A Dose-Ranging Study of Behavioral and Pharmacological Treatment for Children with ADHD


ABSTRACT

Behavioral and pharmacological treatments both have an evidence base for the treatment of children with ADHD. However, the combination of the two treatments has been relatively understudied. In particular, multimodal studies with long-acting stimulant preparations have not been conducted. In this study, placebo and three doses of methylphenidate (MPH) were combined with two behavioral treatments (BMOD) in the context of a summer treatment program (STP). Participants were 27 children aged 6-12 and diagnosed with ADHD. Children received four medication conditions in random order with conditions changing daily. BMOD conditions were implemented for 3-week blocks, with order randomized across groups. Both treatments produced large and significant effects on children’s behavior and performance in the STP. Combined treatment was superior to either treatment alone, and a low dose of methylphenidate (average of 5 mg MPH t.i.d.) combined with BMOD produced equivalent effects as those of a high dose (average of 15 mg MPH t.i.d.) alone.

DESIGN AND PROCEDURES

Design: Two within-subjects factors: medication (placebo, .15 mg/kg MPH tid, .3 mg/kg MPH tid, .6 mg/kg MPH tid) and behavioral modification (BMOD: low-intensity behavior modification [LBM]: high-intensity behavior modification [HBM]). Medication was randomly assigned and varied daily on Mondays–Thursdays for 24 days. Behavioral treatment was varied on a within-subjects basis; medication was varied daily. Children, parents, and staff members were blind to medication conditions. Setting: The investigation took place in the context of the summer treatment program (Pelham, Granger, & Gnagy, 1997; Pelham & Massetti, 1999; Pelham et al., 1994).

MEASURES

Counselor-recorded behavior from the point system: (1) following activity rules and rule violations; (2) noncompliance; (3) interrupting; (4) complaining; (5) problem behaviors (lying, stealing, externalized destruction of property, and internalized aggression); and (6) negative-bullying (verbal abuse to self, teasing peers, and swarming). Behavior ratings: Counselors completed the (1) Teacher/Overactivity subscale from the KOWA Conners Rating Scale (Conners, 1992); (2) Oppositional/Defiant KOWA Conners subscales; and (3) Observed Conners scale. Effectiveness/stress ratings: Counselors rated: pleasantness and stress of interacting with the children, how well the children got along with peers, and their overall effectiveness in the treatment role.

RESULTS

Overview of all dependent measures, 6 drug: placebo, 15, 30, 45 mg/kg MPH tid (BMOD: LBM, HBM, LBM+HBM) multivariate analysis of variance was conducted. Table 1 shows means and standard deviations for each condition. Significant effects of drug were followed up by examining pairwise tests among doses. Significant 2-way interactions were followed up by examining the simple effects of each treatment component. On all behavioral measures, both medication and BMOD produced large and significant main effects. The two treatments interacted such that the dose-response curve was flattened in the presence of behavioral treatment compared to medication alone (see Figure 1 for example). The majority of the medication effect occurred at the lowest dose in the LBM and HBM conditions. A more linear dose-response relationship was found for the LBM condition. Further analyses will include normalization rates and examination of degrees of treatment effectiveness and acceptability.

DISCUSSION

Both medication and behavioral treatment produced large and significant effects on nearly all behavioral measures. These findings expand on previous studies carried out in the classroom setting (Carson et al., 1992; Pelham et al., 1993) by extending the period of evaluation to the entire day (e.g., recreational activities, lunchtime, transitions).

• On most measures, the effects of high-intensity behavior modification was equivalent to high dose medication, and low intensity behavior modification was equivalent to a moderate dose of medication (see figure above).

• Carson et al. (1992) found, the lowest dose of medication produced as much change in the BMI conditions as the higher doses of medication produced in the BMI condition—on some variables, the effect of the highest dose of medication in the BMI condition did not surpass the effect of the lowest dose in the BMI conditions. We have long argued that one of the benefits of combining treatment modalities is that one can produce equivalent behavioral improvement using lower doses of medication. It should be noted that the lowest dose used in this study was equivalent to 5 mg MPH t.i.d.—a very low dose that is half of that used in Carson et al.

• Notably, at the high-dose levels of either condition, there were little if any incremental benefits of adding the other intervention. These results can be compared to those of the MTA, in which little effect of medication was seen in the combined treatment group compared to behavioral treatment only during the STP (Pelham et al., 2000) and little incremental effect of less intensive behavioral treatment compared to higher doses of medication was seen in the end of the study (MA Cooperative Group, 1999).

• Although the group results of this study are clear, we witnessed several individual patterns of behavior that warrant further investigation. First, some children were maintained for a period of several days when the behavioral treatment was fist withdrawn before before medication deterioration. A second behavioral pattern is that some children did not return to their previous rates of behavior, and even deteriorated, the first few days that the behavioral interventions were reinstated. For many children, the second and third HI BMOD weeks resulted in more negative behavior than the first weeks. Finally, some children were maintained in the BMI condition with little behavioral deterioration.

For more information, to download a copy of this poster, or for information about internship opportunities in the Summer Treatment Program, visit the Center for Children and Families on the web: http://wings.buffalo.edu/adhd

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Participants:
- 44 boys and 4 girls between the ages of 5 and 12 entered the investigation.
- Enrolled in the 2002 summer treatment program (STP) for children with ADHD conducted at the University of Buffalo.
- Required to meet DSM-IV diagnostic criteria for ADHD. Full-scale IQ of 80, no documented pain response to methylphenidate.
- Parents and children provided informed consent and the University of Buffalo Health Sciences IRB approved the protocol.
- The sample was 79% Caucasian.
- 50% comorbid oppositional defiant disorder. 21% comorbid conduct disorder.
- One child’s parent withdrew him from the study after two days because of their concerns about possible side effects of the medication. A second boy’s late afternoon dose was reduced in the 0.6 mg/kg condition because of evening side effects. The remainder of the participants completed the study.

Table 1. Participant Characteristics.

<table>
<thead>
<tr>
<th>Item</th>
<th>M (SD)</th>
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<tbody>
<tr>
<td>Age in Years</td>
<td>9.35 (1.9)</td>
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<tr>
<td>Full Scale IQ</td>
<td>106.97 (14.31)</td>
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<tr>
<td>DSM IV Items Endorsed:</td>
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<tr>
<td>Inattention</td>
<td>7.88 (1.67)</td>
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<tr>
<td>Hyperactivity/Impulsivity</td>
<td>6.96 (2.5)</td>
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<tr>
<td>Oppositional/Defiant</td>
<td>4.63 (2.5)</td>
</tr>
<tr>
<td>Conduct Disorder</td>
<td>1.40 (1.5)</td>
</tr>
<tr>
<td>Overall Impairment-Parent</td>
<td>4.89 (1.11)</td>
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<tr>
<td>Overall Impairment-Teacher</td>
<td>4.37 (1.62)</td>
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