CLINICAL ASPECTS

MULTIMODAL THERAPY VERSUS MEDICATION IN TREATING CHILDREN’S ATTENTION DEFICIT HYPERACTIVITY DISORDER. PRELIMINARY RESULTS

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Abstract: Since at present, drawing clear and valid conclusions regarding children’s Attention Deficit Hyperactivity Disorder (ADHD) over the best treatment is still a difficult issue, there is a need for sustained efforts in elaborating therapy strategies to best address a child’s needs. The hereby study, conducted between February and July 2010, analyses the effectiveness of the multimodal treatment compared to the pharmacological approach of ADHD. The evaluated fields were: the level of clinical symptoms, the impact on the child’s adaptation to school and on his social competences. By multimodal therapy, we refer in this project to combining medicine with a training programme for the parent and the teacher, as well as child’s psychotherapy. This therapeutic trial, developed on parallel groups, included schoolchildren, grades I-VIII, who had been diagnosed with ADHD in the Paediatric Psychiatry Clinic from Cluj-Napoca. The results were favourable to the multimodal therapy especially regarding their school adaptation and manifestations in their family and social conduct. Regarding the impact on the symptoms of this disorder, the results of the two therapeutic approaches were close.


INTRODUCTION

The Attention Deficit Hyperactivity Disorder (ADHD), one of the most common pathology in paediatric psychiatry (1), besides being defined by the major symptomatic trio – attention disorder, hyperactivity, impulsiveness – it also has a powerful negative impact on the child’s functionality at home, in school and socially.(2) Considering the fact that the specific medication proved useful in ameliorating the diagnosed symptoms, but not as efficient in controlling the remaining issues the child is confronted with daily, (3) there have been attempts in finding different therapeutic means, non-pharmacological, applied either individually, or combined, under the form of a multimodal treatment.

Recently, a few larger systematic studies have been developed to evaluate the effectiveness of some multimodal approaches, as well as time persistence of their results.(4) Although the results of the studies are encouraging, (5) they are still few, and most of them often use only a single behavioural intervention beside medications. Therefore, coming to a clear and valid conclusion on the best treatment remains a work in progress. In these circumstances, continuing efforts in finding an adequate therapeutic strategy to address the child’s overall needs, with no artificial rupture, is a must.

Starting from these premises, I have engaged in developing a clinical study on ADHD suffering children, in which to analyze the effectiveness of the multimodal intervention, compared to the pharmacological, mono-modal therapy. In this project, by multimodal therapy I am referring to combining drugs administration with a parent and teacher training programme, and psychotherapy for the child. The hereby presented data are part of a project aiming at helping a higher number of patients. This intermediary phase is both necessary and useful, despite its small size limitations, since these preliminary results are a guide to approaching future patients, considering that this intervention is complex and implies a high allocation of time and resources.

PURPOSE

The purpose of this study is to find the possible relation between the type of therapeutic approach and symptomology improvement, as well as the ADHD child’s scholar and social functionality.

Corresponding to the three studied aspects, there are three particular objectives:

1. Evaluation of the effectiveness of the multimodal/monomodal approach of the ADHD child concerning the
improvement of the symptoms.

2. Studying the impact of the multimodal/monomodal therapy on the child’s adaptive functionality and his scholar performance.

3. Studying the influence of the multimodal/monomodal treatment on the ADHD child’s competencies and social functionality.

**METHODS**

This study was approved by the Ethics Committee of the “Iuliu Hațieganu” University of Medicine and Pharmacy, Cluj-Napoca and was led in accordance with good clinical practice guidelines.

The design is that of a longitudinal, prospective study, a clinical trial, randomized with parallel groups: one batch on which the multimodal intervention was applied (MM), one witness batch – with pharmacological therapy (Med). I did not use free treatment batch, or a placebo one, because, on one hand, the effectiveness of the drugs in ADHD was already proven by numerous studies, and on the other hand, I have considered it unethical for a part of the patients not to receive any treatment, bearing in mind the considerable impact of this affection on the child’s life and that of his family. In this first part of the study, conducted between February and July 2010, I have included 17 participants from those who have sought help from the Paediatric Psychiatry Clinic of Cluj-Napoca. The children’s parents and teachers were also attending.

**Selection criteria:** children aged between 6 and 14 years old, included in grades I-VIII, diagnosed with ADHD based on the DSM IV-TR and ICD 10 criteria.

**Exclusion criteria:** presence in children, of comorbidities like mental retardation, severe depression, suicidal behaviour, substance abuse, schizophrenia or schizophrenic disorders, cerebral syndromes, drug incompatibilities or allergies, refusal of medication, illiteracy, or significant psychiatric disorders in parents.

