Research Article

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EVALUATION OF COMBINED EFFECTIVENESS OF PANCHARAVINDA VATI AND PRATIMARSHA NASYA WITH TUNGADRUMADI TAILA ON ATTENTION DEFECIT HYPERACTIVITY DISORDER IN CHILDREN: AN OPEN-LABEL CLINICAL TRIAL

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ABSTRACT

Introduction: Attention Deficit Hyperactivity Disorder (ADHD) is a common neurodevelopmental disorder characterized by difficulty in paying attention, and hyperactivity, which is inappropriate for the age of a child. The disease most commonly affects children of age group 6 to 12. ADHD is more similar to features like manovibhrama (deranged mental status), achara vibhrama (conduct abnormality), sheela vibhrama, etc., explained under Unmada vyadhi. Where-in, sharirika dosha's and manasika dosha's afflicts the shirohridaya, resulting in dhee-dhriti-smriti vibhramsha (deranged status of rational thinking, retaining the power of mind and memory) which are very much obvious in ADHD Children. Methodology: The present clinical study was conducted on 30 patients, wherein Pancharavinda vati which is a combination of Aravinda (*Nelumbo nucifera* Gaertn.) and Hema Shakala (Gold foils) as the chief ingredients, was given orally 500 mg (6-10 years) morning and night, 500 mg 2 tablets (11-15 years) morning and night, followed by Pratimarsha nasya with Tungadrumadi taila 2 drops in each nostril twice a day before food for intervention period of 30 days. The next 30 days was the follow-up period. Results: Statistical analysis based on the scores of DSM-5 for ADHD was obtained on (1st day, 30th day, and 60th day) and the results were tabulated, statistically significant results were obtained on the subjective parameters of DSM-5, Hence oral administration of Pancharavinda vati and Pratimarsha nasya with Tungadrumadi taila has shown considerable improvement in the management of ADHD.

Keywords: Unmada, Manogata Vikara, Attention Deficit Hyperactivity Disorder

INTRODUCTION

Ayurveda emphasizes the rationale of sharira and manas, their inseparable relationship in the form of sukha and dhukha (healthy and unhealthy conditions) throughout our life.[1]

WHO advocates that health is a state of physical, social, and mental well-being too; suggestive of the close relationship between body and mind.[2] The nomenclature of all the diseases can't be possible, as their clinical presentation varies as per the samutthana (the various etiological factors), dosha-dushya sammurchana, sthana (sites of manifestation), samprapti of the disease.[3] The attention deficit hyperactivity disorder (ADHD) is a unique condition where the role of Manas and Vata is evident. However, there is no similar condition in Ayurvedic treatise nearer to ADHD.

Vata is essential for proper day-to-day physical and mental activities in the form of Niyantaa pranetaa cha manasa (regulates and guides the mind), and Sarvendriyaarthanaam abhivodhaa (directs senses to their respective objects).[4] Since Vata is responsible for the normal functional abilities of Manas, the vitiated Vata ultimately affects the efficacy of Manas leading to a deranged state of manovishaya (chintya, vicharya) and manokaryas (indriyabhigraha). As a result, dhee, dhriti, smriti will be in a deranged state, the child indulges in an activity under the influence of deranged dhee, dhriti, smriti which leads to pragnyaparadha and ultimately that affects his day-to-day activities which are clearly explained under the heading of Unmada vyadhi in the form of manovibhrama (deranged mental status), achara vibhrama (conduct abnormality), sheelavibhrama (inappropriate behavior), chesta vibhrama (abnormal activities).[5] Thus, the person is involved in the state of prajnapradha.

METHODOLOGY

Method of collection of data

The children of 6-15 years attending the Inpatient and Outpatient Department of Kaumarabhritya SDMIAH Bengaluru, Karnataka, India, were screened for the clinical features of ADHD and the diagnosis was made based on the INCLEN Diagnostic tool for ADHD. Children with ADHD who fulfilled the inclusive criteria and were willing to participate in the study with parental consent were recruited for 60 days.

