ORIGINAL ARTICLE

A comparative study on *Naladadi Ghrita* in attention–deficit/hyperactivity disorder with *Kushmanda Ghrita*

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Background: Attention–Deficit/Hyperactivity Disorder (ADHD) is the most commonly diagnosed childhood psychiatric disorder. Children with ADHD have been found to have cognitive deficits, lower IQ, impaired social relationships with in the family and with peers as well as poor study skills and lower academic achievement. ADHD prevalence is estimated to be 5% for the Indian paediatric population. The persistence of these problems highlights the need for effective treatment. **Objective:** The main objective of the present study was to evaluate the comparative effect of *Naladadi Ghrita* with *Kushmanda Ghrita* in reducing the signs and symptoms of ADHD. **Materials and Methods:** A total of 20 subjects with ADHD satisfying the DSM-IV TR diagnostic criteria were selected and divided in to two groups by following randomisation method. Trial group received *Naladadi Ghrita* 5 ml twice a day and control group received *Kushmanda Ghrita* 5 ml twice a day for 1 month. Two assessments were done before and after the treatment. Criterion of assessment was based on the scoring of ADHD Rating Scale. Paired and unpaired '*t*'-test was used for statistical analysis. **Results and Conclusion:** *Naladadi Ghrita* and *Kushmanda Ghrita* both were effective on ADHD Rating Scale and they provided 35%, 38.68% of relief, respectively ($P < 0.001$). The difference in between the both groups was statistically insignificant ($P > 0.05$).

Key words: ADHD rating scale, attention–deficit/hyperactivity disorder, *Kushmanda ghrita*, *Naladadi ghrita*

INTRODUCTION

Center for Disease Control and prevention (CDC) identified, 'Attention Deficit/Hyperactivity Disorder (ADHD) as serious public health problem' because of its high prevalence, chronicity and global impairment caused by it. ADHD is present in 3-10% of children.[1] ADHD may present with any or all of the following symptoms: Hyperactivity, distractibility, impulsivity, short attention span, forgetfulness, procrastination, poor consequential thinking, low frustration tolerance, mood liability, temper outbursts and preference for high levels of stimulation.[2]

Naladadi Ghrita is described in *Ashtanga hridaya, uttara tantra* in *rasayana adhyaya*. This formulation contains around 17 herbs, *Katuka rohini* (*Picrorhiza scrophularia flora*), *Payasya* (*Holostemma adakodien*), *Madhuka* (*Glycyrrhiza glabra*), *Chandana* (*Santalam album*), *Sariba* (*Hemidesmus indicus*), *Vacha* (*Acorus calamus*), etc.; the main content is *"Shankha pushpi (Clitoria ternata)"*. This formulation considered as *"Pratibha Rasaayanam" (Intellect promoter)*. By regular intake of this *ghrita,* even mute or retarded persons also will become talkative. It improves the memory, intellect and health.[3] *Shankha pushpi* is known as sedative, anti-stress, central nervous system (CNS) depressant and anti-anxiety agent. In a study of combination of three drugs, namely *Brahmi* (*Centella asiatica*), *Vacha* and *Shanka pushpi* proved beneficial in low grade mentally retarded children. An appreciable increase in verbal mental age was observed. The combined anti-anxiety and sedative action of the three drugs have been attributed for improving the attention, activity level and feedback and in controlling the hyperactivity, aggressiveness, etc.[4]

"Kushmanda Ghrita" is described in *Ashtanga hridaya* in *apasmaar pratishedha adhyaya*.[5] *Kushmanda ghrita* contains *Kushmanda* (*Benincasa hispida*) and *Yashtimadhu* (*Glycyrrhiza glabra*). It has been used to treat ADHD in college hospital, where the present work has been conducted. A research work (unpublished) was conducted in this regard, which showed positive results (30.8% relief on ADHD rating scale). No previous works were conducted on *Naladadi Ghrita* on ADHD. The present study was planned to evaluate the efficacy of *Naladadi ghrita* and *Kushmanda ghrita* individually in the management of ADHD and to compare the efficacy of *Naladadi Ghrita* against *Kushmanda Ghrita* in the management of ADHD.

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MATERIALS AND METHODS

Study Design
A comparative clinical study.

Selection of the Patients
All patients fulfilling the inclusion criteria were selected from the OPD irrespective of caste, religion and economic status with their parent or guardian's written consent.

Inclusion Criteria
- Patients who were fulfilling the Diagnostic Criteria of ADHD according to Diagnostic Statistical Manual of Mental diseases IV Text Revision (DSM IV TR) (314)[6]
- Belonging to the age group between 5 and 12 years.

Exclusion Criteria
- Mental retardation
- Presence of other organic or psychotic or neurological disorder
- Pervasive developmental disorder.

