

Behavioral Interventions with and without Pharmacological Treatment: A Comparative Study at An Autistic Center in Jordan

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ABSTRACT

Autism spectrum disorder (ASD) is a complex and highly variable neurodevelopmental disorder. This manuscript describes an observational study aimed at evaluating the impact of behavioral and pharmacological treatments on autistic patients at a Jordanian Autism Institution. Patients were evaluated every three months to assess their progress in behavioral treatment using the ABLLS (Assessment of Basic Language and Learning Skills) method, which evaluates 25 skills based on a child's performance. The researcher collected all previous assessments and observed at least two evaluation periods. Males comprised 90.38% of the study population. Among psychiatric conditions, hyperactivity (36.54%) and irritability (30.77%) showed the highest prevalence. The first interval served as the baseline. Results from the second and third intervals showed slight differences but were not statistically significant. In contrast, the fourth interval demonstrated a statistically significant difference ($P < 0.0001$). In conclusion, combining pharmacological and behavioral treatments appears more beneficial than behavioral therapy alone, although this benefit may take at least a year to manifest effectively.

Keywords: ASD; Risperidone; ABA; ABLLS.

INTRODUCTION

Autism spectrum disorder (ASD) is a complex and highly variable neurodevelopmental condition [1]; worldwide prevalence is 1 in 100 according to the World Health Organization [2, 3]. Lack of social interaction, impaired communication, and restricted and repetitive behaviors are common in all patients [4]. Scientists from the Centers for Disease Control and Prevention (CDC) have reported that in the United States, the proportion of children aged 3–17 years with a developmental disability increased from 16.2% during (2009–2011) to 17.8% in (2015–2017) [5, 6]. This rise

may partly stem from improved detection tools, diagnostics, and increased awareness among parents and healthcare providers [5, 7, 8].

To date, there have been no studies in Jordan estimating the prevalence of ASD. However, based on studies from other Middle Eastern countries, it is estimated to range between 0.63 and 1.76 cases per 1000 people [9]. Although official data on the prevalence of autism in Jordan is lacking due to limited regional research, experts estimate that there are approximately 8000 individuals with autism in the country [10]. Males are more affected than females, with a long-standing ratio of 4 males to 1 female [11], although recent reports suggest this ratio is now 3 males to 1 female [12].

ASD is a broad category that has replaced previous terms such as autistic disorder, Asperger's syndrome,

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childhood disintegrative disorder, and unspecified pervasive developmental disorder [13]. Symptoms of ASD may appear before the age of two years but are typically more noticeable between ages two and three [14]. The age of diagnosis has decreased in recent years, partly due to improved screening methods, with an average age of diagnosis around 60 months [15]. Children with ASD face varying degrees of developmental challenges in behavior, communication, and socialization [16, 17]. While fundamental areas may improve with age, certain symptom subdomains such as social smiling, emotional expression, and restricted interests may remain unchanged, contributing to the poor outcomes associated with adulthood [18-20].

Despite its growing prevalence, the pathophysiology of ASD remains poorly understood, which may be related to challenges in developing appropriate animal models and understanding the complexities of brain function [21]. Numerous studies indicate that significant genetic and environmental factors contribute to the increasing incidence of ASD in children [22, 23]. ASD is often recognized as a multifactorial condition caused by both hereditary and non-genetic risk factors [24]. A growing body of literature reports that genetic factors play a role in ASD development, with siblings born into ASD families being more likely to acquire the condition [25]. Regarding environmental factors, several variables are considered ASD risk factors, including advanced parental age, maternal smoking, assisted reproductive technologies, nutritional issues, maternal infections and disorders, environmental pollutants, toxic exposures, and medications [26, 27].

The primary treatment for children with ASD is early intervention with behavioral, occupational, and speech therapy to promote healthy development and sociability [28]. No pharmacological treatment has demonstrated efficacy in clinical trials or received approval from regulatory authorities for treating core ASD signs and symptoms [29]. However, pharmacological therapies are

sometimes prescribed adjunctively to address co-occurring behavioral issues and support children's development and social functioning. They are also used to manage related comorbidities such as hyperactivity, sleep difficulties, and gastrointestinal issues, which may not improve with rehabilitation therapy alone but do not target core impairments [16, 17, 30-32].

Interventions based on Applied Behavior Analysis (ABA) principles are commonly used with children diagnosed with ASD and have been extensively studied [33]. ABA employs behavioral principles to identify environmental factors influencing socially significant behaviors and to design individualized interventions [34].

