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## Review

# Conspicuous by their absence: Studies comparing and combining risperidone and applied behavior analysis to reduce challenging behavior in children with autism

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## ABSTRACT

Both risperidone, an atypical antipsychotic drug, and function-based behavior-analytic interventions are popular and empirically validated treatments for reducing challenging behavior in children with autism. The kind of research that supports their effectiveness differs, however, and no published study has directly compared their effects or examined the two in combination. The research methods characteristic of applied behavior analysis may provide a useful basis for comparing the effects of risperidone and behavior-analytic treatments, alone and in combination, and researchers are encouraged to pursue this line of investigation.

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Autism is characterized by impairments in social interaction, atypical language development, and patterns of behavior that are restricted and repetitive (American Psychiatric Association, 2000). In addition to exhibiting these core symptoms, children with autism sometimes engage in self-injury, aggression directed towards property or other people, temper tantrums, and other behaviors that cause problems and therefore are targeted for reduction (see review by Matson & Nebel-Schwam, 2007). In October of 2006, the Food and Drug Administration of the United States (U.S. FDA) approved the antipsychotic drug, risperidone (Risperdal<sup>®</sup>), for the treatment of such behaviors, collectively labeled as “irritability”, in children with autism between the ages of 5 and 17 years (U.S. FDA, 2006). The decision to approve risperidone for this purpose was based on the results of two 8-week placebo-controlled trials involving 156 children with autism. Overall, irritability as measured by the Aberrant

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Behavior Checklist was lower when risperidone was administered, although the drug's effects differed across children.

A number of other published studies also demonstrated generally beneficial effects and it now appears that risperidone is reasonably effective in reducing challenging behavior in children with autism (e.g., Miral et al., 2008; McCracken et al., 2002; Shea et al., 2004). It is the case, however, that not all children benefit from risperidone and the drug can produce a range of side effects, including tremor, drowsiness, fatigue, drooling, weight gain, and enuresis (e.g., Ghanizadeh & Kianpoor, 2008; Scahill, Koenig, Carroll, & Pachler, 2007). Nonetheless, risperidone is a popular treatment for reducing problem behavior in children with autism (and other autism spectrum disorders). For example, results of a 2006 survey completed by the parents of 552 children with autism indicated that 12.2% of them had been treated with the drug in the past and 10.2% were currently using it (Green et al., 2006). The values are probably higher at present, because the drug has now been FDA-approved for more than 2 years.

Of course, other interventions are also available for reducing problem behaviors in children with autism. A substantial literature suggests that function-based behavior-analytic interventions (which comprise a range of specific treatments) are useful (e.g., Athens, Vollmer, Sloman, & Pipkin, 2008; Dwyer-Moore & Dixon, 2007; Langdon, Carr, & Owen-DeSchryver, 2008) and applied behavior analysis (ABA) is widely used to reduce problem behavior (as well as to establish desired behavior) in children with autism (e.g., Ahearn, Clark, MacDonald, & Chung, 2007; Foxx, 2008; Jones, Feeley, & Takacs, 2007). Results of a survey by Green et al. (2006), described previously, indicated that the children of 22.7% of respondents had been treated with ABA in the past and 36.4% were currently being treated with it.

Both risperidone and ABA are empirically validated treatments for reducing problem behaviors in children with autism. The kind of research that supports their effectiveness differs, however. Most studies evaluating risperidone used a substantial number of participants, indirect measures of problem behaviors, and statistical data analyses (for a review see Jesner, Aref-Adib, & Coren, 2007). In contrast, most studies evaluating behavior-analytic interventions used relatively few subjects, direct measures of problem behaviors, and visual data analysis (for a review see Fahmie & Hanley, 2008). These are fundamentally different research strategies and people who favor one approach are frequently dismissive of the other. For example, most conventional research design and statistics textbooks devote few pages to within-subject, small-N designs and essentially dismiss them collectively as “quasi-experimental” or “case studies” (see Dermer & Hoch, 1999). On the other hand, many behavior analysts are openly critical of research that uses indirect measures of behavior and assesses treatment effects by statistically comparing group means (e.g., Johnson & Pennypacker, 2009; Kazdin, 1982; Poling, Methot, & LeSage, 1995).

