

Pioglitazone in conjunction with risperidone for children with autism



Overview of therapy

According to Weissman & Bridemohan (2018), “ Autism spectrum disorder (ASD) is a biologically based neurodevelopmental disorder characterized by persistent deficits in social communication and social interaction and restricted, repetitive patterns of behavior, interests, and activities” (para 1). The etiology of autism is not known; however, several theories exist, including factors associated with genetic, neurobiological, environmental, immunological, and metabolic (Samsam, Ahangari, & Naser, 2014). The U. S. Food and Drug Administration (FDA) approved the drug risperidone for treating irritability in children with autism (5-16 years of age) in 2006 (Department of Health and Human Services, 2017). Currently, risperidone, an anti-psychotic medication, which antagonizes dopamine D2 receptors, and serotonin 5-HT2 receptors (Epocrates, 2018), is the only FDA-approved drug for the treatment of specific autism symptoms (DHHS). The research article that was reviewed investigated the use of pioglitazone in conjunction with risperidone and the effects this therapy had on aberrant behavior in children with autism (Ghaleiha, Rasa, Nikoo, Farokhnia, Mohammadi, & Akhondzadeh, 2015).

Pioglitazone, is a thiazolidinediones (TZD) antidiabetic drug, approved by the FDA and widely used clinically to treat type 2 diabetes mellitus (Edmunds & Mayhew, 2014). TZD is also thought to increase metabolic activity in the brain, produce anti-inflammatory responses in the brain, and effect a component of autoimmune diseases (Boris, Kaiser, Goldblatt, Elice, Edelson, Adams, & Feinstein, 2007), making pioglitazone a treatment option. It is a selective agonist for peroxisome proliferator-activated receptor-gamma, <https://assignbuster.com/pioglitazone-in-conjunction-with-risperidone-for-children-with-autism/>

crosses the blood brain barrier, and produces an anti-inflammatory effect (Edmunds & Mayhew). The use of pioglitazone is not a new therapy for autism, in 2007 research examined the effects that the single use of pioglitazone had on the behavioral symptoms in children with autism (Boris et al.).

This combination pharmacological treatment in the autistic population may improve behavior symptoms associated with autism since the clinical trial and previous research resulted in the decrease of some autistic behaviors, such as irritability, lethargy, stereotypy, and hyperactivity (Boris et al.; Ghaleiha et al.). The results also showed that pioglitazone did not have significant side effects. Both studies found that the use of pioglitazone, whether used independently or in conjunction with risperidone, decreased multiple symptoms associated with autism in children.

Analysis of the study

The study was a 10-week randomized, double-blind, parallel group, placebo-controlled clinical trial to investigate the effects of pioglitazone in combination with risperidone to treat irritability in children with autism.

Inclusion to the clinical trial was based on a) children who were in the range of 4 to 12 years of age, b) had a DSM IV-TR diagnosis of autism, c) scored equal to or greater than 12 on the Aberrant Behavior Checklist-Community (ABC-C) Irritability subscale, d) held a chief complaint of severely disruptive symptoms associated with autism, and e) risperidone was considered as a medical intervention. Exclusion from the study were patients with any other medical or psychiatric disorder(s), had used psychotropic medication(s) 6 weeks prior to the screening procedure at the baseline visit, and had a <https://assignbuster.com/pioglitazone-in-conjunction-with-risperidone-for-children-with-autism/>

history of liver disease, seizures, diabetes treated with medication(s), or congestive heart failure. Prior to starting the clinical trial, the participants went through a screening procedure to check for the excluded medical diagnoses.

A total of 44 patients participated in the trial; however, 40 patients completed the clinical trial with a sample size of 20 children in each group. The two groups were randomly defined in a 1: 1 ratio of participants taking pioglitazone and risperidone, and those assigned to taking a placebo and risperidone. The effectiveness of the study was measured by visits to the outpatient clinic at baseline and on week 5 and week 10 of the clinical trial. Strengths of the trial were that there were no significant adverse effects seen or reported in the participants, the use of the ABC-C Irritability subscale tool, and assessment of the children's behavior at baseline and again at the two scheduled interval times during the study. The intervention of adding pioglitazone showed substantial results in decreasing irritability, stereotypy, hyperactivity, and lethargy in children with autism who completed the clinic trial.