30 patients were selected for this clinical study. Clinical assessment was done with a subjective questionnaire (on 1 day, 30th day, and 60th day) and analysis was done based on the scores of DSM-5 for ADHD.

Study design	Single Arm Prospective Interventional Clinical Study.
Sampling technique	Convenience Sampling
Total duration	60 days
Interventional period	30 days
Follow up	30 days
Sample size	30

Inclusion criteria: The children of age group 6-15 years, fulfilling the DSM-5 diagnostic criteria of ADHD and INCLEN diagnostic tool for ADHD, irrespective of gender, religion, and socioeconomic status.

Exclusion criteria

1. ADHD children with other neurological complaints such as seizures, bipolar mode disorder, and autistic spectrum disorder.
2. Children suffering from chronic illness, developmental disorder, and other congenital disorders/neurobehavioral disorders and mild to severe mental retardation were excluded.
3. Children under other medications or interventions such as behavior therapy were excluded from the study.

Diagnostic criteria: INCLEN diagnostic tool for ADHD.[6]
Assessment criteria: DSM-5 CRITERIA for ADHD.[7]

Intervention

Pancharavinda Vati	**Tungadrumadi Taila**
500 mg (6-10 years) morning and night, before food with milk. Before food with milk, 500 mg 2 tablets (11-15 years) morning and night.	2 drops in each nostril after food morning and night.
Intervention: 30 days	
Follow-up period: 30 days	

Consent and Ethical Statement: The study is carried out as per ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. The trial is registered in the Clinical Trials Registry India with CTRI reference number: CTRI/2023/05/053167.
Ethical clearance reference number: SDMIAH/IEC/50/2022.

Statistical analysis: Data was collected using the structured case Proforma and analyzed using SPSS (Statistical Package for Social Sciences) by version 27. Demographic data and other relevant information were analyzed with descriptive statistics. Ordinal data was analyzed using Friedman's test.

OBSERVATIONS AND RESULTS

Table 1: Observation of 30 patients related to Demographic data and Disease

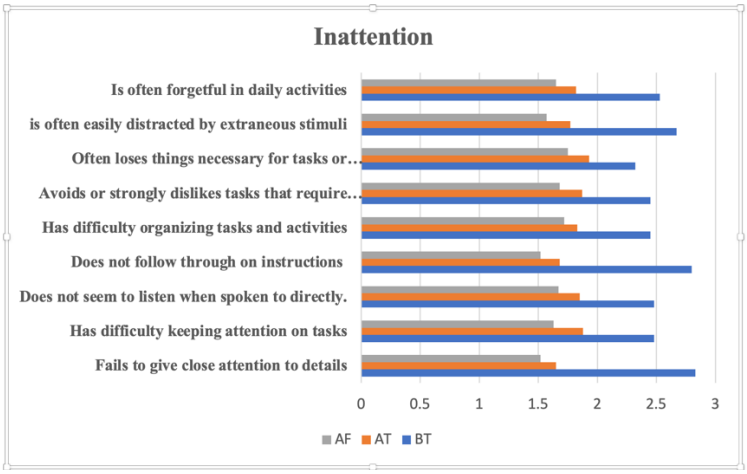
Observation	**Maximum incidence**	**Percentage**
Age	6-10 years	84.4%
Gender	Male	65.6%
Kuppuswamy socio-economic scale	Lower Middle Class	37.5%
Sibling Relationship	Congenial	43.8%
Parent attitude towards child	Supportive	78.1%
Maternal Psychological Status	Stress and anxiety	39.9%
Gestational Age	Preterm	31.3%
Birth Cry	Feeble Cry	25.1%
Neonatal Illness	Jaundice	53.1%
NICU Stay	Yes	78.1%
Agni	Mandagni	59.4%
Developmental Milestones as per Chronological Age	Achieved	100%
Schooling History	Irregular	25%
Scholastic Performance	Poor	56.3%
Peer Relationship	Partially Suitable	71.9%
Type of ADHD	Combined type	40.6%

