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Survey and intervention study to evaluate the efficacy of Ayurvedic formulation and *Shirodhara* in Attention Deficit Hyperactivity Disorder

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ABSTRACT

Attention deficit hyperactivity disorder (ADHD) is a mental disorder of the neuro-developmental type. The core symptoms of ADHD are inattention, hyperactivity, and impulsivity. It is one of the most common and most extensively studied behavioral disorders in school-age children. In this study and Ayurvedic formulation 'Tab. Eleva', showed extremely significant improvement in Inattention, Hyperactivity, and Impulsivity as well as on the Diagnostic and Statistical Manual of Mental Disorder IV edition (DSM-IV) criteria. However, *Shirodhara* also shows statistically significant improvement in Inattention, Hyperactivity, and Impulsivity but the percentage of relief is less than the *Ayurveda* formulation. The survey study, conducted with a sample size of 1000 cases, revealed that the prevalence of ADHD among males was 34.35%, while in females it was 10.64%, within the age range of 6-12 years.

Key words: Attention Deficit Hyperactivity Disorder (ADHD), Inattention, Hyperactivity, Impulsivity, *Shirodhara*

INTRODUCTION

Ayurveda is an eternal, scientifically time-tested ancient science that has been systematically divided into eight clinical branches as evidenced from the literature. Among the eight literature of *Ayurveda*, *Kaumarbhritya* or *Bala Chikitsa* has been mentioned with prime importance and compared to *Agnidevta*. In *Kashyapa Samhita*, *Acharya Kashyapa* placed *Kaumar-*

-bhritya above all the other eight branches.

Childhood is a period in which growth and development are at their peak level. Any factor may be affecting this period not only the growth of a child but also its activities, social behaviour, concentration power, immunity, and school performance. Symptoms of ADHD are one of the leading causes of academic underachievement in children and disturbed concentration. This is the major concern for the parents to visit the paediatrician.

Attention deficit hyperactivity disorder (ADHD) is a neurodevelopment disorder characterized by persistent hyperactivity, impulsivity, and inattention that significantly impairs educational achievement or social functioning.^[1] It is one of the most common and most extensively studied behavioral disorders in school-age children. Genetic, epigenetic, and environmental factors interact to give rise to ADHD phenotypes. Biological and psychosocial factors also contribute to ADHD. Prenatal exposure to alcohol,

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cocaine, and nicotine are associated with ADHD phenotypes. Recent functional magnetic resonance imaging (MRI) brain studies indicate that the disorder may be caused by atypical functioning in the frontal lobe, basal ganglia, corpus callosum, and cerebellar vermis. Pharmacological studies have also implicated dysregulation of frontal-subcortical-cerebellar catecholaminergic circuits (dopamine and norepinephrine neurotransmitter system) in the pathophysiology of the disorders.^[1] Attention deficit hyperactivity disorder has strong familial associations. Parents and siblings of a child with ADHD carry a 2 to 8-fold increase in the risk for ADHD.

Core symptoms of ADHD challenge school-related activities and tasks, relationships, and other functions. Cognitive impairments include a lack of impulse control and a deficit in attention, memory, organization, time management, and judgment. Activity limitations include difficulties in learning and applying knowledge (reading, writing, and mathematics), problems with carrying out single or multiple tasks, studying, and self-managing behaviour. Attention deficit hyperactivity disorder also impacts interpersonal interaction; communication and self-care; adjusting and succeeding in educational programs; leaving school to enter work; and establishing a community, social, and civic life.

Children with ADHD have been found to have a significant functional impairment in the areas of academic achievement, family relationships, peer relationships, self-esteem and self-perception, accidental injuries, and overall adaptive function. It may be due to the self-esteem of children with ADHD is often lower than their peers. Children with ADHD often receive high levels of negative peer rankings of social standings.^[2]

The prevalence of ADHD depends on the precise definition adopted and methods used for evolution. The most common evolutionary method is DSM IV (Diagnostic and Statistical Manual- IV).^[3] Incidence in school-aged children 3-5% (Estimated ranged from 1% - 20%). Boys : Girl's ratio is 4:1 (More prevalent in boys). ADHD occurs with association with other disorders in childhood.

- 50% = oppositional disorders.
- 30-40% = conduct disorders.
- 20-25% = Anxiety disorders.
- 10-15% = Mood disorders.
- 10-20% = Learning disabilities.
- In adolescence, it may be associated with substance abuse disorders.^[4]

Considering the present scenario of the high prevalence of ADHD among behavioural disorders, its ill outcomes in multiple areas of a child's functioning, and lack of safe and effective medication, the disease ADHD has been selected for the proposed study.