**The work stages** were as follows:
- selecting the eligible patients;
- obtaining the informed consent;
- deciding on the pharmacological approach by the attending physician: atomoxetine or metformidate;
- random repartition of the children in the two batches;
- applying the pre-intervention evaluation questionnaires;
- administration of medications and programmes to the children in the multimodal intervention group, and consequently administration of only the medication to the witness group;
- final evaluation of all participants.

For the batch under the multimodal therapy, I have combined the pharmacological treatment (the same as in the witness batch) with a package of psycho-social interventions: a training and guidance programme for the parent and the teacher in child psychotherapy. For each participant in this batch, there was a work protocol established, with objectives, intervention methods, number of meetings, rhythm and schedule of the meetings. Regarding the intervention in school, a guide for the teachers was drawn up.(6) To train the parents, I have used work meetings. Regarding the intervention in school, a guide for the methods, number of meetings, rhythm and schedule of the intervention was developed in order to meet the common objectives for all children, but overall, it was less child’s psychotherapy was developed in order to meet the objectives 3 – the CBCL questionnaire, the competence scale. The assessment was made with the same instruments for all patients, applied twice: before and after the intervention. The database and the statistical analyses were made with the help of SPSS, 17.0 version.

**RESULTS**

The multimodal therapy batch had 8 patients, of which 1 girl (average age ~8,7 years), and the witness batch had 9 patients, of which 1 girl (average age ~8,3years old). After gathering the data of simple descriptive statistics, I have applied the “t” test for independent samples, to verify if the batches are homogeneous in what concerns the severity of the pre intervention symptoms, in order to avoid the impact on the results in favour of the batch with a possible lower level of average symptoms degree. (table no. 1)

<table>
<thead>
<tr>
<th>Scale</th>
<th>M multimodal batch</th>
<th>M witness batch</th>
<th>t</th>
<th>df</th>
<th>p bidirectional</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBCL-syndrome</td>
<td>11.00</td>
<td>1.85</td>
<td>11.00</td>
<td>2.91</td>
<td>0</td>
</tr>
<tr>
<td>CBCL-DSM</td>
<td>11.25</td>
<td>1.28</td>
<td>10.88</td>
<td>1.05</td>
<td>0.85</td>
</tr>
<tr>
<td>TRF-syndrome</td>
<td>37.12</td>
<td>4.35</td>
<td>35.55</td>
<td>7.10</td>
<td>0.54</td>
</tr>
<tr>
<td>TRF-DSM</td>
<td>22.25</td>
<td>4.46</td>
<td>19.88</td>
<td>5.32</td>
<td>0.98</td>
</tr>
</tbody>
</table>

M=medium score; AS=standard deviation

Both from the parent’s perspective (CBCL) and of the teacher’s (TRF), the average scores registered on both scales (the one with the syndromes, the one with DSM criteria), prior to the intervention, are not significantly different. On applying the same test to both batches, as well for the assessment of the level of competences, social functionality and scholar adaptive functionality, prior to the intervention, one can see that:
- the level of the scholar adaptive functionality and of scholar performance is close in the two batches at the beginning of the study: multimodal batch (M=13.87, AS=1.55); witness batch (M=13.67, AS=1.87; t=0.24, df=15, p bidirectional=0.80 (P>0.05).
- the level of competences is close in the two batches: multimodal batch (M=15.87, AS=4.91); witness batch (M=15.66, AS=3.79); t=0.098, df=15, p bidirectional=0.923 (p>0.05).

For the demographic data of the participants, I have used a data gathering record. The evaluation was made using the Achenbach System of Empirically Based Assessment - ASEBA, for the age range 6-18, a set of scientific validated questionnaires, adapted and published in Romania.(11) I have used 2 categories of questionnaires: Child Behaviour Checklist-CBCL (the child behavioural assessment questionnaire addressed to their parents) and the Teacher’s report form-TRF (child assessment made by their teachers). From each questionnaire category, I have selected the one compatible to each of the 3 specific objectives, previously established.

Objective 1 - the CBCL and TRF questionnaires: scales that measure syndromes – subscale VI of attention problems, DSM derived scales – subscale 4 that measures ADHD problems. Objective 2 - the TRF questionnaire, the adaptive functionality scale. Objective 3 - the CBCL questionnaire, the competence scale. The assessment was made with the same instruments for all patients, applied twice: before and after the intervention. The database and the statistical analyses were made with the help of SPSS, 17.0 version.
Furthermore, by the “t” test for paired samples, I have investigated whether there is a significant difference between the average scores shown in pre and post intervention on each batch. In what concerns the study of the level of the symptoms, there is a significant decrease between the average scores registered pre and post intervention in the cases of the TRF and CBCL-syndromes. There was no statistically significant difference on the CBCL-DSM scale, on either batch. (table no. 2)