Given that both risperidone and ABA are popular, empirically validated treatments for reducing problem behaviors in people with autism, an obvious and important question is: Which is more effective? The best way to answer this question is to compare the two in a single, well-controlled study. To our knowledge, no such study has appeared.

In fact, a recent (May 7, 2009) search of the Scopus, PsychInfo, and MedLine data bases using risperidone, autism, and behavior analysis as key words failed to reveal *any* study that directly compared risperidone and ABA in children with autism. Therefore, a well-informed caregiver choosing between the two would have to make her or his decision based on a comparison of findings from studies that used fundamentally dissimilar research tactics. This is an “apples to oranges” comparison. How, for example, does a statistically significant difference in the mean level of irritability as measured by the Aberrant Behavior Checklist in a group of children with autism who received risperidone relative to a group who received placebo relate to a 50–70% reduction in daily occurrences of directly observed tantrums in two children going from a baseline to a function-based treatment condition under a multiple-baseline arrangement? In the absence of a standard metric, which appears to be lacking, there is no meaningful comparison.

Even if she or he was fully aware of the relevant research literature, a caregiver, such as a parent, searching for an intervention to reduce problem behavior in a child with autism would have a difficult time determining whether risperidone or ABA would be a better option. If the caregiver sought an expert's opinion, that opinion is likely to vary across experts, depending on their disciplines, hence training and experience. A psychiatrist would probably, and from her or his perspective appropriately,

recommend risperidone. A behavior analyst, also appropriately for him or her, would opt for ABA. Both could do so on the basis of data, but neither could do so on the basis of a direct comparison of the two interventions.

From our perspective, it appears that there is real need for such a comparison. In addition, there is need for research examining the effects of combining risperidone with ABA. Although no data are available regarding how frequently the two are used in combination in people with autism, our experience and findings regarding the prevalence of use of each intervention suggests that the practice is relatively common. Nonetheless, a recent (May 7, 2009) computer search of the Scopus, PsychInfo, and MedLine databases did not reveal a single study examining the effects of risperidone and ABA in combination, and it appears that no such study has been published. However, some recent behavior-analytic studies (Crosland et al., 2003; Valdovinos et al., 2002; Zarcone et al., 2004), summarized later, suggest that risperidone may influence the function of environmental stimuli, hence the effectiveness of interventions based on manipulations of those stimuli.

The 14-month Multimodal Treatment Study of Children with Attention Deficit Hyperactivity Disorder (ADHD), commonly called the MTA (MTA Cooperative Group, 1999a), is an influential comparison of pharmacological and behavioral interventions, alone and in combination, and merits discussion as a possible model for comparing risperidone and behavior-analytic techniques, alone and in combination, as treatments for the challenging behavior of children with autism. The MTA examined the behavior of 579 elementary school children between the ages of 7 and 9.9 years with ADHD who were assigned at random to one of four conditions: (1) medication (methylphenidate, Ritalin<sup>®</sup>) alone, (2) behavioral treatment alone, (3) medication in combination with behavioral treatment, and (4) routine community care (a control condition).

The medication alone condition began with a 28-day, double-blind, daily-switch titration of methylphenidate, during which randomly ordered repeats of placebo, 5, 10, and 15 or 20 mg (for children weighing over 25 kg) were used. Doses were given at breakfast and lunch, with a half-dose administered in the afternoon. Parent and teacher ratings of responses to each dose were graphed and blindly reviewed by cross-site teams of experienced clinicians. The child's best dose was determined by consensus and the blind was then broken. The agreed-on dose was subsequently used as the child's initial maintenance dose. For those children who did not achieve the desired effect, dextroamphetamine, pemoline, or imipramine was openly titrated until a satisfactory response was established. A cross-site panel approved other medications for those still not obtaining an adequate response. Of the 289 children assigned to either the medication alone ( $n = 144$ ) or the combination treatment ( $n = 145$ ) conditions, 256 completed titration. Of these, 198 were given an average initial dose of methylphenidate of 30 mg/day, 26 were openly titrated to dextroamphetamine, and 32 were given no medication due to a robust placebo response.

