

Leading Article

Medication, Behavioral, and Combination Treatments for School-Aged Children with ADHD

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ADHD, like its predecessors minimal brain damage, minimal brain dysfunction, and attention deficit disorder with or without hyperactivity, is defined by a set of behavioral observations. Diagnosis is dependent on a history of symptoms of inattention, hyperactivity, and impulsivity that are persistent, pervasive, manifest in the first decade of life, and cause clinically significant impairment. In 1937, Bradley made the astute observation that stimulant medication improved concentration and productivity [1], although behavioral treatments remained a significant part of the recommended treatment regimen. Throughout the last century, the recommendations from medical texts, as well as from consensus statements of national specialty societies, gave preference to psychosocial and educational treatments and viewed medication as an adjunctive treatment. In 1987, the American Academy of Pediatrics (AAP) re-affirmed an earlier position [2] and stated that “Medication for children with attention deficit disorder should never be used as an isolated treatment. Proper classroom placement, physical education programs, behavior modification, counseling, and provision of structure should be used before a trial of pharmacotherapy is attempted” [3].

However, since the publication of the Multimodal Treatment Study of Children

with ADHD (MTA) in 1999 [4], the tables have turned and medication is recommended as a primary treatment for ADHD. The AAP now recommends that medication and/or behavioral management be initiated [5]. In 2002, the American Academy of Child and Adolescent Psychiatry (AACAP) published guidelines for the use of stimulants (not limited to ADHD) [6] and gave only a brief mention to behavioral treatments for ADHD. In 2007, the AACAP issued new guidelines for the treatment of ADHD that again de-emphasized the role of behavioral management in favor of medication as the primary treatment for children with ADHD [7]. Shortly after the publication of the first MTA reports, true long-acting stimulants first became available. The combination of long-acting medication and the “authoritative” recommendation to use medication as a first-line treatment has led to a singular growth in the use of medication and decrease in the emphasis on behavioral management for children with ADHD. The purpose of this article is to enhance awareness of behavioral management as an important component of ADHD treatment. As most of the literature available concerns school-aged children (5–12 years), the review will be limited to evidence in children of that age group. This age represents the

onset of ADHD for most individuals, although diagnosis may be delayed for years or even decades.

Efficacy versus effectiveness

To understand the current knowledge of ADHD treatments, it is important to review the concepts of efficacy and effectiveness. An excellent explanation of the difference between these terms was offered by Ernst and Pittler: “Seemingly similar in meaning, efficacy and effectiveness express distinctly different concepts. A medical intervention is efficacious if it works under strictly controlled (laboratory) conditions and it is considered effective if it works under real life conditions. Efficacy (or fastidious) trials test for efficacy and effectiveness (pragmatic) studies for effectiveness of a therapy” [8]. Analog classroom studies of pharmacological treatments are efficacy studies, and community-based studies are effectiveness studies; both types are needed to ensure treatments that are appropriate and acceptable.

The MTA

The MTA is a landmark study of the effectiveness of medication and behavioral treatments for ADHD. It was a multisite, multiyear, US National Institute of Mental Health-sponsored, randomized, controlled study involving almost 600 children with ADHD who were receiving state-of-the-art treatments at the time. Subjects were randomized to receive intense medication treatment (MED group), intense behavioral treatment (BEH group), or a combination of both (COMB group), or to a control group who were referred back to their communities for treatment as usual (community care [CC] group). Analysis of the data after 14 months by several statistical methods showed that ADHD symptoms in all groups had improved. The COMB group showed the greatest improvements, but these were not significantly different from the MED group. Both the COMB and MED groups showed significantly greater improvements than the BEH and CC groups in measures

of symptoms, from multiple observers (direct observation, parents, and teachers; p values 0.001–0.003). However, these groups did not show a greater benefit in terms of other outcomes [4]. In consideration of the significantly increased effort and cost of combined treatments [9], guidelines for the treatment of ADHD have since emphasized medication as primary therapy [5,7].

Several criticisms of this landmark study have been made (see [10,11] for a more complete overview). Significantly, it is important to note that, compared with typical patients treated in a typical outpatient setting, the MED and COMB groups received intensive treatment with higher doses, much more frequent visits with clinicians, clinical counseling for problems, and general advice for school interventions (as it was the intent of the study to measure the response to optimum therapy). One of the most important criticisms is that the outcome measures that differed after 14 months were symptom counts of the Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition. While they do reflect improvement, and are an underlying component of the desired treatment response (reduction in the impairment in social, academic, or occupational functioning), improvement in symptoms often does not reflect normalization of behavior. Several of the MTA results indicate that there might be advantages associated with the behavioral treatments in this regard, including a higher rate of normalization in those children who received behavior management plus medication [9]. Another important finding is that many of the parents preferred the BEH or COMB treatments. Also, there may have been some subgroups of the cohort that benefited most from BEH (e.g. those with comorbid anxiety).