Table 2: DSM-5 SCALE OF ADHD Friedman's test

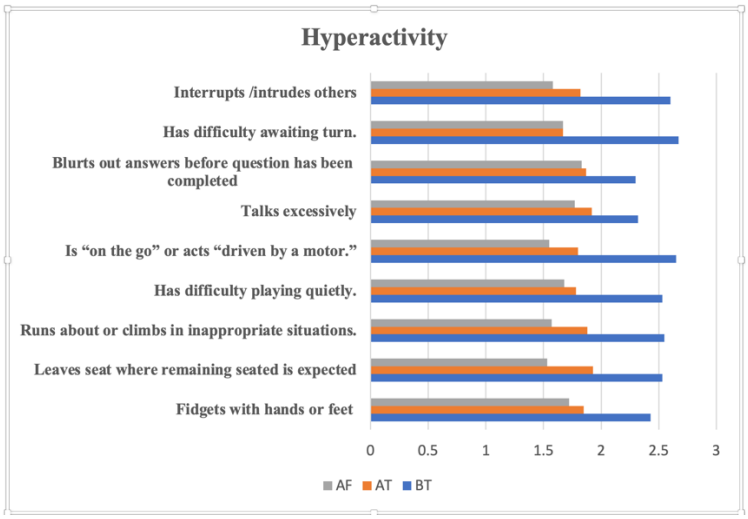
Parameter	**Mean**	**rank**		**N**	**Chi-square**	**p-value**	**Remarks**
	BT	AT	AF				
Fails to give close attention to details	2.83	1.65	1.52		47.873	.001	HS
Has difficulty keeping attention on tasks or play activities.	2.48	1.88	1.63		26.941	.001	HS
Does not seem to listen when spoken to directly.	2.48	1.85	1.67		26.980	.001	HS
Does not follow through on instructions and fails to finish schoolwork	2.80	1.68	1.52		45.532	.001	HS
Has difficulty organizing tasks and activities	2.45	1.83	1.72		25.409	.001	HS
Avoids or strongly dislikes tasks that require sustained mental effort	2.45	1.87	1.68		25.087	.001	HS
Often loses things necessary for tasks or activities.	2.32	1.93	1.75		17.706	.001	HS
is often easily distracted by extraneous stimuli	2.67	1.77	1.57		37.455	.001	HS
Is often forgetful in daily activities.	2.53	1.82	1.65		29.925	.001	HS
Fidgets with hands or feet or squirms in seat	2.43	1.85	1.72		24.326	.001	HS
Leaves seat in situations in which remaining seated is expected	2.53	1.93	1.53		30.400	.001	HS
Runs about or climbs in situations where it is inappropriate.	2.55	1.88	1.57		30.746	.001	HS
Has difficulty playing quietly.	2.53	1.78	1.68		30.471	.001	HS
Is "on the go" or acts "driven by a motor."	2.65	1.80	1.55		36.273	.001	HS
Talks excessively	2.32	1.92	1.77		17.636	.001	HS
Blurts out answers to questions before the questions have been completed	2.30	1.87	1.83		17.429	.001	HS
Has difficulty awaiting their turn.	2.67	1.67	1.67		40.000	.001	HS
Interrupts /intrudes others	2.60	1.82	1.58		33.475	.001	HS

BT: Before Treatment, AT: After Treatment, AF: After Follow-up

In the current study results were obtained and the data observed Before Treatment (1st Day), After Treatment (30th day), and After Follow-up (60th day) are compared by using the Friedman test on applying the Friedman test there is mean rank reduction from BT to AT in all the questions of DSM-5 scale which shows statistical significance. Overall, the p-value obtained from BT to AT was 0.001 at 95% confidence interval which shows that there is statistical improvement across all the questions of inattention and hyperactivity/ impulsivity.



