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Effect of hyperbaric oxygen therapy and Tomatis sound therapy in children with autism spectrum disorder

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Highlights

- This study explored the efficacy of hyperbaric oxygen therapy (HBOT) and Tomatis sound therapy (TST) in children with ASD.
- After intervention, the experimental groups (HBOT, TST, and combined) had significantly lower CARS scores than controls.

- The group with combined therapies had improved CARS scores compared to group I and II with one interventional therapy.
- Our study provides some evidence of the benefit of combination therapy (HBOT and TST) for children with ASD.

Abstract

Many therapeutic and dietary regimens have been studied for children with autism spectrum disorder (ASD) in the last three decades. We aimed to evaluate the efficacy of hyperbaric oxygen therapy (HBOT) and Tomatis sound therapy (TST) in an Egyptian cohort of children with ASD. This study was a prospective, open label, randomized interventional clinical trial. One hundred forty-six children with ASD with no previous rehabilitation therapy were enrolled in our study. Patients were randomly divided into four groups: the first group received hyperbaric oxygen therapy, the second group received Tomatis sound therapy, the third group received a combination of both modalities, and the fourth group, the control group, received no intervention. We found that the combination of Tomatis sound therapy with hyperbaric oxygen therapy had a superior effect in improving autism symptoms than each intervention alone (CARS after therapy 35.04±13.38 *versus* 49.34±17.54 before the intervention, $p<0.001$). *The* combination of both modalities may be helpful for children with ASD. The most distinctive evidence that supports the use of combination therapy for ASD is still controversial; however, our study provides some evidence of the benefit of combination therapy for children with ASD. Future studies should use a more sophisticated research design and begin by finding a consistent baseline measure that can be used to evaluate the effects of these therapies for ASD.

Previous Next

Keywords

Autism; Clinical trial, CARS; Hyperbaric oxygen; Tomatis sound therapy

1. Introduction

Autism spectrum disorder (ASD) is one of the most common neurodevelopmental disorders. In recent years, as a result of more accurate diagnostic techniques and the recognition of several grades of ASD, the reported prevalence of ASD has risen, and its current incidence has been estimated at approximately 1–2% of the total human population (Blumberg et al., 2013; Saad et al., 2017; Bjørklund et al., 2018). In developed countries, the current prevalence is estimated to be at least 1.5%. However, there is considerable variation between studies and countries, with prevalence estimates from 0.2% in some parts of Asia and Europe to much higher levels in other countries, such as 2.50% in the US and Australia, and 3.13% in Iceland (Morales Hidalgo et al., 2021). Studies have suggested that both genetic and environmental factors play an essential role in the occurrence of ASD. The environmental factors include maternal diet during the prenatal period and gastrointestinal (GIT) problems described in children with ASD (Bjorklund et al., 2016). The GIT symptoms in patients with ASD may be due to increased intestinal permeability, changes in microbial composition, allergic reactions, and intestinal inflammation (Saad et al., 2015; Bjørklund et al., 2018). Previous research in the last three decades revealed some evidence of impaired sensory processing, including hyper- and hypo-responsiveness to sensory stimuli in children with ASD. Some of these abnormalities have been linked directly or indirectly to the core manifestations of ASD (Baranek, 2002; Ghanbari and Rezaei, 2016). Although the mechanism of ASD pathogenesis has not yet been identified, many therapeutic approaches have been developed to control ASD and relieve the burden of autism from behavioral and various health impairments. There is no curative pharmacological treatment for ASD (Saad et al., 2015). Several complementary or alternative treatments for ASD have been widely used, with the aim to ameliorate ASD symptoms. These alternative treatments include melatonin, secretin, immunotherapy, Hyperbaric oxygen therapy (HBOT), auditory integration therapy (AIT), modified diets, and supplementation with vitamins and long-chain polyunsaturated fatty acids (Whitehouse, 2013; Bjørklund et al., 2018). However, the lack of rigorous studies and controversial results have impeded healthcare professionals from drawing definitive conclusions. Tomatis sound therapy (TST) and HBOT have recently been used but the exact mechanisms of action are not fully understood. Hyperbaric oxygen therapy is a relatively new technique for treating ASD, with promising results. Although current research has not found strong clinical evidence to support the use of HBOT for ASD patients (Podgórska-Bednarz and Perenc, 2021), HBOT has been shown to have potent anti-inflammatory properties and upregulate enzymes, which help with detoxification problems (Rossignol, 2007; Rossignol et al., 2009). Some studies have found positive effects of HBOT in children with ASD (Rossignol et al., 2009). Speech therapy has an important role in language improvement and enhancing the communication skills of patients with ASD (Neysmith-Roy, 2001; Corbett et al., 2008). Alfred Tomatis developed TST, which utilizes electronically modified human voice and music delivered *via* the “Electronic Ear”. TST is similar to AIT, which uses frequency filtered music therapy. However, the techniques are different in the application and intensity of sound therapy. In TST, mother voice is a part of the sound therapy schedule. Tomatis method teaches autistic children to recognize and respond to the sound of their mother's voice (Sinha et al., 2011). The electronic ear could be used to simulate the sound of the mother's voice as it is heard in the uterus, gradually trying to adjust the child to respond to the mother's true unfiltered voice. Few reports showed improvement of ASD symptoms after