The study was cleared by the institutional ethics committee. Written consent was taken from the parent or guardian of each patient willing to participate before the start of the study. A detailed history of each patient was taken. A general physical examination of all systems was performed. After establishing the diagnosis, the patients were allocated to trial group and control group. Patients were free to withdraw from the study at any time without giving any reason.

A total of 20 patients were registered in the present study. In trial group, 10 patients were registered and in control group also ten patients were registered. All of the patients in both groups have completed the course of the treatment without drop out.

Laboratory Investigations
Routine haematological tests, biochemical investigations and urine analysis had been carried out according to the necessity. All these investigations were carried out before the treatment to exclude organic pathology and to assess the general condition of the patient. If any of the abnormalities found in investigation reports those patients were excluded from the study.

Grouping
Selected patients were randomly divided in two groups (trial and control groups) by following alternate method (first patient in trial group, second patient in control group, third patient in trial group like that alternatively).

Intervention
In Trial group, *Naladadi ghrita* was given with the dose of 5 ml twice a day through oral route before intake of food for 30 days. In control group, *Kushmanda ghrita* with the dose of 5 ml twice a day through oral route before food for 30 days has been given. Follow up period was kept for 30 days in both groups after the treatment period.

Assessment
Before and after treatment, two assessments were carried out. A criterion of assessment was based on the scoring of ADHD rating scale. This scale is composed of 14 items (Questions), which measures inattention, hyperactivity and impulsivity. The frequency of each item or symptom was delineated on a 4-point 'Likert scale' ranging from never or rarely '0' to very often '3', with higher scores indicative of greater ADHD-related behaviour. The ADHD Rating Scale was developed specifically to obtain parent ratings of the frequency of DSM-III-R symptoms of ADHD.[7] In present study this scale has been used for assessment.

Statistical Analysis
The information gathered on the basis of observations was subjected to statistical analysis in terms of mean difference, standard deviation (SD), standard error (SE), Paired '*t*'-test and unpaired '*t*'-test. The obtained results were interpreted as
Insignificant – $P > 0.05$
Significant – $P < 0.05$.

Overall Effect of Therapy
Overall effect of therapy on 20 patients of ADHD was calculated by taking the percentage of relief based on the scores of ADHD rating scale and categorised as
- 100% relief – Complete relief
- >75% to <100% – Marked improvement
- >50-75% – Moderate improvement
- >25-50% – Mild improvement
- 0-25% – No relief.

OBSERVATIONS AND RESULTS

The demographic data of the present study showed that, maximum, that is 85% patients were male, 30% patients belong to the age group of 7-9 years, 65% were Muslims, 85% belong to rural areas and 90% of ADHD children were deprived from parents (65% from father, 25% from mother). Maximum number, that is 30% of patients reported positive family history of ADHD (in 1st and 2nd degree relatives) and 30% of ADHD children showed positive family history of psychiatric illness. In this study the observations regarding the birth history showed that, 5% reported premature labour, 30% of the patients were born with low birth weight, 10% reported neonatal illness and 30% presented the history of delayed mile stones. Majority of cases, that is 60% reported poor adjustment to school, 35% reported change of school, 70% showed poor scholastic performance

and 40% had poor peer relationships. Excessive intake of sweets/chocolates was found in 45% of ADHD children, excessive intake of bakery items was found in 45% and 60% were non-vegetarians.

Out of 20 ADHD children, 50% were combined subtype of ADHD (ADHD-C), 45% were inattentive subtype of ADHD (ADHD-I) and 5% were hyperactive–impulsive subtype of ADHD (ADHD-HI).

In the trial group, maximum relief was observed in, Item 7, Item 8, Item 14 and Item 6 [Table 1]. In the control group, maximum relief was observed in, Item 12, Item 13, Item 14, Item 1, Item 6 and Item 7 [Table 2]. Comparison between the two groups revealed that there was statistically no significant difference observed ($P > 0.05$) in all items except item no 5 (often blurts out answers to questions), in which trial drug proved better than control drug ($P < 0.05$).

On total score of ADHD rating scale, trial drug provided 35% of relief after treatment period, whereas control drug provided 38.68% of relief ($P < 0.001$) [Table 3], however, the difference between the two groups was statistically insignificant ($P > 0.05$) on total score of ADHD rating scale. In the trial group, maximum percentage of patients (50%) got mild relief, whereas in the control group maximum patients (50%) got moderate relief [Table 4].