For the psychotic disorder, *Ayurveda* explained a lot of range in the formulation, and treatment procedure. *Jyotishmati* (*Celastrus paniculatus*), *Akarkara* (*Anacyclus pyrethrum*), *Vacha* (*Acorus calamus*), and *Gandira* (*Coleus forskohlii*) are some of the best drugs for psychotic disorders and *Shirodhara* is known as best therapy for the controlling & regularization of the brain functions. In the present study, Tab. Eleva and *Shirodhara* are proposed to evaluate the efficacy in known ADHD patients.

Table 1: Contents of Tab. ELEVA (Dr. Vasishth's Ayu Remedies)^[5]

| SN | Name of Drug | Latin name | Family | Useful part | Ratio (in %) |
|----|--------------------|------------------------------|--------------|----------------|--------------|
| 1. | <i>Jyotishmati</i> | <i>Celastrus paniculatus</i> | Celastraceae | Seed and oil | 250 mg |
| 2. | <i>Akarkara</i> | <i>Anacyclus pyrethrum</i> | Asteraceae | Root | 150 mg |
| 3. | <i>Vacha</i> | <i>Acorus calamus</i> | Araceae | Root & Rhizome | 50 mg |
| 4. | <i>Gandira</i> | <i>Coleus forskohlii</i> | Lamiaceae | Whole plant | 50 mg |

AIM AND OBJECTIVES

1. To study the prevalence of ADHD in school children (6-12 years) in Jaipur, Rajasthan.

2. To study the gender difference in the prevalence of ADHD.
3. To assess the clinical efficacy of tab. Eleva (Dr.Vasishth Pharm.) in ADHD.
4. To assess the clinical efficacy of *Shirodhara* in ADHD.
5. To provide relief in the symptoms of ADHD.

MATERIALS AND METHODS

Phase 1: Cross-sectional, School-based survey study to assess the prevalence of ADHD in school children (6-12 years) of Jaipur city for 08 Months and sample size - Maximum number of 1000 students will be included (10% of non-response error 100)

Statistical Analysis of the Survey will be done by using Statistical Product and Service Solution (SPSS) 20.0 software.

Phase 2: To evaluate the Clinical efficacy of Tab. Eleva and *Shirodhara* in ADHD patients. An open randomized parallel clinical study.

Selection of Cases

1. Source of Patients: All affected children for the present study were selected from OPD of the PG Department of *BalRoga*, National Institute of *Ayurveda*, Jaipur, and several schools, located in Jaipur by survey method.
2. Age group: Children between 6 to 12 years were included in the study.
3. Number of cases: 34 patients are registered for clinical trial, 04 patients were left from the trial because they have not completed their follow-ups.
4. Grouping of Patients:

Group A: This group of 17 Children was given the *Ayurvedic* formulation Tab. Eleva 1 Tablet twice a day with Honey after meal for 3 months.

Group B: This group of 17 Children was given the *Shirodhara (Ksheerdhara)* procedure for 15days followed once a week for 3 months in the morning with milk for 45 Minutes.

Diagnostic Criteria

ADHD-suffering children were screened via pre-assessment criteria based on DSM IV (Revised)^[3] (Diagnostic and Statistical Manual for Mental Disorders.)

A. Inclusion Criteria

1. School children aged between 6 to 12 years of both sexes having fulfilled DSM IV criteria.
2. Having signs and symptoms for ADHD.
3. Children with average/normal IQ

B. Exclusion Criteria

1. Children with known physical disability (deafness or visual problems)
2. Children with psychiatric disorders.
3. Children with gross brain damage causing mental retardation.
4. Children with any genetic disorder.
5. Children with, epilepsy, chronic medication (e.g. steroids), previous history of an infectious disease involving the central nervous system (e.g. encephalitis), intellectual disability, and autism.
6. Unreliable history.

C. Discontinuation Criteria

1. Parents not willing to continue the treatment
2. Any acute or severe illness.

D. Assessment Criteria

1. DSM. IV criteria
2. Attention span by Coefficient of Division
3. Reaction time
4. Finger Dexterity test
5. IQ assessment

E. Side Effect Evaluation Criteria

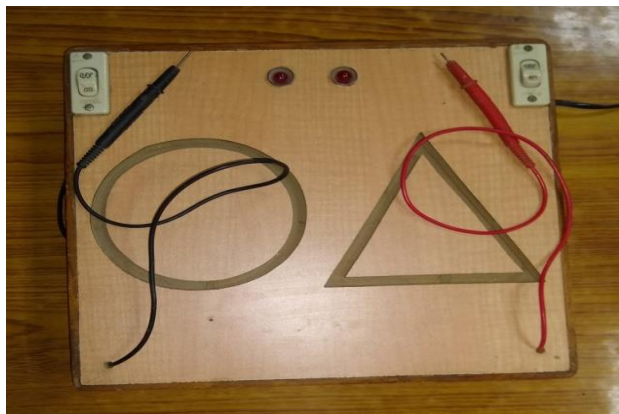
To rule out possible side effects of the study drugs, clinical criteria were adopted. It included the documentation of information related to loss of

appetite, insomnia, sleep, irritability, drowsiness, headache, anxiety, etc.