TST therapy (Brbic and Tomic, 2020). The present study aimed to explore and identify the efficacy of HBOT and TST in an Egyptian cohort of children with ASD.

2. Material and methods

Our study was approved and carried out following the code of Ethics of the Ethical Committee of Assiut Faculty of Medicine, Assiut University, Egypt (IRB: 17300664). Patients were given a comprehensive explanation of the study and written informed consent was obtained from all patients' caregivers.

2.1. Study design

This study was a prospective, open-label, randomized interventional clinical trial undertaken in Asyut city, Egypt. *TRIAL REGISTRATION NUMBER*: UMIN000043362 (retrospective).

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2.2. Patients

The study population included 146 Egyptian children diagnosed with ASD selected from a sample of 209 patients, 88 males (60.3%) and 58 females (39.7%). The mean age was 6.8 years (SD=3.06), ranging from 5 to 14 years. They were all diagnosed with ASD at outpatient clinics of the Assiut University hospitals, Egypt, with no previous rehabilitation therapy. All patients were evaluated by an experienced psychologist (IMA) and a senior psychiatrist (IS). The ASD diagnosis was established by the same psychologist for all patients, using the DSM 5th edition (American Psychiatric Association, 2013), and confirmation, classification, and follow-up of patients were done using the Childhood Autism Rating Scale, 2nd edition (CARS II) (Schopler et al., 2010). Two interviews with parents, each lasting 30 min, were conducted. The first interview was for ASD diagnosis by DSMV, and the second was to assess disease severity using CARS. Childhood Autism Rating Scale is a well-established scale for the diagnosis and classification of ASD that has a high degree of concordance with DSM-V. It evaluates behavior in fourteen domains impacted by ASD problems, as well as one domain of ASD impressions, with the goal of distinguishing ASD from other developmental disorders. The psychologist assigned a score of 1–4 to each domain: one indicates behavior consistent with age level, while four indicates a significant deviation from age level-appropriate behavior. The total scores for all items indicate whether the child is not autistic (score less than 30), mild or moderate ASD (30–36.5), or severe ASD (score greater than 36.5) (Schopler et al., 2010). Before starting the interventions, CARS was performed and repeated after three months.

All participants were in good general condition. We excluded 63 patients who met one or more of the following exclusions criteria: i) Other neurological and metabolic disorders (*e.g.*, cerebral palsy, phenylketonuria, neurocutaneous diseases, fat metabolism disorders, chronic metabolic acidosis, and pyruvate carboxylase deficiency), ii) chronic kidney and liver diseases, iii) epileptic disorders, iv) feeding problems, failure to thrive, anemia and autoimmune disorders, v) Chronic ear and/or sinus infections, vi) chronic endocrine, cardiovascular and pulmonary diseases, vii) patients taking any antipsychotic medications, supplements, and multi-vitamins, in the previous 30 days before the interventions.

3. Methods

Using a simple random grouping method, and with the help of the Excel software Rand function, the research patients were randomly assigned to one of the four intervention groups:

I. The first group (HBOT): Thirty-four patients with ASD received 40 sessions of HBOT. All sessions were carried out at a pressure of 1.5 ATA (atmosphere absolute), at 100% oxygen concentration, each lasting for at least one hour in a multiplace chamber. All participants completed the 40 sessions within three months. During each HBOT session, all patients were accompanied by an adult caregiver.

II. The second group (TST): Thirty-eight patients with ASD received TST. Patients treated with TST underwent the Tomatis listening therapy for 30 h (15 sessions) within three months. Tomatis Method utilizes recordings by Mozart and Gregorian Chant, as well as the patient's mother's voice. The listening room is large and comfortable, and can easily accommodate the child, caregiver, and Tomatis aides. The room is very kid-friendly, with puzzles and other interactive toys. The headphones are placed on the ears and firmly secured with a cloth hairband to keep them in place and at the proper tension.

III. The third group (combined therapy): Forty-nine patients received combined HBOT and TST therapies similar to the first and the second groups for three months.