Pharmacotherapists provided encouragement, support, and practical advice during half-hour maintenance visits each month. Readings from an approved list were provided upon parental request or when deemed as necessary by the pharmacotherapists. Parent- and teacher-provided information was carefully reviewed by clinicians and algorithm-guided dose adjustments of 10 mg/day of methylphenidate were then made. If the subject was taking a different medication, an equipotent amount was assigned. A cross-site panel of experienced pharmacotherapists approved dose adjustments of  $\pm 10$  mg/day. Dose reductions were typically carried out to address side effects.

The 13-item Pittsburgh Side Effects Rating Scale was completed by parents and reviewed monthly during maintenance visits. At the end of the study, 245 medication alone/combination treatment families furnished information regarding side effects. Of these, 88 (35.9%) reported no side effects, 122 (49.8%) reported mild side effects, 28 (11.4%) reported moderate side effects, and 7 (2.9%) reported severe side effects. It should be noted that some families reported more than one side effect. Those figures, according to The MTA Cooperative Group (1999a), may overestimate severe side effects (depression, irritability, or worrying) because they could have been due to factors other than medication.

The behavioral treatment component of the MTA study consisted of parent training, child-focused treatment, and a school-based intervention. Parent training, based on work by Barkley (1987) and Forehand and MacMahon (1980), and teacher consultation were conducted by therapist-consultants and included 27 group (6 families per group) and 8 individual family sessions. Each therapist-

consultant had a caseload of 12 families and training occurred weekly with biweekly teacher consultation sessions taking place on a concurrent basis. The frequency of training and consultation sessions gradually decreased as the study progressed.

The child-focused treatment involved an 8-week, 5-days-per-week, 9-hours-per-day summer treatment program (STP) as described by Pelham and Hoza (1996). The behavioral interventions used in the STP were implemented in group-based recreational settings by counselors/aides supervised by therapist-consultants who carried out teacher consultation and parent training. A point system tied to specific rewards, time out, social reinforcement, modeling, group problem solving, sports skills, and social skills training was used. The STP provided individualized academic skills practice and reinforcement of appropriate classroom behavior.

The school-based intervention comprised two components: 12 weeks (60 school days) of part-time, one-on-one, instruction (based on methods described by Swanson, 1992) by a behaviorally trained paraprofessional and 10–16 sessions of biweekly teacher consultation that emphasized classroom behavior management techniques. The paraprofessionals had been STP counselors, which aided in the generalization of the STP procedures to the students' classrooms during the fall semester. A report card, which consisted of a 1-page teacher-completed checklist detailing the child's successes on specific behaviors of interest, was sent home with the child each day. Based on the daily report card, each child's parents provided putative reinforcers (e.g., snacks, access to preferred activities).

Families given both behavioral and combined treatment attended an average of 77.8% of parent training sessions and 90.5% of STP days. During the school component, children attended an average of 47.6 of a possible 60 sessions with the paraprofessional while teachers attended an average 10.7 consultation sessions. The extent of attendance for the two components (one-on-one sessions with a paraprofessional and parent training) varied significantly across sites. There were no significant differences between behavioral and combined treatment, either within or across sites, in the extent to which the behavioral components were attended/implemented. Further, a summary measure of attendance/compliance for all behavioral treatment components was unrelated to treatment outcomes and attendance did not mediate any site by treatment interactions on outcomes (MTA Cooperative Group, 1999b).

The presence of staff responsible for the implementation of the behavioral treatments was gradually reduced, with the goal that parents would take on a greater role in the management of their child's behavioral treatment. By the end of the study, therapist contact with parents was minimal with sessions occurring a maximum of once per month in most cases.

During the combination treatment phase, behavioral treatment and medication management procedures were integrated to approximate clinical practices. Information was shared regularly between pharmacotherapists and teacher-consultants; procedural changes were made according to standard, pre-determined guidelines. By the end of the study, subjects in the combined treatments group received lower mean daily doses of methylphenidate (31.2 mg/day) than those in the medication alone group (37.7 mg/day).