Material & Methods adopted for Diagnosis

Material

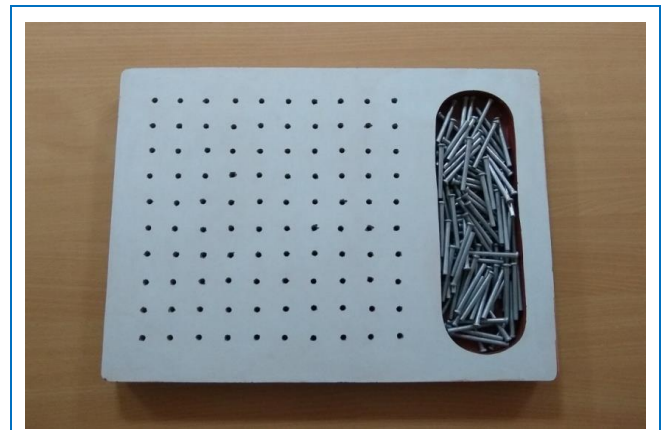
- A pre-assessment questionnaire was made based on DSM IV criteria, which included 18 questions, which were filled out by school teachers & parents of the children.
- Division of Attention Board (Electrical) – For Attention Spasm. (Pic. No. 01)
- Vernier Chronoscope (Electrical) – For Assessment of Reaction Time. (Pic. No. 02)
- Finger Dexterity Board with pins – For Assessment of Motor Ability. (Pic. No. 03)
- ‘Draw–A–Man’ Test for Indian children for assessing the IQ of the children.



Pic. 1: Division of attention board (electrical)



Pic. 2: Vernier Chronoscope



Pic. 3: Finger Dexterity

Methods

By survey method, ADHD-affected children were screened out through a questionnaire (which had 18 questions out of which 9 for hyperactivity and impulsivity and 9 for inattention) based on DSM IV criteria for ADHD. The questionnaire was filled out by teachers and parents of children in which scoring more than or equal to 6 points in each category were further assessed for IQ (Intelligence Quotient).

For IQ assessment ‘Draw – A – Man’ Test was adopted for Indian children and is valid for children of age group 4-15 years. Children with average or above IQ were considered for further screening.

Screened children by pre-assessment questionnaire and average IQ or above average IQ were further screened by DSM IV criteria. 6 (or more) out of 9 criteria (symptoms) of inattention, persisted for at least 6 months to a degree that is maladaptive and inconsistent with development level were considered as positive assessment for ADHD. Similarly, six (or more) of the symptoms of hyperactivity-impulsivity persistent for at least 6 months to a degree that is maladaptive and inconsistent with developmental level were considered positive assessments for ADHD.

Screened-out children were given three tests, namely-

1. Test for inattention span - performed by an instrument Division of Attention Board (electrical)
2. Test for reaction time - performed by an instrument Vernier Chronoscope (electrical)

3. Test for finger dexterity for motor ability - performed by an instrument “Finger Dexterity Board with Pins

Detailed information about the diagnosed children was recorded in Performa and prepared based on standard Ayurvedic parameters as well as modern. The information included immunization schedule, perinatal & post-natal history, history of past illness, socioeconomic status, family and personal histories like appetite and bowel status, developmental milestones, *Sattva, Sara, Samhanana, Ahar Shakti, Vyayam Shakti* and all Ayurvedic parameters.

Institutional Ethics Committee (IEC) Clearance

Approval for the design of the study and ethical clearance was obtained from the Institutional Ethical Committee of N.I.A. Jaipur Letter No. IEC/ACA/2017/93 date 26/04/2017, The CTRI (Clinical Trials Registry-India) registration no. is CTRI/2018/05/014001.

