Risperidone and Aripiprazole in the treatment of ADHD. Moreover, in this study, we investigate the effect of these two drugs in reducing the disorder's symptoms and the side effects, and the tolerability for children.

MATERIAL AND METHODS

This study is a 12-week[1], placebo-controlled trial in the pediatric psychiatry clinic of Taleghani Hospital [Golestan University of Medical Sciences, Iran] from March 2015 to August 2016.

Participants

From the 3 to 6 years old children referred to the psychiatry clinic by their parents with ADHD symptoms, those diagnosed for the first time to have ADHD were considered for enrollment 55 participants in this study. ADHD diagnosis was made based on the ADHD-RS questionnaire and according to the DSM-5-Text revision. Children who had morbid obesity and excessive polyphagia or unstable physical conditions that prevented drug intake were excluded from the study. Moreover, those who had been in treatment with any psychotropic drug during the two prior weeks and had co-psychiatric disorders such as bipolar mood disorder, mental retardation, and autistic disorder were excluded from the study. Furthermore, children were also excluded from the study whenever children showed significant or intolerable adverse effects during the treatment.

This study was approved by the Institutional Research Board (IRB) of Golestan University of Medical Sciences (ethical code: 280221941104233). Patients with informed consent entered the study and stated that they could withdraw from the study at their will. The trial was performed by the Declaration of Helsinki and subsequent revisions. The trial was registered in Iran: IRCT2015123025768N1.

The sample size was 20 Participants, Including 20% loss in each group; 50 Participants are needed.[22]

$$N = \frac{(S_1^2 + S_2^2)(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2}{(\mu_{1-} - \mu_2)^2}$$

Intervention

The parents provided written informed consent for their children's participation after the procedures and purposes of the study were explained to them. Participants were randomly assigned to one of the treatment groups of Aripiprazole (Group A) or Risperidone (Group R).

Risperidone was started at a dose of 0.25 mg/day in one dose and was increased based on the therapeutic response and the patient's tolerance by 0.25 mg weekly increments, to a maximum dose of 1.25 mg/day. Aripiprazole was started at a dose of 2.5 mg per day and gradually increased by 1.25 mg every week based on the therapeutic response and the patient's tolerance, to a maximum dose of 6.25 mg/day. As a double-blind cross-over test, the patients were evaluated by a clinician who was blind to the patients' group assignment.

Measurements

Treatment outcomes were assessed using the Parent ADHD-RS, Strengths and Difficulties Questionnaire (SDQ), and Children's Global Assessment Scale (CGAS) [23]. Patients were assessed by a pediatric psychiatrist before the beginning of the treatment and subsequently 2, 4, 8, and 12 weeks after the medication started.

Side effects

Side effects were followed throughout the study and were assessed using a checklist administered by a resident psychiatrist at baseline and 4, 8, and 12 weeks after the onset of treatment.

Statistical analysis

The statistical analysis was done by the Social Sciences software (SPSS, version 18 for Windows). The results were reported as the mean ± standard deviation. Moreover, the normality of the data was checked by the Kolmogorov-Smirnov test. Student t-test was used for normally distributed variable (SDQ), Mann-Whitney U test was used for not-normally distributed variables (ADHD-RS, CGAS, age and weight), and Chi-square test was used for qualitative variables (gender). The statistical significance was set at a p-value < 0.05.

RESULTS AND DISCUSSION

Results

Fifty-five preschoolers with ADHD (42 boys and 13 girls) aged 3 to 6 (mean ± SD, 3.98 ± 0.95) participated in the study. 22 participants were assigned in the Aripiprazole group, and 21 of them were assigned in the Risperidone group who completed the treatment protocol. Six patients from each group discontinued the treatment. One child from the Risperidone group discontinued the treatment due to severe anxiety, generalized skin rash, and no response to the treatment. The two groups were not significantly different in age, gender, weight, and severity of illness.

Table 1: Demographic data and pretreatment scores of the study population

	Aripiprazole group	**Risperidone group**	**P value**
Girls (%)	8(28.60%)	5(18.50%)	0.38*
Boys (%)	20(71.40%)	22(81.50%)	
Age (years)	4.18 ±0.98	3.77 ± 0.88	0.11**
Weight (kg)	16.7 ±4.5	14.9 ±2.9	0.08**
Weight gain (g)	1.1 ±0.86	1.3 ±0.93	0.49**
ADHD-RS	29.75	29.96	0.869**
CGAS	61.89	62.71	0.584**
SDQ	27.3	29.25	0.123***

* Chi-square test
** Mann-Whitney U test
*** Student t-test

The study showed that the ADHD-RS score of both groups was significantly reduced after starting the treatment and increasing the drug dosage. The rate of improvement of the ADHD-RS score was more prominent during the first few weeks, as depicted. There was no significant difference between the ADHD-RS score of the two groups up to 8 weeks after the beginning of treatment. However, after the 12th week, the score of group A was significantly less than the score of group R (*p*-value = 0.019).