The current study assessed the effects of combining pharmacological and behavioral management for autistic patients at the Autism Academy of Jordan, a private center in Jordan. We chose to focus on a single center's patient population to minimize variability in diagnosis and treatment approaches across different medical centers.

METHODOLOGY

Study Design and Setting

This retrospective-prospective observational study [35] evaluated the effects of pharmacological treatment as an adjunct to behavioral therapy in managing autism among patients at a private center in Jordan. The study included all patients at the center at the beginning of the research, following IRB approval. The researcher retrieved previous assessment results from patients' records and personally observed at least two assessments during the study period (December 2016 to June 2017). This center was selected due to its large patient population and consistent use of the ABLLS evaluation tool.

Study Population

Medical records of 54 male and female patients, both inpatient and outpatient, were included in the study. Records of 2 patients were excluded due to incomplete assessments. Inclusion criteria required patients to be diagnosed

according to DSM-5 criteria by an autism specialist at the center, of any gender and age, and residing both internally and externally while exclusively treated at the Autism Academy of Jordan. All patients received behavioral therapy using the Applied Behavior Analysis (ABA) system for a minimum of 30 hours per week. To be included, patients needed to have more than one assessment period, with the first assessment serving as the baseline. The intervention options included behavioral therapy alone or combined with pharmacological treatment. The intervention spanned four intervals, each lasting three months, with assessments conducted at the end of each interval. The first interval served as the baseline assessment. Patients were followed up every three months to evaluate improvement using the ABLLS system.

The researcher (AA) was familiar with the patients' identities as she collected data from their records and observed their behavioral therapy sessions, where their names were used.

Data Collection

Social, demographic, and clinical data of patients were collected from their medical records to assess potential associations with disease prevalence or therapy progress. Demographic data included: age, gender, birth order among siblings, mode of delivery, nationality, family history of psychological or neurological disorders, housing type (internal/external), and parents' request for therapy. Clinical data encompassed EEG findings, epilepsy diagnosis, age at diagnosis, and age at enrollment in the center. It also included comorbid psychiatric conditions and symptoms such as Attention-Deficit/Hyperactivity Disorder (ADHD), bipolar disorder, tantrums, irritability, hyperactive symptoms, insomnia, aggression, and self-harm, along with details of medications used, including name, dose, and indication.

Assessment of therapeutic interventions: Behavioral intervention utilized the Applied Behavior Analysis

(ABA) system, which applies behaviorist principles directly to improve human behavior. Each patient received ABA for at least 30 hours per week (6 hours per day, 5 days a week). No additional home-based or external behavioral interventions were provided. Periodic assessments using the ABLLS system were conducted every 3 months to evaluate the efficacy of the ABA system. Effectiveness was measured by overall progress across all skills. The researcher attended these evaluation sessions, and medication adherence was ensured by observing medication intake in front of the therapist.

Medication doses were gradually adjusted to balance efficacy and minimize side effects, tailored to each patient's body weight and severity of ASD. The maximum dose of risperidone used was 2 mg/day.

The ABLLS system was employed by the center to monitor progress in behavioral therapy with or without pharmacological interventions. ABLLS is an educational tool used to assess strengths and weaknesses in 25 areas of basic functional communication skills in patients with developmental delays or disabilities. Each of the 25 skills is ranked in ascending order based on complexity across multiple subdivisions. The following skill areas were measured: A-cooperation and reinforce effectiveness (A1-A19), B- visual performance (B1-B27), C-receptive language (C1-C57), D-limitation (D1-D27), E-vocal limitation (E1-E20), F-requests (F1-F29), G-labeling (G1-G47), H-intra verbal (H1-H47), I-spontaneous vocalizations (I1-I9), J-syntax and grammar (J1-J20), K-play and leisure (K1-K15), L-social interaction (L1-L34), M-group instruction (M1-M12), P-generalized responding (PA-P6), Q-reading (Q1-Q17), R-math (R1-R29), S-writing (S1-S10), T-spelling (T1-T7), U-dressing (U1-U15), V-eating (V1-V10), W-grooming, X-toileting (X1-X10), Y-gross motor (Y1-Y30), Z fine motor (Z1-Z28). Each assessment was scored and converted into a percentage of achievement. Advantages of ABLLS include providing a quick overview to parents and therapists about the patient's skill levels, and it can

be administered with minimal understanding of ABA principles. However, its lack of full standardization is considered a drawback of the ABLLS system.