Participants in the community care group received none of the treatments mentioned above. They were, however, given a list of mental health resources and a report of their initial assessments conducted at the beginning of the study. Reassessments occurred in parallel with the other three treatment groups and treatments received in the community were documented. Interestingly, many participants in this group ( $n = 97$  [67.4%]) received ADHD medications from their own provider over the 14-month duration of the study: methylphenidate ( $n = 84$ ), pemoline ( $n = 7$ ), amphetamine ( $n = 6$ ), tricyclics ( $n = 6$ ), clonidine/guanfacine ( $n = 4$ ), and/or bupropion ( $n = 1$ ) (10 of the 97 children were treated with more than one medication). It should also be noted that 16 of the 97 children were prescribed antidepressants other than tricyclics or bupropion. The children treated with methylphenidate received an average total daily dose of 22.6 mg by the end of the study, with an average of 2.3 doses per day. Those in the MTA-treated group averaged 3.0 doses per day.

All treatment groups showed marked reductions in symptoms over the course of the study with degree of change varying significantly across groups. The combined treatment and medication alone procedure produced clinically and statistically greater benefits with respect to reduction of ADHD

symptoms than did community care and behavioral treatment. Also, participants in the combined treatment group, currently the criterion standard in ADHD interventions, did not achieve a level of benefit that was significantly greater than those in the medication management group with respect to the core symptoms of ADHD.

The MTA has been criticized in several regards (e.g., Barkley, 2000; Breggin, 2000; Harwood & Beutler, 2001). Breggin (2000) states that proponents of the study “claim that it demonstrated the superiority of stimulant treatment over behavioral treatments and routine community treatment” (p. 63) when, in fact, the data collected by blind classroom raters (the only blind raters used in the study) showed no difference between any of the treatments used in the study. In contrast, teachers and parents who provided ratings used in the study were aware of which children were receiving medication and which were not receiving medication. In addition, of the 144 medication management subjects, 46 (32%) were receiving ADHD medication at the beginning of the selection process. This may indicate that the parents of these children were predisposed to favorable ratings of drug treatments, thus calling into question their ability to provide unbiased ratings. Further, adverse drug effects were evaluated by the aforementioned parents and teachers, rather than by trained professionals, thereby possibly compromising the accuracy of the results. Perhaps most importantly, Breggin points out that the MTA study was not a placebo-controlled, double-blind clinical trial and lacked a non-treated control group, thus limiting the validity of any of the conclusions drawn from the study. These factors and many others, he states, are major flaws that would render the MTA unacceptable as a study for the FDA-approval process, for example.

Harwood and Beutler (2001) make the point that the behavioral treatment was “at best, a single mismatched treatment and, at worst, comprised of an unspecified variety of nonsystematic and erroneous efforts to fit the treatment to the patient, post hoc, and without clear feedback on progress” (p. 142). In contrast, the medication treatment was tailored to each participant.

Barkley (2000) calls attention to the fact that behavioral treatment procedures were “faded out before the post-treatment evaluation was conducted...” (p. 596). The medication management component, however, was continued up until the study’s conclusion. This, at minimum, suggests that participants in the medication management and behavioral treatment components of the study were exposed to their respective independent variables for unequal durations, thereby making comparisons between the two difficult.

Although the MTA was a large and expensive undertaking that attempted to address an important issue, it falls far short of being a well-controlled and compelling investigation. Nonetheless, it has been widely cited – as of May 22, 2009, 1019 Scopus citations are listed – and apparently is quite influential.

Using methods comparable to those of the MTA to compare the effects of risperidone, ABA, and the two in combination would not provide compelling information. One can, however, envision a large-N group-comparison study that would do so. Such a study would be double-blind and placebo-controlled, with drug and behavioral interventions carefully tailored to produce maximal benefit, and their desired and untoward effects accurately measured. It is important to emphasize that pharmacological and nonpharmacological treatments characteristically have different side effect profiles, and this difference would need to be taken into account in a high quality investigation.

Although easy to envision, a methodologically sound group comparison of risperidone and ABA would be expensive and difficult to conduct. Including a combined treatment condition would only increase the difficulty. Nonetheless, such a study is justified. Autism is a relatively common condition that generates worldwide attention, and challenging behavior frequently occurs in children with this diagnosis. Scientific evaluation of the relative value of two common interventions for reducing such behavior, risperidone and ABA, alone and in combination, would provide invaluable to caregivers. In that regard, it is noteworthy that the National Institutes of Health has provided funding for a large multi-site study comparing the effects of risperidone alone with the effects of risperidone plus parent training on measures of noncompliance, irritability, and adaptive functioning. The design of the study, which does not allow for a direct comparison of risperidone and parent training alone, is described by Scahill et al. (2009) and the parent training component is detailed by the [Research Units on Pediatric Psychopharmacology \(RUPP\) Autism Network \(2007\)](#). It is our understanding that initial results have been analyzed and a article describing them will soon appear. Those results undoubtedly will be

important, but they will not provide information about the relative value of risperidone and ABA for reducing challenging behaviors.