Graph 1: Results based on DSM-5 Scale (Inattention)



Graph 2: Results based on DSM-5 Scale (Hyperactivity/ Impulsivity)

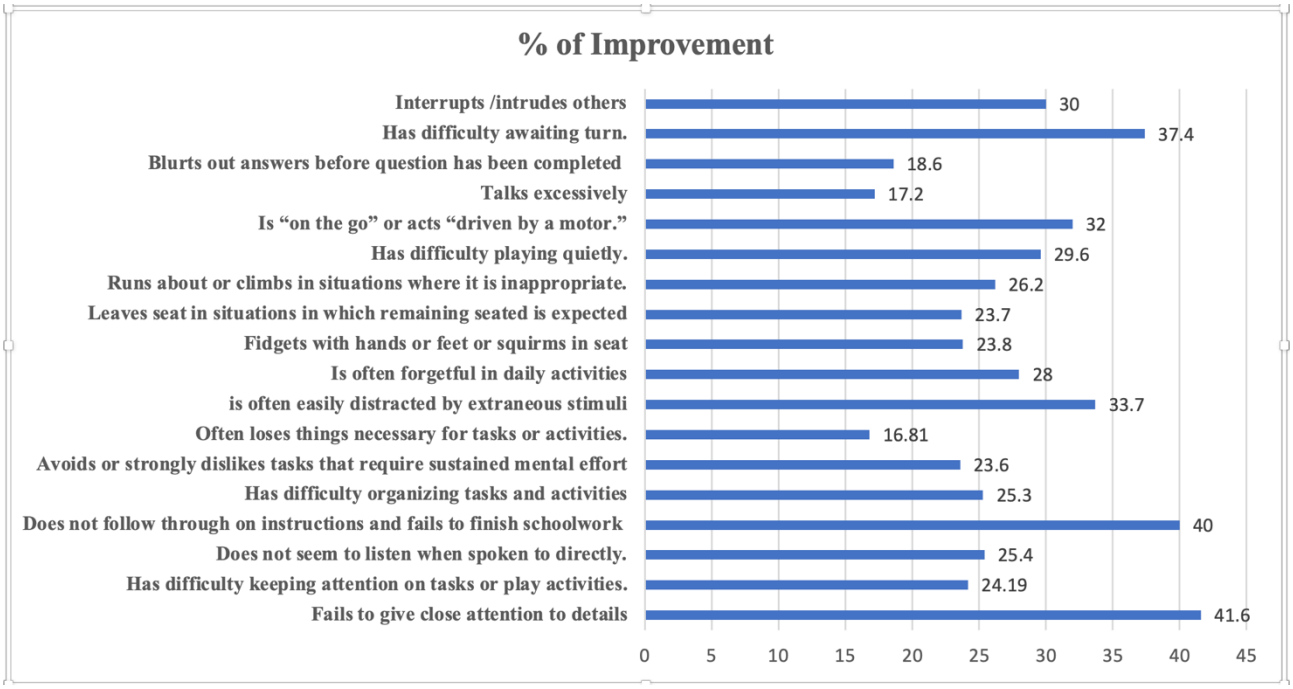
Table 3: Effect of Intervention after the treatment period on the 30th day (AT)

DSM-5 Criteria of Assessment	% of Improvement
Fails to give close attention to details	41.6
Has difficulty keeping attention on tasks or play activities.	24.19
Does not seem to listen when spoken to directly.	25.4
Does not follow through on instructions and fails to finish schoolwork	40
Has difficulty organizing tasks and activities	25.3
Avoids or strongly dislikes tasks that require sustained mental effort	23.6
Often loses things necessary for tasks or activities.	16.81
is often easily distracted by extraneous stimuli	33.7
Is often forgetful in daily activities.	28.0
Fidgets with hands or feet or squirms in seat.	23.8
Leaves seat in situations in which remaining seated is expected	23.7
Runs about or climbs in situations where it is inappropriate.	26.2
Has difficulty playing quietly.	29.6
Is “on the go” or acts “driven by a motor.”	32.0
Talks excessively	17.2
Blurts out answers to questions before the questions have been Completed	18.6
Has difficulty awaiting their turn.	37.4
Interrupts /intrudes others	30

Table 4: Overall Improvement of Intervention on Inattention and Hyperactivity /Impulsivity (DSM-5 Scale) after the treatment period on the 30th day (AT)