Statistical Analysis

Descriptive analyses were used to summarize the data of the total sample. Continuous data were expressed as means \pm standard error of the mean, while categorical data were presented as numbers and percentages. Categorical variables were analyzed using the Chi-square (χ^2) test or Fisher's exact test as appropriate.

Each score in every assessment was transformed into a percentage achieved. An overall percentage was calculated by summing percentages from all letters A to Z. A t-test was used to assess significant differences in overall percentage efficacy between the two treatment modes (behavioral vs. pharmacological plus behavioral). Additionally, two-way ANOVA was used to evaluate significant differences in overall percentage between the two intervention modalities across different assessment intervals. Statistical analyses were performed using SAS 9.2 (Cary, NC, USA). All significant differences were considered at $\alpha \leq 0.05$.

Ethical statements

Approval for this study was obtained from the Institutional Review Board (IRB) of the Ethical Committees at Jordan University of Science and Technology, Deanship of Research (Grant Number 2016/462).

Consent:

Patients at the center were unable to provide consent. Consent was obtained from their legal guardians (parents) upon admission to the center. The center provided access to records with legal confirmation.

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RESULTS

Demographics:

Data were collected from patient records at the Autism Academy of Jordan, with fifty-two participants enrolled in the study. As shown in Table 1, the majority of participants (41, 78.85%) were aged between 4 to 10 years, and 47 (90.38%) were male. Most participants ranked second among siblings in their families. Eighteen patients (34.62%), fifteen patients (28.85%), eight patients (15.38%), and seven patients (13.46%) were classified as first, third, and fourth in birth order, respectively. The mode of delivery for most patients (33, 63.46%) was vaginal birth, with the remainder (19, 36.54%) delivered via cesarean section. The majority of patients were housed internally (44, 84.62%) and were of Libyan nationality (33, 63.46%). Further details are included in Table 1.

Parents-requested behavioral modifications:

The therapist considers parents' requests to focus on and guide them to special programs designed according to their wishes and applied within the home. Specifically, 45 parents (86.54%) requested behavior modification, whereas only 4 parents (7.69%) requested speech skill modification. Further details are illustrated in Table 2.

ASD characteristics

Eight patients (15.38%) had confirmed epilepsy diagnosis; none of them had recorded changes in EEG, while six patients (11.53%) were not diagnosed with epilepsy but had sharp waves in EEG record. Details in Table 3.

Among psychiatric related conditions[36], hyperactivity symptoms (19 patients, 36.54%) followed by irritability (16, 30.77%) had the highest prevalence. Further details are shown in Table 4.

Table 1: Social and demographic Data

Social and demographic data		Number	Percentage (%)
Age	4-10 years	41	78.85
	11-17 year	9	17.31
	18-24 year	2	3.85
Gender	Male	47	90.38
	Female	5	9.62
Rank among siblings	1 st	15	28.85
	2 nd	18	34.62
	3 rd	8	15.38
	4 th	7	13.46
	5 th , 6 th , 7 th , 8 th	4	7.69
Mode of delivery	Vaginal	33	63.46
	Cesarean Section	19	36.54
Internal/External Housing	Internal Housing	44	84.62
	External Housing	8	15.38
Nationality	Libyan	33	63.46
	Saudi	14	26.92
	Jordanian	2	3.85
	Kuwaiti	2	3.85
	Iraqi	1	1.92

Table 2: Parents' request of therapist

Parent request	Frequency	Percentage%
Behavior Modification	45	86.54
Speech	4	7.69
Independence, toilet training	2	3.84
Learn to walk	1	1.92

Table 3: Epilepsy diagnoses and EEG changes

Condition	Confirmed epilepsy N (%)	No epilepsy diagnosis N (%)	Total
No changes in EEG	8 (15.38%)	38 (73.08%)	46 (88.46%)
Sharp waves in EEG	0 (0%)	6 (11.53%)	6 (11.53%)
Total	8 (15.38%)	44 (84.61%)	52 (100%)

Table 4: Frequency and percentage of psychiatric conditions among patients.

Condition	N (%)
Hyperactive symptoms	19 (36.54)
Irritability	16 (30.77)
Self-Harming	4 (7.69)
ADHD	4 (7.69)
Insomnia	2 (3.85)
Aggression	2 (3.85)
Bipolar disease	1 (1.92)
Tantrum	0 (0)

Pharmacological treatment and indications: Various psychiatric and neurological conditions associated with ASD include attention deficit hyperactivity disorder (ADHD), schizophrenia, bipolar affective disorder, eating behavior problems, and self-harming, which warranted medication use [37]. As shown in Table 5, corresponding medications, names, and prescribed doses were detailed alongside concurrent conditions. Risperidone was the most frequently prescribed medication during this study.