Although not widely accepted in clinical psychopharmacology, behavior analytic research tactics (i.e., intensive study of relative few subjects using within-subject experimental designs, repeated and direct measures of target behaviors, visual inspection of data, and social validation of the acceptability of goals, procedures, and results) can provide the framework necessary to produce a standard metric whereby these two treatments can be meaningfully compared without the extreme effort, time, and expense of large group studies (Barlow & Hersen, 1984; Kollins, Ehrhardt, & Poling, 2000; Poling & Ehrhardt, 1999; Schroeder, 1985). As noted previously, such methods have been widely used to confirm the effectiveness of ABA interventions for reducing challenging behaviors in people with autism.

As also mentioned previously, in recent years behavior-analytic strategies have been used in three related studies to investigate the effects of risperidone in people with autism (Crosland et al., 2003; Valdovinos et al., 2002; Zarcone et al., 2004). In the first of these studies (Valdovinos et al., 2002), the destructive behavior of two adults with autism was examined at home and in a clinical setting under conditions where placebo and four doses of risperidone (1.0, 1.6, 2.0, 2.5 mg/day) were administered. Direct observation and three rating scales were used to quantify destructive behavior in an experiment that used a withdrawal design. Weekly functional analysis sessions (using methods described by Iwata, Dorsey, Slifer, Bauman, & Richman, 1994) to determine the consequences controlling destructive behavior also were conducted.

Results indicated that risperidone decreased destructive behavior and that the four measures of such behavior (direct observation, three rating scales) yielded comparable results. Functional analysis did not reveal the variables that controlled destructive behavior in either participant.

The second study (Crosland et al., 2003) used the general functional analysis strategy described by Iwata et al. (1994) to examine levels of destructive behavior in an adult (Reggie) and a child (Sean) and to examine possible controlling variables for such behavior. Destructive behavior was maintained by escape from demands, attention, or access to tangible items. Risperidone (1.0 and 1.5 mg/day for Reggie, 2.0 and 3.5 mg/day for Sean) reduced destructive behavior in the demand condition for both participants, but such behavior remained high in the tangible condition for Reggie and in the attention condition for Sean.

The third study reported a functional analysis of the destructive behavior of 13 people with developmental disabilities, including 10 with an autism spectrum disorder, under conditions where they received placebo or risperidone (Zarcone et al., 2004). Caregiver ratings of destructive behavior, using two rating scales, also were obtained. Two doses of risperidone were evaluated. Caregiver ratings indicated that the drug reduced destructive behavior in 10 of 13 individuals. For 7 of these 10 individuals, risperidone produced similar effects across functional analysis conditions. In the remaining three, risperidone produced function-specific reductions in destructive behavior. Side effects of risperidone varied across participants. Increased appetite for food and weight gain, common side effects of the drug (e.g., Aman, DeSmeldt, Derivan, Lyons, & Fielding, 2002; Snyder et al., 2002), were frequently observed. For 5 of the 13 participants, the scheduled high dose was reduced due to significant sedation and lethargy, which are also common side effects of risperidone.

The three studies just summarized, as well as other recent investigations (Garcia & Smith, 1999; Valdovinos, Ellringer, & Alexander, 2007), provide evidence that behavior-analytic research methods, including functional analysis, can be used productively to study drug effects in people with autism and other developmental disabilities. None of these studies compared the effects of risperidone with those of ABA, or examined the two in combination. One can, however, readily envision how behavior-analytic research methods could be used for both purposes. Although comparing interventions poses methodological problems, such as possible order and carry-over effects (Poling et al., 1995), these problems can typically be solved. In truth, the extent to which they create serious obstacles for researchers can only be ascertained by actually conducting relevant studies. It is our belief that such studies could play an invaluable role in allowing those concerned with the proper treatment of people with autism to choose the best available treatments for challenging behavior, and it is our hope that this manuscript encourages researchers to conduct such studies.

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