IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 17, Issue 7 Ver. 4 (July. 2018), PP 17-19
www.iosrjournals.org

Efficacy and tolerability of Methylphenidate in Attention Deficit Hyperactivity Disorder (ADHD): A 12 week prospective study

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Abstract : *The present study was designed to study the efficacy and tolerability of methylphenidate in Indian children with Attention Deficit Hyperactivity Disorder (ADHD). Drug naïve patients, 52 in number were recruited for this study. The CGI scale and Vanderbilt ADHD Diagnostic Parent Rating Scale (VADPRS) was used to access the efficacy and tolerability of methylphenidate over a period of 12 weeks. Methylphenidate was found to be an efficacious drug in Indian children with ADHD as assessed with scores of Vanderbilt and CGI scale in all the subgroups.*

Keywords: *ADHD, CGI, Methylphenidate, Vanderbilt Parent Rating Scale*

Date of Submission: 27-06-2018 Date Of Acceptance: 12-07-2018

I. Introduction

Attention Deficit Hyperactivity Disorder is one of the common psychiatric problems affecting children [1]. Psychostimulants like methylphenidate that increase dopamine concentrations have been used in the treatment of ADHD by targeting the central nervous system[2]. Methylphenidate is the first-line drug for treatment of children and adolescent of ADHD[3]. The present study was planned with the objective of studying the efficacy and tolerability of methylphenidate in Attention Deficit Hyperactivity Disorder over a period of 12 weeks in drug-naive patients with ADHD in Indian patients.

II. Methods

Clearance was obtained from the institutional ethics committee for human research of Lady Hardinge Medical College, New Delhi (LHMC/ECHR/2015/151 dated 03/11/2015). Parents/guardians brought the patients to the child guidance clinic themselves or were referred to by the school. The principles enunciated in the Declaration of Helsinki[4] and Indian Council of Medical Research[5] were followed. Patients were recruited from the Psychiatry OPD of Smt. Sucheta Kriplani Hospital, New Delhi. They were diagnosed by experienced Psychiatrist and showed signs and symptoms of inattention or hyperactivity-impulsivity or both according to DSM-V criteria for ADHD[6]. Patients showing other psychiatric co-morbidities including autism, oppositional defiant disorder, and conduct disorder were excluded from the study. All the participants, 52 in number, underwent a physical examination before entering into the study. Information regarding medical and psychiatric co-morbid disorders was also taken, and Patient Performa was filled accordingly. No psychotropic medications were permitted before the start of the study. The subjects ranged in the age from 6 to 12 years. No female patient was included in the study group as they did not meet our inclusion criteria. Parents/legal guardians of the patients provided the informed written consent which was written in either Hindi or English. Baseline Vanderbilt Parent ADHD rating scale and CGI scale were recorded. Before initiating treatment, electrocardiogram (ECG) was performed for each patient to rule out any cardiac abnormality.

Patients were started on tablet Methylphenidate (immediate release) 5 mg once a day on their first visit as per Clinical Practice Guidelines of Indian Psychiatric Society[7]. The drugs prescribed were from standard pharmaceutical companies, approved by the drug committee of the institute. The patients were called at an

interval of 15 days or one month at the Psychiatry OPD for follow up to increase the dose of Methylphenidate. The patients were then treated with methylphenidate for 12 weeks. The mean dose per kg of body weight after 12 weeks was 0.70 ± 0.09 mg/ Kg. The above rating scales were repeated at 12 weeks of study period.

Vanderbilt ADHD Parent rating scale[8-12]:- The Vanderbilt ADHD Parent rating scale is based on DSM-V criteria. The scale has two components: symptom assessment and impairment in performance. On this scale the symptom assessment screens for symptoms that meet criteria for both inattentive (items 1–9) and hyperactive ADHD (items 10–18). To meet DSM-V criteria for the diagnosis, one must have at least six positive responses to either the inattentive 9 or hyperactive nine symptoms or both. A positive response is marked as a 2 or 3 (often, very often). There is a place to record the number of positives in each sub-segment, and a place for the total score for the first 18 symptoms. The scale also has symptom screens for three other co-morbidities-oppositional-defiant, conduct, and anxiety/ depression. To meet criteria for ADHD, there must be at least one item of the Performance set in which the child scores a 4 or 5; i.e., there must be an impairment, and not just symptoms to meet the diagnostic criteria. The scale has a place to record the number of positives (4s, 5s) and an Average Performance Score is calculated by adding the number of positives and dividing it by the number of Performance criteria answered.