After 14 months of active intervention, the MTA became an observational study examining various factors as mediators or moderators of outcome. The results for 24-month and 36-month follow-ups have been published [12,13]. After both periods of time, all groups had improved. At 24 months, the advantages for the MED and COMB “remained significant” for ADHD symptoms.

There were no inter-group differences for social skills, academic development, or parental discipline. At 36 months, there was continued overall improvement in symptoms in the MED and COMB groups, but there were no differences between the groups on any outcomes. An impairment rating scale was included for the first time, and these scores also showed no differences between any of the groups. At both time points, fewer of the families who had been originally assigned to BEH had chosen to use medication compared with those in other groups (44% BEH, 86% COMB, 85% MED, and 69% CC at 36 months) [12,13]. Neither of these studies received the widespread publicity of the original study, published in 1999.

Behavioral intervention

Behavioral treatments for ADHD that have an evidence base include behavioral parent training, social skills programs, and school behavioral interventions either for the whole school [14,15] or within the classroom [16]. Pelham and Fabiano have recently provided an excellent review of evidence-based treatments for ADHD [17].

Behavioral parent training is the most commonly applied behavioral treatment and, although programs vary in detail, they have several key components in common: attending to and noticing good behaviors; ability for the child to “earn” positive rewards; clear and consistent commands; appropriate rewards and consequences; and instruction in the use of “time out”. Programs may also include instructions about accommodations in the classroom for eligible students known as 504 plans [18], special education services and laws, individual educational plans [19], and sessions on effective interaction with schools. Programs can be modified to meet the needs of individual families, e.g. a group for fathers that occurs in the context of sports [20], or groups with additional evidence-based treatment for parental issues [21].

School management systems are based on cost–response and build on the types of behavioral systems that are already used in classrooms. A key component is home–school

communication, and often a daily report card is used to accomplish this in a systematic way. This daily report card can also be used to monitor a child for medication adjustment. It is based on problematic behaviors that are identified by the teacher and parent as causing impairment. Before institution of the program, simple counts are made of the problem behavior (e.g. getting out of seat or not starting work). Typically, targets of approximately 33% improvement during the next week are set. It is important to divide the school day into natural segments so that a child who has one difficult period is not doomed to failure for the whole day. A child who meets the goals for each period achieves a “yes” on his/her daily report card. If a child meets 75% of his/her goals for the day, a privilege reward is given by parents (e.g. extra computer time or time with a parent). Good performance for the week earns an extra privilege at the weekend. The rewards are chosen to fit with the individual child and family’s life.

Parents can also use the daily report card for home behaviors. Target behaviors are adjusted so that the child can, with some effort, meet the reward criteria. If he/she does well for 3 weeks, criteria can be made more difficult or new target behaviors can be added. (For details of how to establish and maintain a daily report card, see [22].)

In the MTA, therapy for the BEH and COMB group included a summer treatment program (STP) [23]. This is a program similar to a day camp that lasts 6–9 weeks, in which children with ADHD learn appropriate social skills in a naturalistic setting that includes sports, sports skills training, group practice of social skills, peer-to-peer interactions, classroom time, and computer time. This construction enables a significant amount of contact time to be spent with the child (approximately 300 h). There is constant feedback from trained counselors, daily and weekly contingencies based on performance, and use of a daily report card for home rewards. Parents receive behavioral parent training, and classroom behavior is monitored in a similar way to how it would be

at school. The setting also allows for objective behavioral observations by trained observers in sports activities, classroom situations, and social settings where children are typically involved, e.g. lunch with peers. In the MTA, the children's teachers received consultation on how to use the daily report card and other classroom management strategies, and the child had a trained personal aide for the first semester of school.

There is much less literature on the safety of psychosocial interventions. In a recent review, Evans discussed some of the reasons for undesirable outcomes of psychosocial interventions, including deviancy training, poorly implemented behavioral practices that cause families to stop the psychosocial intervention, the need to implement treatments for long periods of time, inappropriate rewards that have unintended negative consequences, and failure to adhere to manualized programs [24].