Therapeutic assessments

The ABLLS system was utilized by the center to monitor progress in behavioral therapy with or without pharmacological interventions. For each assessment, the calculated score was converted into a percentage achieved. An overall percentage was derived by summing the percentages for all letters from A to Z.

There were four assessment intervals, with the first interval serving as the baseline. No significant difference was observed between the two groups—behavioral therapy with pharmacological treatment and behavioral therapy alone ($p = 0.3103$). Similarly, no significant differences were found in the second and third intervals ($p = 0.0509$, $p = 0.0691$). However, interval four showed a statistically significant difference between the two groups ($p < 0.0001$). Therefore, approximately twelve months were needed to observe a significant improvement when

medications were added to behavioral therapy. Details are provided in Table 6.

DISCUSSION

Multimodal therapy that is holistic in nature is critical for managing ASD. Our study is considered unique as it is the first of its kind. To the best of our knowledge, there is a lack of studies, especially in the Middle East region, comparing the effects of medication on behavioral interventions. Therefore, the outcomes of this study could lay the groundwork for future similar studies. One significant finding from the data is that medication combined with behavioral therapy was more effective than behavioral therapy alone. Additionally, our study found a higher prevalence of ASD in males compared to females, consistent with existing systematic reviews indicating a higher prevalence among males [38]. However, this study did not aim to estimate the male-to-female ratio or study prevalence.

Our study contrasts with previous research suggesting a significantly higher risk of ASD recurrence in siblings than previously estimated. An earlier multinational study reported an 8.4-fold increased risk of ASD after an older sibling's diagnosis [25]. However, other research indicated that 18.7% of children with at least one older sibling with ASD developed the condition [39]. Interestingly, contrary to previous assumptions, our study found that the prevalence was highest among second-born offspring (18, 34.62%), followed by

firstborn offspring (15, 28.85%), with the lowest rate observed among eighth-born offspring (1, 1.92%). To our knowledge, such a ranking among siblings has not been

previously studied, possibly due to cultural perceptions in Middle Eastern countries where families may have larger numbers of children, extending to eighth or ninth births.

Table 5: concurrent medical conditions and medications used for each.

Condition	Medication (Doses)
ADHD	Omega 3 (5 ml) Atomoxetine (18 mg) Quetiapine (50 mg) Citicoline (600 mg)
Aggression	Risperidone (0.5, 0.75 mg)
Hyperactive symptom	Risperidone (0.25, .5, .75, 1, 1.5, 2 mg) Atomoxetine (10, 60 mg) Quetiapine (25 mg) Multivitamin Omega 3(5ml)
Insomnia	Melatonin (5 mg)
Self-Harming	Risperidone (0.5, 0.75, 2 mg) Olanzapine (7.5 mg)
Bipolar disease	Quetiapine (25 mg)
Irritability	Risperidone (0.5, .75, 1, 1.5, 2 mg) Olanzapine (7.5 mg) Quetiapine (25 mg) Multivitamin
Tantrum	Not seen
Speech	Valproic acid (400 mg)
Epilepsy	Carbamazepine (200, 280 mg) Levetiracetam (400, 500, 1500 mg) Valproic acid (400, 600, 900 mg) Lamotrigine (100 mg) Phenytoin (300 mg) Topiramate (50 mg) Oxcarbazepine (900 mg)
Sharp Waves in EEG	Levetiracetam (400, 600, 30000 mg) Carbamazepine (400, 800 mg) Valproic acid (600mg)
Unknown reason	Olanzapine (10 mg) Escitalopram (10 mg) Propranolol (10 mg)

Table 6: Assessment results per each of four intervals

	Number	Mean	Minimum	Maximum	P value
Interval One Non-Medicated	26	2.1440	0.7178	6.0474	0.3103
	Medicated	25	2.7361	0.7178	
Interval Two Non-Medicated	26	4.0396	1.0310	9.4099	0.0509
	Medicated	26	6.0774	1.3267	
Interval Three Non-Medicated	23	4.3610	1.2170	10.0612	0.0691
	Medicated	23	6.4499	1.4929	
Interval Four Non-Medicated	16	4.6959	2.0331	10.3461	< 0.0001
	Medicated	17	8.1218	2.3912	

Patients were more frequently delivered via vaginal delivery, with 33 (63.46%) births, compared to 19 (36.54%) via cesarean section, despite a multinational cohort study suggesting a modest increase in ASD risk associated with cesarean delivery compared to vaginal delivery [40]. This study was conducted at a single center with a small number of patients, so generalizations about risk factors cannot be made.