Clinical Global Impression (CGI) rating scale[13] is amongst the most widely used of assessment tools in psychiatry. The CGI was developed for use in National Institute of Mental Health (NIMH) -sponsored clinical trials to provide a brief, stand-alone assessment of the clinician's view of the patient's global functioning before and after initiating study medication. The CGI provides an overall clinician-determined summary measure that takes into account all available information, including a knowledge of the patient's history, psychosocial circumstances, symptoms, behavior, and the impact of the symptoms on the patient's ability to function.

It is a 3-item observer-rated scale that measures (1) Severity of illness, (2) Global improvement or change and (3)Efficacy index.

Under Severity of illness section, the child is rated under the following headings:- Not at all ill, Borderline, Mildly ill, Moderately ill, Markedly ill, Severely ill. Under the Global improvement part of the scale the child is rated under the following headings: - Very much improved, Much improved, Minimally improved, No change, Minimally worse, Much worse, Very much worse. Under the efficacy index section, the degree of therapeutic effect and side effects are recorded under the following headings:- Marked improvement, Moderate improvement, Minimal improvement and Unchanged or Worse.

The Efficacy index is derived by dividing the therapeutic score by side effect score in an attempt to relate the two.

Data obtained were subjected to statistical evaluation using Graph Pad Prism Version 7 software. The mean and standard error of mean (Mean ± SEM) were calculated after testing for normal Gaussian distribution. Wilcoxon matched-pairs signed rank test was used to compare the difference from baseline to 12 weeks after methylphenidate treatment of the Vanderbilt score. Chi square test was used to compare the difference from baseline to 12 weeks after methylphenidate treatment of the CGI Severity score.

III. Results

A significant decrease in the scores of Vanderbilt and CGI scale was observed implying that the patients in the study group have shown improvement in disease severity. There was also a significant improvement in Vanderbilt performance score post-therapy with methylphenidate(Table 1).

Table 2 shows the CGI global improvement score of the 52 patients.

The mean value of clinical efficacy index was 7.08 with a standard error of mean of 0.28 after 12 weeks of methylphenidate treatment.

IV. Discussion

Methylphenidate is an efficacious drug in Indian children with ADHD as assessed with scores of Vanderbilt and CGI scale in all the subgroups.

LIMITATIONS

Only male patients were recruited for our study as no female patient met our inclusion and exclusion criteria. Our study was conducted on a small sample size of 52 patients. Future studies with larger sample sizes may be taken up in each subtype of ADHD.

Table 1: Changes in Vanderbilt and CGI rating scale from baseline to 12 weeks after methylphenidate treatment in the study group (Mean ± S.E.M values).

Parameters	Baseline (N=52)		After treatment (n=52)		p value
Vanderbilt Inattention score	6.13 ± 0.22		5.04±0.20		0.0001
Vanderbilt Hyperactivity score	6.02 ± 0.24		4.83±0.20		0.0001
Vanderbilt Combined score	12.15 ± 0.28		9.86±0.29		0.0001
Vanderbilt Performance score	2.40 ± 0.11		2.06±0.10		0.0001
CGI Severity score	mildly ill	6	mildly ill	25	P< 0.002#
	Moderately ill	37	Moderately ill	26	
	Markedly ill	8	Markedly ill	1	
	severely ill	1	severely ill	0	

p value- > 0.05-Non-Significant (NS),<0.05-Significant*, <0.01-Very Significant, <0.001-Highly Significant*****

Wilcoxon matched-pairs signed rank test

 # chi square test.

Table 2: CGI global improvement score after 12 weeks of methylphenidate treatment in the study group.

Parameters	**After treatment**	
CGI global improvement score (number of patients)	**Not Assessed**	**0**
	Very much improved	**1**
	Much improved	**11**
	Minimally improved	**40**
	No change	**0**
	Minimally worse	**0**
	Much worse	**0**
	Very Much worse	**0**

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Dr. Pramesh Dogra " Efficacy and tolerability of Methylphenidate in Attention Deficit Hyperactivity Disorder (ADHD): A 12 week prospective study."IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 17, no. 7, 2018, pp 17-19.