Medication

Medication has been documented to have multiple beneficial effects in ADHD over many years. Most research on medication has involved efficacy studies rather than effectiveness studies. It is important to remember that, at the time of study, the MTA medication regimen of methylphenidate (MPH) three times a day, 7 days a week, was significantly more intense than the typical morning and noon school-day dosing that was most popular. As noted previously, the children also received much more frequent clinician visits than is usually found in practice. The effectiveness of this regimen demonstrated in the MTA was matched by the CC group at follow-up.

The side-effects of stimulants are well documented [7]. They include changes in mood, possible initiation or enhancement of tics, headache, stomach ache, decrease in appetite, and delayed onset of sleep. Small but statistically significant increases in heart rate and systolic and diastolic blood pressure have also been found to be associated with use of stimulants. Recently, the importance of cardiac monitoring with an

electrocardiograph for children prior to use of stimulant medication for ADHD was raised by the American Heart Association [25], which later modified the statement in conjunction with the AAP and AACAP [26]. Current recommendations include taking a careful history of the patient and their family in order to be aware of potential cardiac issues.

The issue of growth suppression with stimulant medications has been evaluated for many years, with conflicting results. There is no question that, acutely, the mean rate of growth in the population of treated patients is decreased compared with untreated patients. However, questions remain as to who is most affected, how great is the effect on adult height, and whether there is catch-up growth. Certainly, the current more-intensive treatment paradigms may result in further problems with growth than long-term follow-up studies indicate.

With combined medical and behavioral treatment showing minimal improvements in symptom relief over the intense medication treatment alone in the original MTA study, many in the medical community switched allegiance to medication as the first-line treatment for ADHD, which is reflected in the guidelines from professional organizations [5,27]. However, there are some reasons to consider the utility of psychosocial treatments. Fewer of the children who were initially randomized to the BEH group were taking medication, even at 36 months, than those in the MED and COMB groups, and the doses administered in the former group were smaller (as noted above) [13]. However, at 36 months, outcomes in the MED, COMB, and BEH groups were similar. When questioned, more parents preferred the behavioral treatments than any of the other therapies. After the acute intervention period, when behavioral interventions were faded out, many parents continued to use at least some of the interventions, and fewer chose to add medication to the regimen, especially for afternoon, evening, and weekend treatments. Conversely, few families who were in the medication arm pursued further behavioral treatments.

Combined treatments

There have been several studies of the efficacy of combined treatments for ADHD [28]. A meta-analysis of eight randomized, controlled trials showed large effect sizes for core features of the disorder and also social skills, but not in association with academic abilities [29].

In a crossover study, completed during an STP, the behavioral management of the program was removed for a period of time [30]. Children were randomized to receive different doses of MPH or placebo using the MPH transdermal system. The results showed that medication resulted in a significant, dose-dependent reduction in unwanted behaviors compared with placebo. Since the standard behavioral treatment of the program alone had a significant impact on behavior, the improvement with medication compared with the standard STP treatment was less robust than that seen in previous studies of medication alone.

The expense of the MTA behavioral intervention brought issues of cost-effectiveness to the fore. While there would be little acceptance of such an intensive and costly program in schools and communities, could a less-extensive behavioral program prove to be as efficacious? Can clinicians “dose” behavioral treatment and determine whether a lower level of treatment, with or without medication, would work?

A crossover study to assess the comparative and combined effects of behavioral intervention has been completed and submitted for publication [31]. Over three summer periods, 150 children participating in an STP were enrolled; each child participated for one summer only. The participants were grouped by age, and each group experienced 3 weeks of “low-dose” behavioral intervention (LBMOD) including parent training, camp rules with frequent staff feedback emphasizing positive reinforcement, “when, then” statements (when you do that, this will happen; they may be both reward- or consequence-based), and daily report cards with weekly camp and home rewards. The children also under

took 3 weeks of “high-dose” behavioral intervention (HBMOD) that additionally included a point system for more systematic feedback and daily rewards. Additionally, the participants experienced 3 weeks of essentially no behavioral management (NBMOD), with immediate feedback on behavior, but no contingent rewards. The order by which each group received these behavior conditions was randomly determined. Throughout the study, all children were randomized to receive one of three daily doses of MPH IR (immediate release; 0.15 mg/kg/dose, 0.3 mg/kg/dose, or 0.6 mg/kg/dose) or placebo. Medication was blinded and varied daily.