Overall Improvement	BT (Sum of Ranks)	AT (Sum of Ranks)	Percentage (BT-AT Improvement)
Inattention	23.01	16.28	**29.24%**
Hyperactivity/Impulsivity	22.58	16.52	**26.83%**

BT: Before Treatment, AT: After Treatment



Graph 3: Percentage of Improvement on Day 30(AT) based on DSM-5 Scale of ADHD

DISCUSSION

Attention Deficit Hyperactivity Disorder (ADHD) is the most common neurobehavioral disorder in children characterized by severe and age-inappropriate levels of hyperactivity, impulsivity, and inattention. The prevalence of ADHD among school-going children and adolescents is 7.1%, in different geographical areas of India and in Bangalore, it is 2.3%. [8]

There is no direct description of ADHD in the classical literature of Ayurveda, However, with due consideration of certain factors like - samutthana (the various etiological factors), dosha-dushya sammurchana, sthana (sites of manifestation), lakshana and samprapti of the disease, Unmada can be considered as the most relevant condition in Ayurveda similar to the symptoms of Attention Deficit Hyperactivity Disorder (ADHD), where the role of Manas and Vata is evident in the etiopathogenesis of the disease.

The Presence of Manas is said to be sarvadehika (present all over the body), but shiras is attributed as an important location. Dhee (intelligence), dhriti (governing factor) and smriti (memory) are the faculties of manas responsible for the jnanotapatti (genesis of knowledge) in day-to-day life. However, its deranged status affects the manovishaya (chintya, vicharya) and manokaryas (indriyabhigraha, swanigraha) leading to pragnyaparadha. As a result, the person indulges in abnormal behavior such as achara vibhrama (conduct abnormality), sheela vibhrama (inappropriate behavior), chesta vibhrama (abnormal activities), etc, which are very similar to features of ADHD.

Vata is essential for proper day-to-day activities both physically and mentally in the form of niyantaa pranetaa cha manasa (regulates and guides the mind), and sarvendriyaarthanaam abhivodhaa (directs senses to their respective objects). Since Vata is responsible for the normal functional abilities of Manas.

In this present condition, both Vata and Manas are affected, and all the pathological conditions are clearly described under the heading of Unmada vyadhi which is divided into Vata Kaphaja and Vata Pittaja Unmada which is similar to inattention and hyperactivity respectively based on their clinical presentation.

Thirty diagnosed children with attention deficit hyperactivity disorder in a single group received oral medication Pancharavinda vati and Pratimarsha Nasya with Tungadrumadi taila for 30 days and the effects of the intervention are being discussed under the heading of each parameter.

The effectiveness of treatment was assessed in different intervals before treatment (BT), after treatment (AT), and after follow-up on each parameter of the DSM-5 assessment scale, and the Friedman's test was used to check the statistical significance. Freidman test shows significance for all the 18 subjective parameters of DSM-5.

The Effect of Interventions on the DSM-5 Scale for ADHD

In the present study, the combined effect of the interventions among 30 participants showed statistically significant changes across all the variables in the domain at p-value < 0.05 on day 30, with 29.24% improvement in inattentive features and 26.83% improvement in hyperactivity/ impulsivity features which indicates the effectiveness of Pancharavinda vati followed by

Pratimarsha Nasya with Tungadrumadi taila in the management of ADHD.

Overall maximum changes were seen in questions like failure to give close attention (41%) and failure to finish schoolwork (40%), difficulty in waiting for the turn (37.4%), always-on-the-go mode (32%), and very minimal changes were seen in questions like losses of things required for daily activities (16.81%), talking excessively (17.2%).

The drugs in Pancharavinda vati are said to be medhya by its prabhava, helpful in improving the functional abilities of Sadhaka Pitta and Alochaka Pitta, and Tungadrumadi taila is said to be Vata Pitta-shamaniya and manaprasadaka and nidrajanaka which act on deranged Pitta as well which could have improved the functioning of dhee, dhriti, smriti ultimately imparts the children able to focus and concentrate on things as well as follow the commands.