Phase I

OBSERVATIONS

Table 2: Showing overall observation of Survey Study

| Distr. of Patients of ADHD | Overall Observation | Discussion |
|----------------------------|--|--|
| Age-wise | More in 6-9 years i.e., 56.3% and 43.7% in 9-12 years. | The prevalence of ADHD disease in primary school children is more and gradually attenuation of symptoms with the advancement of age. |
| Sex-wise | 52.1% were male and 47.9% were female. | In a previous study by Jyothsna Akam Venkata et al. ^[6] Prevalence was found to be higher among the males as compared to that of females. |
| Habitat wise | The majority of subjects 81.5% from urban areas and 18.5% of subjects were from rural areas. | This is because the study was conducted in an urban area (Jaipur). |
| ADHD type wise | maximum 40.43% cases belong | According to the previous study by Ramya et al. ⁷ |

| | |
|-----------------------------|---|
| 40.43% to the Combined type | 2017, the prevalence of combined subtypes of ADHD is maximum. |
|-----------------------------|---|

RESULTS

Table 3: Showing age-wise distribution of the Subjects (n=1000)

| SN | Age | No | With ADHD | % with ADHD | χ ² | P Value | Remark |
|----|------------|-----|-----------|-------------|----------------|---------|--------|
| 1. | 6-9 Years | 563 | 148 | 26.28 | 4.965 | 0.0259 | S |
| 2. | 9-12 Years | 437 | 82 | 18.76 | | | |

In this study, it was found that out of 563 cases, 148(26.28%) were in the age group of 6-9 years and had ADHD, followed by 82 (18.76%) in 437 children of age group 9-12 years. On statistical analysis relation between age and prevalence of ADHD was found significant (P<0.05). (Table No. 03)

Table 4: Showing sex-wise distribution of the Subjects (n=1000)

| SN | Sex | No | With ADHD | % with ADHD | χ ² | P Value | Remark |
|----|--------|-----|-----------|-------------|----------------|---------|--------|
| 1. | Male | 521 | 179 | 34.35 | 50.476 | <0.0001 | ES |
| 2. | Female | 479 | 51 | 10.64 | | | |

Out of 521 male children, 179 (34.35%) has ADHD and out of 479 female children, 51 (10.64%) have ADHD. On statistical analysis relation between sex and prevalence of ADHD was found extremely significant (P<0.0001). (Table No. 04)

Phase II

OBSERVATIONS

Table 5: Showing overall observation of Clinical Study

| Distr. of Patients of ADHD | Overall Observation | Discussion |
|----------------------------|---------------------------------------|--|
| Age-wise | The maximum number of children 66.66% | The prevalence of ADHD disease in primary school children is more and gradually attenuation of |

| | | |
|-------------------------------------|---|---|
| | were in the age group 6-9 years | symptoms with the advancement of age. |
| Sex- wise | Maximum numbers of children 70% were male | In a previous study by Jyothsna Akam Venkata et al. ^[6] Prevalence was found to be higher among the males as compared to that of females. |
| Religion-wise | The majority of patients belonged to Hindu religion- 96.66% of the total subjects | Hindu children were more due to the predominance of the Hindu community in the survey area. Because of the higher education level and awareness of parents, they are much more aware of the health and education of their children. |
| Habitat-wise | Majority of Subjects 70% were from urban area | This is because the study was conducted in an urban area (Jaipur). |
| Birth weight wise | Maximum number of subjects 50% having a birth weight of 2.5-3.0 kg | The reason behind this, no relation of birth weight could be established in a small sample size. So, for this purpose larger sample size should be selected. |
| Incidences of Immunization | Most of the subjects 83.33% completed their immunization as per age | Because subjects mostly belong to urban areas, where facility of immunization is easily available and their parents are very aware of the health of their children. |
| Incidences of Dietary Status | Subjects 53.33% were vegetarian | A study by Hae Dong Woo et al. ^[8] which enlisted the traditional healthy dietary pattern was associated with lower chances of having ADHD |
| Incidences of Agni status | Maximum patients 46.66% had <i>Mandagni</i> . 33.33% of | Naturally, <i>Kapha</i> is dominant in childhood age when they consume excess oily substances, it |

| | | |
|--|--|--|
| | <i>Samagni</i> , 13.33% & 6.66% had <i>Tikshna</i> and <i>Vishama Agni</i> respectively. | leads to the formation of <i>Aamdosha</i> . Due to this disturbing <i>Agni</i> , <i>Mandagni</i> appears. |
| School performance wise | The majority of patients 46.66% showed average school performance, followed by 33.33% of patients who showed poor. | The poor and average performance of the subjects directly related to the symptoms of ADHD like easily distracted, lack of concentration, difficulty sustaining attention, etc. |
| Incidences of participation in Extracurricular activities | Of most patients, 40% sometimes Extracurricular activities participation, and 23.33% of patients on stimulation participation. | Extracurricular activities are directly related to the awareness and activeness of parents. Those parents, who know about the disease and its symptoms, try to shift the orientation of his / her child from destructive activity to constructive participation. |
| Type of Family-wise | 56.66% of patients belong to a nuclear type of family while 43.33% belong to a joint family. | Lack of parental bonding and emotional support could be the reason for developed stress, anxiety, and sometimes severe neurological consequences like ADHD in a nuclear family. |
| Incidences of birth order | Majority of patients 43.33% of 1 st birth order, 30% & 23.33% of 2 nd and 3 rd birth order respectively | The reason behind this is that a study of ADHD and birth order provides evidence that birth order does not affect Attention Deficit Hyperactivity Disorder. (Berger I, et al.) ^[9] |
| Mother age-wise incidences | 43.33% Child's mothers' ages were 25-30 years and 30-35 years followed by 10% of them categorized in 35-40yrs age group. | Most subjects present with normal fertile age (25-30yrs) but the finding of the study by Zheng Chang ^[10] et al. 2014 showed that all children born to mothers who bore their 1 st child early in their |

