# Treatment With Buspirone in a Patient With Autism

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This study evaluates the safety and efficacy of buspirone hydrochloride for the treatment of a patient with autism and hyperactivity disorder and determines the effect of buspirone on the number of performance tasks completed by the patient at school. A 3-week, double-blind, placebo-controlled crossover study was performed in a private physician, office-based practice. A child with autism, which was diagnosed by *Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised*, criteria, was studied. The child received placebo for 3 weeks and buspirone for 3 weeks; there was a 1-week interval between the 2 treatments. The outcome was measured by using Conners abbreviated parent and teacher questionnaires and by determining the number of daily performance tasks completed by the child at school. Statistical analysis was performed by linear models and standard F tests. Buspirone was found to be safe and efficacious, without side effects, for decreasing hyperactivity and increasing completed performance tasks. The beneficial effects of buspirone in helping this patient with autism in his natural daily settings suggest that buspirone may be an alternative to neuroleptic agents in the medical therapy of autism; further study in other patients is needed. *Arch Fam Med. 1997;6:368-370*

Autism is a chronic developmental disorder that results in abnormalities in activities and interests, social interactions, and communication. Hematologically, elevated blood serotonin levels have been seen in patients with the disorder.[1,2] Buspirone hydrochloride is a medication that inhibits the serotonergic system.[3,4] Because of this property and its wide safety margins,[5] buspirone has been used in the pharmacotherapy of autism. In an open trial, buspirone was given to patients with autism complicated by aggression and hyperactivity.[6] A case report described the use of buspirone in patients with autism who displayed self-injurious behavior.[7] To my knowledge, no placebo-controlled research investigating buspirone therapy in patients with autism has been done. One double-blind study using buspirone in children with attention deficit hyperactivity disorder showed a significant treatment effect.[8]

The following pilot study, involving a patient with autism who displayed hyperactivity, aggression, and self-injurious behavior, was initiated to further explore this issue and to assess the safety and efficacy of buspirone treatment. The experiment was designed to evaluate the effect of buspirone therapy on the hyperactivity of a patient with autism and to determine if buspirone therapy enhanced this patient's response to the interventions outlined in his individual educational program.

## PATIENTS AND METHODS

The study patient (a boy) was 4 years 10 months when the research was conducted. Two years previously, at age 2 years 8 months, a multidisciplinary evalu-

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**Outcome Measures for Buspirone* Therapy Compared With Placebo**

| | Conners Abbreviated Questionnaires Score | | | | Performance Tasks Completed by the Patient | |
|---|---|---|---|---|---|---|
| | Mother | | Teacher | | | |
| Time | Placebo | Buspirone | Placebo | Buspirone | Placebo | Buspirone |
| Baseline | 27 | | 22 | | 2.0 | |
| Week | | | | | | |
| 1 | 21 | 18 | 21 | 18 | 2.0 | 2.2 |
| 2 | 22 | 22 | 26 | 20 | 2.0 | 2.4 |
| 3 | 22 | 8 | 24 | 7 | 2.2 | 3.4 |

*Buspirone was given as buspirone hydrochloride.

ation of his condition had been started because of developmental delays and extreme behavior that had precluded attendance at day care. The patient was banging his head and hitting himself until bruised. He was also kicking and hitting others. He had poor eating and sleeping habits and was extremely hyperactive. The patient did not establish eye contact or socially interact. He had a propensity for round, shiny objects and put everything into his mouth. He was fascinated by the diaphragm of a stethoscope and would rub it over his lips and face. He did not verbally communicate.

The patient lived with his biological parents and an older sister. Each of these family members was healthy. Both parents were college graduates.

The prenatal history and the labor and delivery were unremarkable, as was the medical history of the patient and the family. The results of a physical examination, a laboratory workup, auditory brainstem response audiometry, an electroencephalogram, a magnetic resonance imaging scan, and chromosome analysis were normal. Neurologic consultation revealed no abnormalities. The results from adaptive behavior testing showed a composite score below 1%. The patient's only strength was gross motor skills. His greatest weaknesses were in socialization and expressive language skills. With the use of *Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised,*[9] criteria, autism was diagnosed in the patient.

At age 3 years 4 months, the patient was eligible for a preschool resource class. During the next 18 months, his uncontrolled behavior persisted. Transfer to a smaller class with a teacher-student ratio of 1:2 did not help. Treatment with haloperidol and clonidine was unsuccessful.

After informed consent was obtained from the patient's parents, a 3-week, double-blind, placebo-controlled crossover study of buspirone compared with placebo was designed. Each form of therapy was used for 3 weeks; there was a 1-week interval between the 2 treatments.

Capsules of lactose hydrose containing 5-mg tablets of buspirone were prepared. These were identical to placebo capsules of only lactose hydrose. The medication (5 mg of either buspirone or placebo) was given at 7:30 AM and noon each day.

Outcome measures included Conners abbreviated questionnaires,[10] which were completed by the patient's mother and teacher, and the number of performance tasks completed by the patient at school, which were recorded by his teacher. The data from each of these measures were collected at baseline and weekly for each 3-week interval (**Table**).

Linear models were fitted separately to the weekly average number of completed tasks and Conners scores for the mother and teacher. Because the effect of buspirone was anticipated to be gradual and to increase across the 3 weeks of administration, this effect was assessed by standard F tests comparing the rates of change in these outcomes when the patient was receiving buspirone compared with placebo.

## RESULTS

The patient completed the study without any side effects of medication noted during buspirone or placebo therapy.

The patient's baseline average was 2 performance tasks completed each school day. During the third week of placebo therapy, the patient averaged 2.2 completed tasks daily. This was a 10% increase compared with baseline.

The average number of completed tasks during the third week of buspirone therapy was 3.4. This was a 70% increase compared with baseline and a 55% increase compared with placebo. The differences in the 3-week rates of change between buspirone and placebo therapy reached statistical significance ($F[1,3]=15.36$, $P=.03$).

The scores on the Conners questionnaires at baseline were 27 for the mother and 22 for the teacher. At the end of week 3 of placebo therapy, these were 22 for the mother and 24 for the teacher. At the end of week 3 of buspirone therapy, the mother's score was 8 and the teacher's score was 7. When the patient received buspirone therapy, the mother's score showed a 70% improvement compared with baseline and a 64% improvement compared with placebo; the teacher's score indicated a 68% improvement compared with baseline and a 71% improvement compared with placebo. The effect of buspirone therapy on the teacher's scores reached marginal statistical significance ($F[1,3]=9.02$, $P=.06$). Its effect on the mother's scores seemed to be less marked ($F[1,3]=3.60$, $P=.15$).

## COMMENT

Buspirone was found to be safe and efficacious for modifying the patient's hyperactive behavior and increasing

his exposure to the interventions outlined in his individual educational program. In addition to these improvements, the patient's mother and teacher also noted a marked decrease in aggressive and self-injurious behaviors.

There are limitations when interpreting the data from a single case study. Double-blind trials of buspirone compared with placebo involving many patients with autism would be optimum.

However, according to a 2-year study by Larson et al,[11] many physicians in everyday clinical practice view the results of randomized single patient trials as sufficient evidence of treatment efficacy and safety.

In the pharmacotherapy of autism, major tranquilizers are frequently prescribed but the side effects of medication are worrisome.[12] Buspirone may be an alternative to neuroleptic agents in the medical treatment of this disorder and should be studied further.

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