IV. The fourth group (control): Twenty-five patients received no intervention—the control group.

3.1. Statistical analysis

We used SPSS (version 22, IBM, NY) for data analysis. Data were compared between the four groups using the Kruskal Wallis test followed by the Mann Whitney test between the two groups. The CARS scores before and after therapy in different groups were compared using the Wilcoxon Signed rank. *P*-value was significant at <0.05.

4. Results

The baseline CARS scores ranged from 34 to 58.5 (mean 49.26; SD 12.34). Before the interventions, all patient groups were comparable regarding age, gender, anthropometric data, and classification of autism. The baseline CARS scores were not significant among all patient groups (p=0.230; Table 1). After the interventions, the experimental groups (I, II, and III) had significantly lower scores of total CARS than the control group (Table 1). Furthermore, group III with combined therapies had improved CARS scores compared to group I and II with one interventional therapy each. There was no significant difference between groups I and II (Table 1). After therapy, HBOT group had decreased CARS scores between 5 and 7.5 points with improvement of communication (verbal and non-verbal), relating to people and emotional response. TST group had decreased CARS scores between 2.5 and 4.5 points with improvement of listening response and verbal communication. Group III with combined therapies had decreased CARS scores between 6 and 14.5 points with improvement of communication, activity level, relating to people, emotional and listening responses (Table 1).

Table 1. Comparison of the demographic and CARS scores for the four groups.

	Hyperbaric oxygen therapy group I (*n*=34)	**Tomatis sound therapy group II (*n*=38)**	**Combined therapy group III (*n*=49)**	**Control group IV (*n*=25)**	**p-value**
Age (years)					
Minimum	2.16	2.41	2.33	2.08	0.329
Maximum	12.50	13.08	13.41	13.66	
Mean±SD	6.3±2.65	5.9±2.21	6.8±3.84	7.2±2.92	
Sex	Male (*n*=19)	Male (*n*=21)	Male (*n*=33)	Male (n=15)	0.272
	Female (*n*=15)	Female (*n*=17)	Female (*n*=16)	Female (*n*=10)	
Baseline CARS	50.47±12.32	51.84±14.04	49.34±17.54	50.99±13.11	0.230
CARS after interventions	43.79±11.41	45.63±12.15	35.04±13.38	49.73±14.03	0.008
***P* value between pre- and post-interventions**	0.023	<0.05	<0.001	0.103	–
% Change	13.2%	12%	28.9%	2.4%	<0.0001

P1=0.51 (group I versus group II) after completing therapy.

P2<0.002 (group I versus group III) after completing therapy.

P3<0.01 (group I versus group IV) after completing therapy.

P4<0.001(group II versus group III) after completing therapy.

P5=0.02 (group II versus group IV) after completing therapy.

P6<001 (group III versus group IV) after completing therapy.

CARS=Childhood Autism Rating Scale.

Regarding the side effects of HBOT, there were no episodes of severe barotrauma. Mild barotrauma was found only in 13 patients in the first sessions, and that resolved spontaneously.

5. Discussion

To ameliorate the ASD symptoms, several complementary or alternative treatments have been widely used, such as modified diets, supplementation with vitamins, especially vitamin D and polyunsaturated fatty acids, immune therapy, and recently HBOT and TST (Corbett et al., 2008; Rossignol et al., 2009; El-Rashidy et al., 2017). The new trend is to adopt more than one therapeutic approach that might synergize for the best outcomes depending on the stage of intervention and severity of the ASD. However, the lack of rigorous studies and controversial results has impeded definitive conclusions about these treatments for ASD (Bjørklund et al., 2018).

5.1. Hyperbaric oxygen therapy

Despite the lack of definitive conclusions about its efficacy, the use of HBOT has recently increased, although it is not yet approved by FDA. Rigorous studies are not only scarce but also the interpretation of their findings has been somewhat ambiguous among the scientific community. Some studies have found positive effects of HBOT for patients with ASD (Rossignol, 2007; El-baz et al., 2014), while others have found no effect (Granpeesheh et al., 2010; Sampanthavivat et al., 2012). In line with our findings, previous studies (Rossignol, 2007; Rossignol et al., 2009; El-baz et al., 2014) showed that HBOT has positive effects in children with ASD. Rossignol et al., 2009 studied the efficacy of HBOT in 33 patients with ASD in a double-blind, randomized, controlled trial. Children with ASD had improved sensory (cognitive) awareness, receptive language, social and eye contact compared to the control group. Moreover, the