Table 2: the total score of ADHD-RS, CGAS, and SDQ between two groups

	ADHD-RS			**CGAS**			**SDQ Score**		
	A group	**R group**	**P value***	**A group**	**R group**	**P value***	**A group**	**R group**	**P value****
T_0	29.75	29.96	0.869	61.89	62.71	0.584	27.3	29.25	0.123
T_2	18.54	21.52	0.058	66.7	72.68	0.001	23.3	23.29	0.993
T_4	12.42	14.67	0.201	74	78.04	0.039	20.29	20.23	0.959
T_8	8.52	10.19	0.371	77.43	79	0.51	18.76	29.09	0.796
T_{12}	4.45	7.76	0.019	79.57	83.5	0.079	18.33	17.86	0.633

* Mann-Whitney U test

** Student t-test

T0 = Baseline, T2 = 2 Weeks After the Treatment, T4 = 4 Weeks After the Treatment, T8 = 8 Weeks After the Treatment, T12 = 12 Weeks After the Treatment.

The total SDQ score_ which is a globally recognized instrument for assessing the mental health status of children and young people_ SDQ scoring provides a rough overview to help detect mental health issues. However, it does not provide a clear-cut screening. It was significantly reduced after the beginning of the treatment for both groups. The rate of the reduction was more significant in the first few weeks than in the last ones. However, no significant difference was observed between the two groups.

The emotional symptoms, as well as hyperactivity-attention deficit symptoms, were reduced (based on the SDQ score) for both groups. However, there was no significant difference in the score of the two groups until the 12th week of as shown.

The patient's peer problem scores (based on the SDQ test) declined until the 8th week of the treatment but were slightly increased in the 12th week for both groups. The prosocial behavior scores (based on the SDQ test) of both groups improved during treatment. However, there was a significant difference in the score of the two groups at the 12th week of treatment, which had existed before starting the treatment.

Moreover, there were no statistically significant differences observed between the adverse effects of the two drugs.

Table 3 : SDQ scores

	emotional symptoms based on the SDQ score			**Hyperactivity-attention deficit symptoms based on the SDQ score**			**peer problems based on the SDQ score**			**prosocial behavior based on the SDQ score**		
	A group	R group	P value*	A group	R group	P value*	A group	R group	P value*	A group	R group	P value*
T_0	3.36	3.19	0.123	7.11	7.11	0.989	5.14	5	0.81	7.86	6.56	0.039
T_2	3.11	3	0.993	4.68	5.59	0.052	3.71	3.89	0.753	8.18	7.22	0.066
T_4	2.58	2.62	0.959	3.58	4.04	0.311	2.81	2.96	0.773	8.77	8.08	0.21
T_8	2.48	2.62	0.796	3	3.52	0.297	1.26	1.29	0.957	9.22	8.57	0.107
T_{12}	2.23	2.24	0.663	2.41	3.57	0.003	1.86	2.33	0.256	9.64	8.86	0.031
* Student t-test												

T_0 = Baseline, T_2 = 2 Weeks After the Treatment, T_4 = 4 Weeks After the Treatment, T_8 = 8 Weeks After the Treatment, T_{12} = 12 Weeks After the Treatment.

Clinical complications and side effects

In this study, disturbances were examined and was no significant difference between the two groups in terms of these disturbances.

Discussion

The results of this study have shown that aripiprazole and risperidone are both significantly effective drugs for treating ADHD. Both drugs reduced the signs and symptoms of ADHD and were tolerated well in preschoolers. Both drugs significantly reduced the ADHD-RS score and the total SDQ score and improved the CGAS. These findings are consistent with the result of a study conducted by Safavi et al. (2016). They found risperidone and aripiprazole were relatively effective and safe for treating disruptive behavior disorders co-morbid with ADHD among preschoolers with mild to moderate side effects. No significant differences were found between both drugs for CGAS score and total SDQ score. However, after the 12th week, the ADHD-RS score was significantly lower when participants were treated with aripiprazole. in another study, results showed risperidone and aripiprazole are also effective in children under six years[24].