On day 60, there were statistically significant changes noticed in symptoms of hyperactivity/impulsivity and inattention at p-value < 0.05 which indicates that changes could be due to the carrying-over effect of the medicine that contains Swarna as a chief ingredient, the nanoparticles of Swarna interact with cellular receptors and modulate neurotransmitter in brain and has carry over effect over 3 months in cognitive function.

Mode of Action of Pancharavinda vati

Pancharavinda vati is a modified form of ghrita yoga with five parts of Aravinda (*Nelumbo nucifera* Gaertn.), mrnala (stalk), bisa (tuber), patra (leaves), kesara (stamens), beeja (seed) and hemashakala (gold foils) as chief ingredients along with ksheera (milk) and ghrita (ghee), is specifically indicated in improving nashta pratibha (deranged intellectual skills).

The majority of the ingredients are madhura rasa, sheeta veerya and Pitta prasadaka in nature, and medhya as prabhavi karma. The unique rasapanchaka of Aravinda as well as the Medhya rasayana effect of Suvarna helps in enhancing the functional abilities of Sadhaka pitta and Alochaka Pitta, along with improving the dhee, dhriti and smriti.

Hemashakala is one, which is said to be a low potentiate drug compared to Swarnabhasma since the present yoga is aimed at enhancing cognition compared to Hemashakala, Swarnabhasma would be the more ideal as it is said to be medhya rasayana with a special focus on the enhancement of medha and bala.[10]

However, due to its peculiar odor and taste, its oral administration in ghrita form could be a difficult task, especially in children with attention deficit hyperactivity disorder. Hence few modifications were made to have better palatability convenient, easy, and reliable administration and vati kalpana was taken into consideration.

In ADHD most of the symptoms mentioned under the category of impulsivity/ hyperactivity are comparable with the vitiated status of Sadhaka Pitta and Alochaka Pitta hence the drugs which act upon Sadhaka Pitta and Alochaka Pitta are essential in its management. [9]

Mode of Action of Tungadrumadi taila

Major ingredients of Tungadrumadi taila are sheeta virya, snigdha guna, and Vatapittahara properties, and its karmukata as nidrajanaka, Pitta shamaniya, mana prahladaka.[11] Taila is said to be Vata shamaka and more potent in tissue penetration compared to ghrita, especially in the nasal ciliary area, which is very much essential in the management of ADHD, so in the present clinical trial, Tungadrumadi taila is used as Pratimarsha nasya.

Role of Nasya Karma

"Nasa hi Shirasho dwaram."[12] The nose is considered the gateway to the head. Pratimarsha Nasya offers various advantages, including nearly no contraindications, a relatively low dose (2 drops), has effect equal to marsha nasya, and can be used for daily administration.

Pratimarsha nasya is one such procedure that improves the power of indriya, shira, and kapaladi (sense organs, locomotors, head, and forehead) and it stimulates the shringataka marma and it acts as both shodhana and shamaniya which is very much needed in evacuating the vitiated dosha's from shiras which acts as sthanasamshraya in this condition.

Thus, Tungadrumadi taila is selected for Pratimarsha nasya which is Vata Pitta shamaka and acts on the hypothalamus by its tranquilizing properties and is effective in the management of ADHD.

CONCLUSION

In the present clinical study, Pancharavinda vati followed by Pratimarsha nasya with Tungadrumadi taila was administered for 30 days in 30 children with ADHD. The significant results were seen with an overall improvement of 29.24% in inattention symptoms and 26.83% in hyperactivity/impulsivity symptoms. The probable effect of Pancharavinda vati in the management of ADHD could be because of the Suvarna and Aravinda as chief ingredients which help in improving the dhee, dhriti, and smriti in the child.

On the other hand, Pratimarsha nasya was done with Tungadrumadi taila which could have acted on symptoms of vitiated Vata and Pitta as most of the drugs in Tungadrumadi taila are said to be Vatapittashamaniya and Manaprasadaka and thereby relives the symptoms of hyperactivity/impulsivity. Results obtained during the intervention period were carried out throughout the follow-up period which shows that the drug has the carry-over effect and was effective even after cessation of oral administration.

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