The therapist considered parents' requests to tailor behavioral treatments accordingly. The highest request was for general behavior modification, with 45 (86.54%) parents, while 4 (7.69%) parents specifically requested speech-related interventions. Parents requesting behavior modification strategies such as self-management and joint attachment were trained to implement these techniques at home. Parents seeking speech-related interventions were taught narrative-based strategies to describe activities to their child and label objects.

Since the Food and Drug Administration (FDA) has not approved medications for treating core symptoms of ASD, behavioral symptoms such as hyperactivity and irritability are primarily managed. However, aripiprazole and risperidone have been FDA-approved to manage irritability in ASD patients [41] [37]. A recent systematic review highlighted significant improvements in autism-related symptoms with risperidone compared to placebo,

reporting a 43% improvement in irritability on average [42]. At this center, risperidone was the most frequently prescribed and administered medication.

Divalproex sodium has demonstrated significant efficacy in controlling aggression and irritability in ASD patients in a randomized controlled trial [43]. In this study, valproic acid, carbamazepine, and levetiracetam were used for epileptiform EEG patterns, even in cases where epilepsy diagnosis was not confirmed. Sharp waves were observed concurrently with aggression and irritability, and both antipsychotic and antiepileptic drugs were employed for management.

Therapy management assessments were conducted every three months. In the first three months, there was no significant difference between the two intervention groups (behavioral therapy with pharmacological treatment versus behavioral therapy alone). During the second and third intervals, there was an increase in mean and maximum values, indicating improvement in learned skills among those receiving medication in addition to behavioral therapy. However, this difference was not statistically significant when comparing the combined pharmacological and behavioral therapy to behavioral therapy alone. A noticeable and significant difference was observed only after the fourth interval. This suggests that it takes a considerable amount of time to observe the effects of medication when combined with behavioral

therapy compared to behavioral therapy alone.

A study supporting our findings indicated that combining behavioral therapy with antipsychotic medication was the most effective method for controlling aggressive symptoms in ASD patients, albeit requiring at least 30 sessions to achieve prominent results [44].

CONCLUSION

In conclusion, our research emphasizes the importance of combining pharmacological and behavioral therapies, which proves more effective than behavioral therapy alone. However, achieving this favorable outcome typically requires at least 12 months. Both behavioral and pharmacological therapies necessitate time to achieve efficacy. Symptoms

such as aggressiveness, irritability, hyperactivity, or ADHD must be managed consistently for at least 12 months to optimize the effectiveness of behavioral therapy.

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تدخلات سلوكية مع وبدون علاج دوائي: دراسة مقارنة في مركز للتوحد في الأردن

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ملخص

اضطراب الطيف التوحدي هو اضطراب عصبي معقد ومتغير للغاية. يصف هذا المخطوط دراسة مراقبة هدفها تقييم تأثير العلاج السلوكي والدوائي على المرضى الذين يعانون من التوحد في مركز التوحد في الأردن. تم تقييم المرضى كل ثلاثة أشهر لتحديد تقدمهم في العلاج السلوكي باستخدام طريقة (ABLLS). قام الباحث بجمع جميع التقييمات السابقة للمرضى المتواجدين في المركز، وشهد على ما لا يقل عن تقييمين في كل فترة. النتائج: يشكل الذكور نسبة (90.38%)، بين الحالات النفسية، يظهر اضطراب الفرط النشاطي 19 (36.54%)، تليه التهيج 16 (30.77%) بأعلى انتشار. كانت الفترة الأولى هي الفترة الأساسية. في الفترتين الثانية والثالثة، تظهر النتائج فرقا طفيفاً ولكنه غير ذلك بشكل ذي دلالة إحصائية. من ناحية أخرى، أظهرت الفترة الرابعة فرقا ذا دلالة إحصائية، $P < 0.0001$. في الختام، يعتبر الجمع بين العلاج الدوائي والعلاج السلوكي أكثر فعالية من العلاج السلوكي بمفرده، على الرغم من أن هذه الفائدة تتطلب على الأقل سنة لتكون فعالة.

الكلمات الدالة: اضطراب طيف التوحد، ريسيريديون، تحليل السلوك التطبيقي، تقييم اللغة الأساسية ومهارات التعلم.

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