In agreement with previous research[25-29], the results of this study showed risperidone reduced both the hyperactivity-attention deficit and emotional symptoms of ADHD [30] and improved peer problems and prosocial behaviors based on SDQ scores. Eapen and Gururaj[26] conducted a cohort clinical trial to examine the effect of risperidone on ADHD signs and symptoms among 12 patients aged 4 to 14. Günther *et al.*[27] also examined the effect of risperidone among 23 patients with ADHD and disruptive behavior disorder, aged 8-15 years, in a double-blind placebo-controlled clinical trial. Both studies found that risperidone was modestly effective for the treatment of ADHD. Furthermore, Valle Krieger *et al.*[28] that ADHD symptoms significantly improved two weeks after treatment with risperidone.

Findling et al. found that aripiprazole reduced ADHD symptoms and improved overall functioning. This study's findings showed that aripiprazole was well-tolerated among preschoolers with ADHD and improved CGAS, SDQ, and ADHD-RS scores[30]. The results of this study are also consistent with the findings of other study. aripiprazole significantly improves inattention and hyperactivity/impulsivity among children and adolescents with ADHD and conduct disorder[30&31].

In conclusion, both risperidone and aripiprazole are effective in the treatment of ADHD among preschool-aged children. Both drugs are well-tolerated, significantly reduce the ADHD-RS score and the total SDQ score and improve the CGAS score.

Limitation

It is recommended to repeat the study with a larger sample size and in a more geographical area.

Another limitation was that the patients were not followed for a longer duration. and a higher percentage of boys

Abbreviation

- **ADHD:** Attention-deficit hyperactivity disorder
- **SDQ:** Strengths and Difficulties Questionnaire
- **CGAS:** Children's Global Assessment Scale

Declaration

Availability of data and materials

The datasets for the current study are available from the corresponding author on reasonable request.

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Funding

There is no funding for the present study.

Ethics approval and consent to participate

The IRB approved this study of Golestan University of Medical Sciences (ethical code: 280221941104233). Patients with informed consent entered the study and stated that they could withdraw from the study at their will.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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أريبيبرازول وريسبيريدون في علاج الأطفال الذين يعانون من اضطراب نقص الانتباه / فرط النشاط: دراسة تجريبية سريرية مزدوجة التعمية

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يُعد اضطراب فرط الحركة ونقص الانتباه (ADHD) أحد أكثر الاضطرابات النفسية شيوعًا عند الأطفال. يعد ضعف الاستعداد الأكاديمي للالتحاق بالمدرسة ، والمهارات الحركية الدقيقة ، والضعف الاجتماعي أكثر شيوعًا في مرحلة ما قبل المدرسة من الضوابط الصحية. نظرًا لأن ضعف نظام الدوبامين مرتبط بالعديد من الأمراض العصبية والنفسية ، بما في ذلك اضطراب فرط الحركة ونقص الانتباه ، يتم استخدام الأدوية المضادة للذهان لعلاج اضطراب فرط الحركة ونقص الانتباه. بالنظر إلى أهمية علاج اضطراب فرط الحركة ونقص الانتباه في الأطفال في سن ما قبل المدرسة وحقيقة أن أدوية المنبهات النفسية أقل فعالية في مرحلة ما قبل المدرسة ولها آثار سلبية أكثر ، أجريت هذه الدراسة لمقارنة سلامة وفعالية ريسبيريدون وأريبيبرازول في علاج اضطراب فرط الحركة ونقص الانتباه. تم اختيار خمسة وخمسين طفلًا تتراوح أعمارهم بين ٣ و ٦ سنوات مصابين باضطراب فرط الحركة ونقص الانتباه بشكل عشوائي إلى تجربة لمدة ١٢ أسبوعًا من العلاج باستخدام ريسبيريدون أو أريبيبرازول ١. تم إجراء التقييم من قبل الوالدين ADHD-RS ، استبيان نقاط القوة والصعوبات (SDQ) ، مقياس التقييم العالمي للأطفال (CGAS) قبل العلاج ، والأسابيع ٢ و ٤ و ٦ و ١٢ من العلاج. أظهرت الدراسة أن درجة ADHD-RS لكلا المجموعتين قد انخفضت بشكل ملحوظ بعد بدء العلاج. بعد الأسبوع الثاني عشر ، كانت درجة مجموعة أريبيبرازول أقل بكثير من درجة مجموعة ريسبيريدون (القيمة الاحتمالية = ٠.٠١٩). بالإضافة إلى ذلك ، تحسنت درجات CGAS وإجمالي نقاط SDQ لكلتا المجموعتين دون أي فرق ذي دلالة إحصائية بينهما. كل من ريسبيريدون وأريبيبرازول فعالان في علاج اضطراب فرط الحركة ونقص الانتباه بين الأطفال في سن ما قبل المدرسة. كلا العقارين جيد التحمل ، ويقلل بشكل كبير من درجة ADHD-RS وإجمالي درجة SDQ ويحسن درجة CGAS .