The results paralleled those of the previous study [29], showing that behavioral management and medication had significant effects when used alone. In this study also, medication alone, i.e. on days with NBMOD, had a significant effect, with improvement on multiple measures [31]. Similarly, on days when the child took placebo and received LBMOD, improvements were shown in multiple measures that were both statistically and clinically significant. These effects were greater than with medication alone. When the second modality was added to the regimen, continued improvement was shown, although the additive effect was not as pronounced. This result held true in the classroom setting as well as the recreation setting [32]. The findings indicated that either of these treatment modalities would be effective and that perhaps a lower level of behavioral intervention, either alone or especially in combination with low-dose medication, was effective and certainly more likely to be adaptable to the community. However, the study was conducted in the controlled setting of the STP and, therefore, can be regarded as a good study of efficacy, but not effectiveness.

To explore the issue of effectiveness, the current author’s center is currently engaged in a study involving dosing of behavioral intervention in the school and home settings. A total of 150 stimulant-naïve children aged 5–6 years who had been diagnosed with

ADHD were recruited through physicians, mental health clinics, schools, mailings, and radio advertisements. They were randomized to receive a standard school and home behavioral intervention, an enhanced school and home behavioral intervention, or monitoring for 3 years. The children were followed bi-weekly using several measures, including ratings of impairment [33]. Families who were randomized to receive the standard intervention receive behavioral parent training, child social-skills training, initial consultations with the child's teacher, and limited phone consultations when difficulties arise. Families in the enhanced condition group additionally receive booster parent training sessions, increased consultations with teachers (including meetings), and voluntary participation in the STP for two summers. If needed, a rapid response team can work with the child in the classroom and assist in establishing or refining the behavioral plan. Emergency meetings are also available to families when they have crises at home. Families in the monitoring group are encouraged to access any community services available and may even obtain parent training and individual family sessions from the study staff.

Data from parents and teachers are reviewed bi-weekly. If the child's behavior meets established criteria for further intervention, and behavioral interventions available to that family have already been used, then the parents are offered the choice of trialing a low-dose medication (MPH IR at approximately 0.15 mg/kg/dose). Further medication titration and adjustment is based on continuing bi-weekly data. Preliminary results show that only a minority of families in all groups have chosen to adopt medication. This may be a function of recruitment bias or because of the close professional follow-up. Also, perhaps working with the teachers and parents to make them aware of ADHD and to monitor the child's behaviors closely has created enough improvement to avoid medication use.

A second effectiveness study of behavioral and pharmacological interventions is

underway to address the issue of sequencing of evidence-based treatments. The study population comprises 150 children with ADHD aged 5–12 years (three cohorts of 50 children, each followed for 1 school year). These children have been randomized to receive either behavioral intervention or medication initially. The behavioral intervention is similar to the standard intervention in the previously mentioned studies [30–32]. If the first intervention is not completely successful, the child is then randomized again to receive either additional behavioral treatments or additional medication. Therefore, there are six possible treatment regimen combinations: initial medication and remaining on low-dose medication; initial medication treatment followed by increased medication; initial medication treatment followed by low-dose behavioral intervention; initial behavioral intervention that was sufficient; initial behavioral intervention followed by medication; and initial behavioral intervention with an increase in behavioral interventions. One important preliminary finding that corroborates empirical experience is that families who received medication first were much less likely to attend later parent training than families who received behavioral training first, indicating that at least for intervention with medication there is a significant sequencing effect [34]. Further evaluation awaits completion of the study.

Future studies might evaluate the effectiveness of combinations of medication and behavioral management in populations with significant comorbidities. Future research could also focus on developing more effective ways to manage behaviors in the educational setting. Another possible area for study is the issue of how to individualize manualized behavior programs and still retain the key evidence base.

Conclusions

ADHD is a multifaceted disorder with significant genetic and environmental contributions, significant developmental

variation, and an impact on many life functions [35–37], resulting in a tremendous cost to both individuals and society.

The need to devise, test, and promulgate a variety of treatments to seek relief of symptoms will continue. Algorithms for treatment that meet the immediate needs of families and impact long-term outcomes safely and effectively are necessary. Combinations of evidence-based medication and behavioral treatments have the demonstrated potential to help achieve these goals. It is important to continue to study the effectiveness of ADHD treatment and to remain open to combinations of treatment that prove both efficacious and effective.

Disclosures: Dr Hoffman has served on the advisory committee and Speaker's Bureau for Shire.

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