| | | |
|--|--|--|
| | | reproductive lives were at increased risk of ADHD. |
| Socio-economic status wise | Max. 50% subjects of middle-class socio-economic status, 30% of middle higher class. | The higher socioeconomic status of parents is not supported for children, The previous study Beiderman ^[11] et al., Chawla ^[12] PL et al.1981 |
| The child's parents relationship-wise | In a maximum number of cases, 50% had an average Child's-Parent relationship. 43.33% had a good relationship | Parenting is more important than we could ever have imagined. According to study ^[13] [Robert Winston, London J Prim Care. 2016; 8(1)] |
| Sattva- wise | The majority of subjects 56.66% were observed in <i>Madhyama Satva</i> and 26.66% subjects of in <i>Avara Satva</i> | According to morphological features like the luster of skin, morbidity incidence, appetite, response during <i>Shirodhara</i> , and activities to obeying commands during follow-ups. |
| Prakriti wise | 26.66%of patients have <i>Vata-Pitta Prakriti</i> followed by 20% cases having <i>Pitta-Kapha and Kapha-Pitta Prakriti</i> | The behavior of <i>Vata Prakriti</i> individuals is more similar to that of ADHD. The Predominance of <i>Pitta Prakriti</i> over <i>Vata</i> is comparable to the co-morbidities and associated problems with ADHD like violence, aggression, antisocial behavior, etc. so it can be concluded that <i>Vata Pitta-Prakriti</i> predisposes to the development of ADHD. |
| Incidences of Subtype of ADHD | Maximum no. 80% of patients were combined type | According to the previous study ^[7] Ramya et al. 2017, the prevalence of combined |

| | | |
|--|--|----------------------------|
| | | subtype of ADHD is maximum |
|--|--|----------------------------|

Regarding the probable mode of action of drug

The effect attained by the study drug can be explained by multiple mechanisms. The ingredients of Tab. ELEVA is a combination of *Jyotishmati (Celastrus paniculatus)*, *Akarkara (Anacyclus pyrethrum)*, *Vacha (Acorus calamus)* and *Gandira (Coleus forskohlii)*. It has predominantly *Laghu, Ruksha, Tikshna, Sukshma* and *Sara Guna*. *Laghu Guna* by its property of *Sattva Guna* increases the *Sattva* part of *Mana*. *Rukshna* and *Tikshna Guna* help to normalize the function of *Kapha Dosh* thus removing the *Avarana* of *Tamas* and increasing the *Sattva*. *Sukshmaguna* helps penetrate the deeper tissue (up to the cellular level) or *Shrotas* for the proper action of drugs.

Analysis of rasa present in the individual drugs reveals that most drugs have *Tikta Rasa*. *Tikta Rasa* being predominant in *Akasha Mahabhuta* and *Laghu Guna* increases the *Sattva* part of *Mana* and the *Agnideepana* function of *Tikta Rasa* increases the metabolism, especially of glucose in the brain and *Arochakaghna* property helps to treat *Mandagni*. *Katu Rasa* dominates in *Agni Mahabhuta* and *Ruksha Guna* that are responsible for *Indriyauttejaka* and *Sanjnanasa*. *Madhura Rasa* being predominant in *Parthivamahabhuta, Snigdha*, and *Guruguna* increases the *Medhya* effect *Indriyaprasadhana, Brihana* (improves cellular nourishment) and *Sarvadhaturvardhaka* helps in proper development of all tissues. *Kashaya Rasa* has a predominance of *Vayu Mahabhuta* and *Laghu Guna* which also increase the *Sattavika* property of *Mana*.