HBOT group had significantly higher Clinical Global Impression (CGI) scores (80% *versus* 38% in the control group; p=0.0024) (Rossignol et al., 2009). In contrast to our results and the previous reports, two large studies (Granpeesheh et al., 2010; Sampanthavivat et al., 2012) found insignificant differences in behavioral core manifestations after HBOT therapy in children with ASD. Cerebral hypoperfusion, or insufficient blood flow to the brain, has been demonstrated in several studies of patients with ASD compared to healthy controls as measured by functional magnetic resonance imaging (fMRI), positron emission tomography (PET), or Single-photon emission computed tomography (SPECT) (Bjørklund et al., 2018). Gas dissolution in liquid is directly and positively related to pressure (Boyle's law). Therefore, because HBOT increases both the partial pressure of oxygen and the absolute pressure of the gas mixture, more oxygen gets dissolved into body fluids and the brain is irrigated by blood richer in oxygen. This, then, compensates for the decreased blood flow found in the autistic brain, restores the normal oxygen delivery, and satisfies the brain's oxygen demands (Matchett et al., 2009). A recent study found enhanced cerebral perfusion in most areas of the brain accompanied by a general improvement in ASD symptoms after receiving HBOT (1.56 ATM and 100% O_2) (El-baz et al., 2014). In addition, HBOT has strong anti-inflammatory properties and may improve immune function. Additionally, HBOT stimulates enzymes that may aid the detoxification process and porphyrin production in children with ASD (Rossignol et al., 2009; El-baz et al., 2014).

5.2. Tomatis sound therapy

Previous studies revealed the needs of ASD children for music therapy. Music therapy improves social skills engagement and emotional behaviors, lessens abnormal behavior, and educates children with ASD on emotional engagement and communication skills. Music may improve the awareness of both human and musical relationships (Gerritsen, 2010; LaGasse, 2014). Auditory stimulation by Tomatis method was utilized to enhance listening skills and increase communication skills, particularly in patients with ASD (Gerritsen, 2010). Previous reports revealed that patients with ASD have severe impairment in sensory input processing, particularly auditory data, which may be associated with communication, language, and social deficits (Kellerman and Gorman, 2005). As regards the use of TST in ASD, the studies are inadequate, and the interpretation of findings has been somewhat confusing among the scientific community. Some studies have found positive effects of TST for ASD (Neysmith-Roy, 2001; Vervoort et al., 2007; AbediKoupaeia et al., 2013), whereas others have found no significant effect (Corbett et al., 2008). In line with our findings, Neysmith-Roy, 2001 showed that TST had positive effects in five out of six males with severe ASD. They showed development of prelinguistic behaviors in three children after TST, and one of them had normal CARS scores after TST sessions. Another study showed significant positive changes in four children with severe autism. The researchers reported significant changes in EEG and auditory evoked potentials after TST (Vervoort et al., 2007). Researchers in a larger study (AbediKoupaeia et al., 2013) of 34 pediatric patients with ASD found that after thirty sessions of TST, there was a significant reduction in the core autism manifestations, including improvements in communication, social interaction, and a decrease in stereotypy.

Contrary to these studies and our findings, Corbett et al., 2008 studied eleven patients with ASD. Their results did not indicate any significant changes in language skills between the TST group and controls. Numerous studies hypothesized the neural mechanisms to explain enhancements in motor, speech, and memory functions following music-based interventions. They proposed priming the neural networks linking music therapy with language, memory, auditory-motor coupling, and neuroplasticity (Sihvonen et al., 2017; Sacarin, 2013; Särkämö et al., 2016; Brancatisano et al., 2020). In our study, we used the Tomatis electronic ear, and the mother's voice was a part of the TST schedule. The Tomatis method helps ASD patients identify and react to their mother's voice. The TST with an electronic ear can mimic the sound of the mother's voice as received in the uterus, which helps the children to gradually understand and respond to an unfiltered mother's voice (Sacarin, 2013).

In our study, we found that patients treated with combined therapy (HBOT plus TST) showed significantly lower CARS after therapy than patients treated with either HBOT or TST alone. To the best of our knowledge, we are the first to use HBOT and TST as a combination therapy.

The main limitations of our study were the absence of double-blinded evaluation. Future studies should use a more sophisticated research design and begin by finding a consistent baseline measure that can be used to evaluate the effects of these therapies for ASD.

6. Conclusions

The combination of hyperbaric oxygen therapy and Tomatis sound therapy may be helpful for children with ASD. The most distinctive evidence that supports the use of combination therapy for ASD is still controversial; however, our study provides some evidence of the benefit of combination therapy for children with ASD.

Author contributions

MME, KS, A.S., ARA, and SMK designed the study, followed the patients, analyzed the data, and drafted the manuscript. IMA and IS performed all psychological tests of the study. TAA, AKMA, S.BHA, IS and MME drafted the manuscript. All authors were involved in the critical analysis of the final version of the manuscript. All authors approved the manuscript as submitted and agree to be accountable for all aspects of the work.

Declaration of Competing Interest

The authors declare no competing interests.

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