There were no significant adverse effects reported or noted in the participants that would be concerning. The notable design issues to consider improving were using a larger sample size and allowing a longer time period to follow the participants. Since the population receiving the therapy are mainly children, and the probability that therapy would be long-term, makes it crucial to have follow up evaluations on the effects of children utilizing this therapy long-term to treat this disorder. The results were expressed in a manner that were important in considering conducting further clinical trials <https://assignbuster.com/pioglitazone-in-conjunction-with-risperidone-for-children-with-autism/>

and assessing the outcomes. The results were also useful to the advanced practice nurse in prescribing therapy and considering pioglitazone for monotherapy or as an adjunct to pharmacological treatment in this population. The identification of unique strategies found to serve this patient population provides new information that can help augment advanced practice nurses' knowledge to respond and care for this population.

Discussion.

The results of this study offer a new approach to the pharmacological method currently being used in this population. Medicine treatment with antipsychotics as part of any treatment plan brings up concerns for the severity of side effects of that class of medications. The use of pioglitazone as an adjuvant medication for autoimmune or anti-inflammatory features of autism as an unlabeled indication uncovers the possibility of monotherapy with pioglitazone without the side effects associated with antipsychotics. My primary practice is with adults who have mental health disorders and alcohol and drug addictions, so I do not work with children or adolescents with autism. This topic is important to me because I believe I will encounter children with this disorder and I want to be prepared with information and knowledge to fully participate in their care. I think children diagnosed with autism may require extra time and attention from psychiatric and mental health nurses to ensure therapeutic milieu management, reinforcement of impulse control, relationship interventions, and cognitive-behavioral therapy. Advanced practice nurses have the unique position to have an impact in the therapeutic partnership on patient outcomes through knowledge of various treatment modalities.

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Applications to Case Study.*CC/PMH*

RK is a 7year old autistic patient who has poor academic performance in his first-grade class. This has been brought to the parents' attention by his teacher who was concerned that RK was " falling behind." He is often disruptive to the class, and seems to have a difficult time paying attention. Height – 50", weight – 55lbs.

*Medications:**Risperidone 0. 5mg orally daily**Physical examination and labs : WNL**Questions for Discussion:*

1. What pharmacological options exist for the treatment of Autism?

Although pharmacological agents are not the first line of treatment for autism, the FDA has approved risperidone and aripiprazole for patients experiencing irritability, self-injury, and aggression. Additional pharmacological therapy based on treatment of symptoms include: selective serotonin re-uptake inhibitors (SSRIs), tricyclics, stimulants, anti-anxiety, and anticonvulsant medications (DHHS). However, they may be used in conjunction with other interventions, or for behavioral disturbances.

Medications based on treatment of symptoms include, methylphenidate for inattention and hyperactivity (not related to or with any other symptoms or disorders), risperidone or aripiprazole for maladaptive behaviors, fluoxetine for repetitive behaviors, SSRI to treat anxiety, and atypical antipsychotic or SSRI for dysregulated moods (Weissman & Bridgemohan).

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2. What non-pharmacological recommendations should be considered for the treatment of Autism?

A variety of nonpharmacological treatment options are available, and interventions are very individualized; therefore, a thorough and accurate assessment must be done on the patient to determine the appropriate treatment options (Autism Society, 2016). Activity based interventions, applied behavioral analysis, assistive technology, cognitive behavioral interventions, exercise, and structured play therapy are a few examples of hands-on involvement to maintain the patient's independence with activities of daily living. Interventions guided by using a multidisciplinary approach, to increase social skills, communication, strengthen processing, recognize inappropriate behaviors, and help to alter thoughts and behaviors are most beneficial for optimal outcomes (Autism Society, 2016).

3. What monitoring should be done for patients on pioglitazone for autism therapy?

According to Ghaleiha et al., monitoring the patient's weight, and laboratory test values for the presence of diabetes, liver disease, and cardiac problems are advised. Ordering specific serum tests to examine values for a complete blood count, fasting blood sugar, and aminotransferases are beneficially for therapy. Parents must be instructed to monitor for any adverse events or unexpected symptoms and report them immediately and be advised that the most common side effects reported were vomiting and headaches.

4. What are some of the advantages and disadvantages of adding pioglitazone to risperidone for the treatment of Autism?

The advantages of adding pioglitazone as an adjuvant are the significant changes that occurred on the ABC-C scale. Scores showed a noteworthy decrease in irritability, stereotypic behavior, hyperactivity, and non-compliance (Ghaleiha et al.; Boris et al.). Another advantage is that little to no adverse symptoms associated with the administration of adjuvant medication treatment was noted. Disadvantages to this treatment are the possible long-term side effects and need to discontinue treatment if any adverse effects were noted after long-term therapy. Edmunds & Mayhew (2014) identify that pioglitazone carries a warning associated with a risk for possible bladder cancer and use of this medication for greater than one year.

References

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