Considering the *Vipaka* of all the ingredients of the study drug has *Katu Vipaka*. *Katu Vipaka* helps in accelerating overall metabolism in the body including the brain, helps in the absorption of micro and macro nutrients as per requirement in the body, and thus helps to minimize the nutrient deficiencies and stimulates all the sense organs to perceive their respective objects. Thus, it helps in alleviating ADHD symptoms.

Ingredients used in the study drug chiefly *Ushna Virya*. *Ushna Virya* by its *Vata* alleviating property specifies the vitiated *Vata Dosha* in the ADHD condition. At the same time, *Ushna Virya* also increases blood circulation in the brain.

Most of the drugs are *Kapha Vata Shamaka*. Since ADHD in *Ayurveda* is similar to the condition *Anavasthita Chitta*, which is one of the *Vata Nanatmaja Vyadhi*, the drugs by their *Vatashamaka* property may help in alleviating the symptoms of ADHD. The *Kaphashamaka* property of drugs helps in breaking the *Shrotorodha* and digestion of *Ama* which leads to the proper function of the body as well as brain. *Kaph Shamaka* drugs have properties opposite to *Tamasha Dosha* which helps in removing the *Avarana* and normalizing the *Tamasa Dosha* so, it helps keep the equilibrium of *Trigunas* and maintain the proper functioning of *Manas*. Ingredients used in the study drug mostly have *Medhya Prabhava*. It has been mentioned by *Nagarjuna* in *Rasa Vaisheshika Sutra* that *Medhya* drugs act mainly by their "*Achintya Virya*" which is the *Prabhava*. This indicates that these drugs direct impact on the *Medha* (intellect). The exact mode of action is not very clear, but these drugs ultimately increase the cognitive capacity of the brain either by improving blood circulation or by enhancing metabolic activities. Honey has the property of dissolving *Kapha Dosha*, initiating the growth of healthy granulation tissues, helping in quick healing, and helping in the metabolism of fat tissue. So, it may be helpful to the growth and nourishment of brain tissues. It has a special quality known as '*Yogavahi*', which helps in penetrating the deepest tissues (up to the cellular level) and enhances medicinal qualities.

Since ADHD disease is concerned with the brain or *Manas* and *Buddhi* (*Ayurvedic* perspective), the selection of the study drug was based on their therapeutic properties with *Medhya* effect.

Regarding the probable mode action of *Shirodhara*

Shirodhara is an important therapeutic measure in the *Ayurvedic* system of medicine in which slowly and steadily dripping medicated oil or other liquids on the forehead from a specific height of 8 cm in a fixed

fashion in the form of oscillatory movements for 45 minutes daily for two weeks. The types of *Murdha Taila* other than *Shirodhara* are *Shiro Abhyanga*, *Pichu*, and *ShiroBasti*. This procedure induces a relaxed state of awareness that results in a dynamic psycho-somatic balance.

When a constant stream of any liquid is poured over the forehead from a fixed height it results in pressure on the skin of the forehead. It stimulates pacinian receptors or mechanoreceptors present on the skin which, leads to mechanical deformation of the receptors, resulting in the change in the membrane potential of the receptor and a receptor potential is generated.

This receptor potential leads to the generation of action potential, which is then passed to the cerebral cortex via the brain stem or the RAS. In this way, the information from outside reaches the cerebral cortex. The pressure input from the skin over the head is conveyed by the ophthalmic branch of the trigeminal nerve to the reticulospinal neurons via the disynaptic pathway.^[14] When sensory information reaches the cerebral cortex, only a small fraction cause an immediate motor response. Much of the remainder is stored for future control of motor activities and for use in thinking processes.^[15] Regular or continuous pressure input generates a continuous impulse to the CNS thereby continuously stimulating the CNS. Practicing this procedure regularly for 15 days may lead to long-term stimulation of the CNS. The mechanism is comparable to that of CNS stimulant medications advice to ADHD patients. According to the philosophy of *Yoga*, the two *Nadi Chakras* are - *Agyachakra* (situated between two eyebrows) and *Bhramaraguha Chakra* situated at the upper part of the forehead are supposed to be stimulated by *Shirodhara* which interns produce their desired effect.

In *Ayurvedic* classics, the site, which the *Shirodhara* stimulates, is the place of *Sthapnimarma* (situated between two eyebrows), and *Marma* in *Ayurveda* is supposed as a junction of veins, arteries, nerves, joints, sutures, and bones. *Sthapni Marma* controls the sixth *chakra* (*Agyachakra*) and *Prana Vayu*. The therapeutic

effect of medicated oil poured on the forehead may be a Tranquilizing effect, regulation of emotional and behavioral patterns and hormone secretion can also be postulated considering the effect on the hypothalamus as the hypothalamus is the main controller of endocrine secretions.^[16] Ultimately it can be postulated that *Shirodhara* may be having some potential effect on regulating the hypothalamic function. Thus, resulting in a decrease in most of the psychic and somatic disorders and making individuals perform normally and in an organized way.