Table no. 2. Study of the effectiveness of the multi/mono-modal approach on diminishing the symptoms of the disorder

<table>
<thead>
<tr>
<th>Scale</th>
<th>M multimodal batch - pre-intervention</th>
<th>M multimodal batch - post-intervention</th>
<th>M witness batch - pre-intervention</th>
<th>M witness batch - post-intervention</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBCL-syndromes</td>
<td>11.00</td>
<td>6.85</td>
<td>11.00</td>
<td>7.66</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>CBCL-DSM</td>
<td>11.25</td>
<td>9.5</td>
<td>10.88</td>
<td>9.77</td>
<td>0.23</td>
</tr>
<tr>
<td>TRF-syndromes</td>
<td>37.12</td>
<td>26.26</td>
<td>35.55</td>
<td>26.00</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>TRF-DSM</td>
<td>22.25</td>
<td>16.00</td>
<td>19.85</td>
<td>14.44</td>
<td>0.01</td>
</tr>
</tbody>
</table>

M=average score

In what concerns the evaluation of the impact of the multimodal/mono-modal intervention on the adaptive functionality and scholar performance and on the competences and social functionality of the children, I have noticed a significant statistical increase between the average of the scores registered pre and post intervention in the case of the multimodal therapy batch, but not in the case of the witness batch: multimodal batch - Mpre=13.87 Mpost=15.68 p=0.04; witness batch - Mpre=13.66 Mpost=13.44 p=0.66. Also, there is a significant statistical increase between the average scores registered between the two moments of the evaluation in the case of the multimodal batch, but not in the case of the witness batch: multimodal batch – Mpre=15.87 Mpost=20.31 p<0.01; witness batch – Mpre=15.66 Mpost=16.05 p=0.46.

As last stage, I have used the analysis of variance ANOVA, in order to establish whether there is a significant difference between the changes that took place in time, on both batches. In evaluating the symptoms, there is no significant statistical difference between the changes occurring in time on the two batches, regardless of the scale used. (table no. 3)

Table no. 3. The ANOVA results applied to the data obtained from the symptoms evaluation scales.

<table>
<thead>
<tr>
<th>Scale</th>
<th>F</th>
<th>p</th>
<th>Partial $\eta^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBCL-syndromes</td>
<td>0.31</td>
<td>0.58</td>
<td>0.02</td>
</tr>
<tr>
<td>CBCL-DSM</td>
<td>0.17</td>
<td>0.68</td>
<td>0.01</td>
</tr>
<tr>
<td>TRF-syndromes</td>
<td>0.06</td>
<td>0.79</td>
<td>0.005</td>
</tr>
<tr>
<td>TRF-DSM</td>
<td>0.11</td>
<td>0.73</td>
<td>0.01</td>
</tr>
</tbody>
</table>

On the other hand, the same test applied in order to reveal the difference between the changes occurred in time following the two types of interventions, in the scholar, social and family areas, has brought to light a significant statistical difference in favour of the multimodal treatment batch: -the TRF scale of adaptive scholar functionality: F=5.31, p=0.036, partial $\eta^2=0.26$. (figure no. 1)

Figure no. 1. Over time registered changes of the average score, on the TRF scales of adaptive scholar functionality in the case of the two batches

Figure no. 2. Over time modifications of the average score, registered on the CBCL scales of competences, in the two batches. Moment of evaluation: 1=pre intervention, 2=post intervention

DISCUSSIONS

1. Both approaches proved effective in reducing the ADHD symptoms, from the point of view of the parents the decrease of the seriousness of the symptoms being more obvious (viewed statistically) on the syndrome scale than on the DSM scale.
2. From the teacher’s perspective, the ADHD symptoms have diminished in both batches in a similar manner. These changes were registered on both the syndrome scale as well as on the DSM scale.
3. The decrease of the severity of the symptoms is perceived better by the teachers than by the parents.
4. It is only in the multimodal treatment batch that a significant increase of the performance level and of the scholar adaptation functionality has occurred. In the case of the children who received medicine alone, there were no

improvements in this area.

5. Even though there was a slight improvement in the areas of competence and family/social functionality of the child in the mono-modal medication batch, it is only in the multi-modal batch that this improvement was significant.

CONCLUSIONS

The preliminary results, hereby presented, show that the ADHD affected children have experienced a significant increase of their level of scholar and family/social adaptability. This result, together with the need of expanding this study on a larger number of participants, justifies the need for continuing this study.

Since the children included in this first part of the study were younger than 11 years old, it was not possible to evaluate the issues from their perspective as well. In the project follow-up, children aged between 11 and 14 years old would be included, in order to cover as much as possible from the intended age spectrum.

REFERENCES