Results of Clinical Study

Table 6: Showing change in assessment criteria in both groups

| Groups | Mean score | | | N | % | SD of Mean | SE (±) | 't' Value | 'p' Value | Remark |
|---|------------|-------|--------|----|------|------------|---------|-----------|-----------|--------|
| | BT | AT | Diff. | | | | | | | |
| Co-Efficient of Division of Attention (Co. Di.) | | | | | | | | | | |
| Group A | 0.768 | 0.764 | 0.004 | 15 | 0.52 | 0.0209 | 0.00541 | 0.7385 | 0.4724 | NS |
| Group B | 0.784 | 0.778 | 0.006 | 15 | 0.79 | 0.0386 | 0.00998 | 0.6677 | 0.5152 | NS |
| Reaction Time (R.T.) | | | | | | | | | | |
| Group A | 0.935 | 0.891 | 0.044 | 15 | 4.35 | 0.075 | 0.0195 | 2.252 | 0.04 | S |
| Group B | 1.013 | 0.954 | 0.059 | 15 | 4.95 | 0.152 | 0.0394 | 1.506 | 0.15 | NS |
| Finger Dexterity / Motor Ability Test (FDT) For Left-Hand | | | | | | | | | | |
| Group A | 7.113 | 6.758 | 0.3553 | 15 | 4.92 | 0.485 | 0.1253 | 2.835 | 0.013 | S |
| Group B | 7.232 | 6.961 | 0.2707 | 15 | 3.73 | 0.346 | 0.0893 | 3.039 | 0.009 | VS |
| Finger Dexterity / Motor Ability Test (FDT) For Right-Hand | | | | | | | | | | |
| Group A | 5.977 | 5.509 | 0.468 | 15 | 7.79 | 0.349 | 0.0903 | 5.181 | 0.0001 | ES |
| Group B | 6.109 | 5.783 | 0.3267 | 15 | 5.24 | 0.336 | 0.0869 | 3.759 | 0.0021 | VS |

| Intelligent Quotient (IQ) | | | | | | | | | | |
|---------------------------|-------|--------|-------|----|------|-------|--------|-------|-------|-----|
| Group A | 98.06 | 100.21 | 2.14 | 15 | 2.18 | 2.207 | 0.5698 | 3.756 | 0.002 | VS |
| Group B | 88.78 | 91.973 | 3.193 | 15 | 3.59 | 5.879 | 1.518 | 2.104 | 0.05 | NQS |

Statistically, no significant change in the Coefficient of Division of Attention was observed in Group A and Group B. Group A showed a statistically significant change in reaction time (P<0.04) and Group B showed a statistically not significant change in reaction time (P>0.05). Group B showed a statistically very significant improvement in the Finger Dexterity Test (FDT) for the Left Hand (P<0.009) and Group A showed a statistically significant improvement in FDT (P<0.01). Group A showed a statistically extremely significant improvement in the Finger Dexterity Test (FDT) for the Right Hand (P<0.0001) and Group B showed a statistically very significant improvement in FDT (P<0.002). Group A showed a statistically very significant improvement in intelligence quotient (IQ) (P<0.002) and Group B showed statistically not quite significant improvement in IQ (P<0.05). (Table No. 06 & Graph no. 01)

Graph 1: Showing change in assessment criteria in both groups

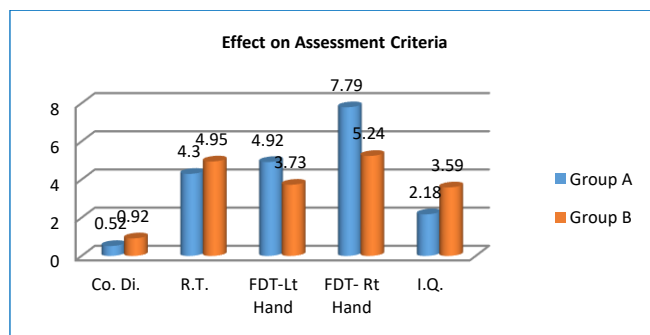


Table 7: Showing the total effect of therapy on core symptoms of ADHD

| Groups | Mean score | | | N | % | SD of Mean | SE (±) | 't' Value | 'p' Value | Remark |
|------------------------------|------------|-------|-------|----|-------|------------|--------|-----------|-----------|--------|
| | BT | AT | Diff. | | | | | | | |
| Effect on Inattention | | | | | | | | | | |
| Group A | 1.466 | 0.844 | 0.622 | 15 | 42.46 | 0.2309 | 0.0769 | 8.084 | 0.0001 | Es |

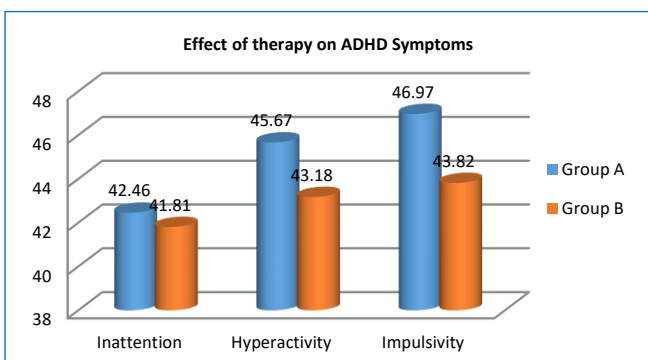
| | | | | | | | | | | |
|--------------------------------|-------|-------|-------|----|-------|--------|--------|-------|--------|----|
| Gro up B | 1.651 | 0.955 | 0.696 | 15 | 41.81 | 0.2083 | 0.0694 | 10.02 | 0.0001 | Es |
| Effect on Hyperactivity | | | | | | | | | | |
| Gro up A | 1.411 | 0.766 | 0.644 | 15 | 45.67 | 0.2445 | 0.0998 | 6.46 | 0.001 | Vs |
| Gro up B | 1.248 | 0.709 | 0.539 | 15 | 43.18 | 0.1665 | 0.0679 | 7.929 | 0.0005 | Es |
| Effect on Impulsivity | | | | | | | | | | |
| Gro up A | 1.422 | 0.755 | 0.667 | 15 | 46.97 | 0.2 | 0.1155 | 5.776 | 0.028 | S |
| Gro up B | 1.622 | 0.911 | 0.711 | 15 | 43.82 | 0.1544 | 0.0891 | 7.978 | 0.01 | S |

Statistically extremely significant improvement in symptoms of Inattention was observed in both groups A & B (P<0.0001). (Table No. 07& Graph no. 02) on comparing the intergroup differences was observed not significant for all symptoms of inattention.

Statistical evaluation showed extremely significant effect of therapy on symptoms of hyperactivity was observed in group B (P<0.0005) and a very significant effect in group A (P<0.001). (Table No. 07 & Graph no. 02) On comparing the intergroup differences of changes in the score of hyperactivity showed no significance in all symptoms except H(a) - Fidgeting with hands or feet or squirming in seats.

Statistical evaluation showed significant effect of therapy on symptoms of impulsivity was observed in both groups A & B (P<0.01). (Table No. 07& Graph No. 02) On comparing the intergroup differences of changes in the score of impulsivity showed no significance in all symptoms.

Graph 2: Showing the effect of therapy on all symptoms of ADHD



CONCLUSION

The prevalence of the present survey study was 230 cases of ADHD found in 1000 subjects in the age group 6–12 years, out of which 26.28% were from 6 to 9 years and 18.76% were from 9 to 12 years. In the overall 230 ADHD cases, 34.35% were male, while 10.64% were female in the age group 6–12 years in 1000 subjects. On the Statistical Analysis tab. ELEVA on Diagnostic and Statistical Manual of Mental Disorder IV edition (DSM–IV) criteria showed extremely significant improvement in Inattention, very significant in Hyperactivity, and a significant effect on Impulsivity. *Shirodhara* on DSM–IV criteria showed statistically extremely significant improvement in Inattention, Hyperactivity, and a significant effect on Impulsivity. Tablet ELEVA showed statistically significant results on Reaction time (R.T.), very significant Improvement in the Finger Dexterity Test (FDT) left hand, extremely significant improvement in FDT right hand, and very significant in I. Q. *Shirodhara* showed very significant Improvement in both FDT -left hand and FDT- right hand statistically. This work has been done by keeping in view all the cautions of bias in research, and also in the interpretation of concepts in an appropriate way. This study would serve as a guideline for research workers of the future; the author would feel his efforts have been productive.

Limitations of this study

- In the survey study, only DSM-IV criteria for diagnosis are not sufficient.
- Sample size of the present study was limited.
- Limitation related to the accuracy of answers to Questionnaire DSM-IV.
- In the case of ADHD duration of treatment was short.

Further suggestions for study

- Combination of Tab. ELEVA along with the *Shirodhara* procedure will be more effective in alleviating the symptoms of ADHD as compared to a single drug or procedure.

- Treatment duration should be longer than 3 months.
- A study may be planned in a large sample size.
- A standard scale should be made for Indian children to assess ADHD.

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