Table 1: Effect of therapy on ADHD rating scale in trial group (*n*=10)

ADHD rating scale (ITEM)	Mean score BT**	Mean score AT*	M. Diff with SD***	% of relief	*t* value	*P* value
1	2.5	1.6	0.9±0.57	36	5.01	<0.001
2	2.6	1.8	0.8±0.92	30.76	2.75	<0.05
3	2.5	1.7	0.8±1.03	32	2.45	<0.05
4	2	1.3	0.7±0.82	35	2.69	<0.05
5	1.9	1.2	0.7±0.67	36.84	3.28	<0.01
6	2.5	1.5	1±0.67	40	4.74	<0.01
7	2.9	1.6	1.3±0.82	44.82	4.99	<0.001
8	2.7	1.5	1.2±0.79	44.4	4.81	<0.001
9	1.4	1	0.4±0.70	28.57	1.81	>0.05
10	1.1	0.8	0.3±0.48	27.27	1.96	>0.05
11	2.5	1.7	0.8±0.53	32	2.75	<0.05
12	2.6	1.8	0.8±0.63	30.78	4	<0.01
13	2.5	1.9	0.6±0.84	24	2.25	>0.05
14	2	1.2	0.8±0.79	40	3.20	<0.05

AT* – After treatment; BT** – Before treatment; SD*** – Standard deviation; ADHD – Attention-deficit/hyperactivity disorder

Table 2: Effect of therapy on ADHD rating scale in control group (*n*=10)

ITEM	Mean score BT**	Mean score AT*	M. Diff with SD***	% of relief	*t* value	*P* value
1	1.8	1	0.8±0.79	44.4	3.20	<0.05
2	1.8	1.1	0.7±0.82	38.88	2.69	<0.05
3	2.7	1.7	1±1.05	37.04	3.00	<0.05
4	1.6	1.3	0.3±0.48	18.75	1.96	>0.05
5	0.7	0.7	0±0.47	0	0	>0.05
6	1.8	1	0.8±0.92	44.44	2.75	<0.05
7	2.7	1.5	1.2±0.92	44.44	4.13	<0.01
8	2	1.2	0.8±0.79	40	3.20	<0.05
9	1.1	0.9	0.2±0.42	18.18	1.50	>0.05
10	1.4	1.2	0.2±0.42	14.28	1.50	>0.05
11	1.7	1.2	0.5±0.92	29.41	3	<0.05
12	1.3	0.5	0.8±1.03	61.5	2.45	<0.05
13	2.2	0.9	1.3±0.82	59.09	4.99	<0.001
14	1.5	0.7	0.8±0.92	53.33	2.75	<0.05

AT* – After treatment; BT** – Before treatment; SD*** – Standard deviation; ADHD – Attention-deficit/hyperactivity disorder

DISCUSSION

In the present study maximum children were male. On average, male children are between 2.5 and 5.6 times more likely than female children to be diagnosed as ADHD within epidemiological samples, with the average being roughly 3:1.[8] In the present study, the age group was between 5 and 12 years because recent research has also revealed that impairments of ADHD often are not apparent in early childhood but may become noticeable only in junior high, high school, or early adulthood, when the individual is required to self-manage an increasingly wide range of tasks.[9]

In the present study, 65% were Muslims and 85% belongs to rural areas, this may be because of the geographic distribution of this particular religion where the present work has been carried out. Ethnic differences, however, may arise in part because of socioeconomic factors that are differentially associated with different ethnic groups. These ethnic factors no longer make a significant contribution to the prevalence of ADHD.[10]

Table 3: Effect of therapy on total score of ADHD rating scale

Group	Sample size (*n*)	Mean score BT**	Mean score AT*	M. Diff with SD***	% of relief	*t* value	*P* value
Trial	10	31.7	20.6	11.1±5.49	35	6.39	<0.001
Control	10	24.3	14.9	9.4±4.60	38.68	6.46	<0.001

AT* – After treatment; BT** – Before treatment; SD*** – Standard deviation; ADHD – Attention-deficit/hyperactivity disorder

Table 4: Overall effect of the therapy based on ADHD rating scale

Result	Trial group (*n*=10)		Control group (*n*=10)	
	No.	%	No.	%
Complete relief	0	0	0	0
Marked improvement	0	0	0	0
Moderate improvement	4	40	5	50
Mild improvement	5	50	3	30
No relief	1	10	2	20

Evidence for a genetic basis to this disorder is now overwhelming and comes from four sources: Family studies of the aggregation of the disorder among biological relatives, adoption studies, twin studies and, most recently, molecular genetic studies identifying individual candidate genes.[11,12] For years, researchers have noted the higher prevalence of psychopathology in the parents and other relatives of children with ADHD. Between 10% and 35% of the immediate family members of children with ADHD and 32% of siblings of ADHD are also likely to have the disorder.[13] In the present study similar findings were also observed (30% of children having positive family history of ADHD and other psychiatric illness).

Most studies have found a greater incidence of pregnancy or birth complications in ADHD compared with normal children.[14] Children born prematurely or who have markedly lower birth weights are at high risk for later inattention, hyperactivity or ADHD.[15] In the present study premature labour, low birth weight, neonatal illness and delayed mile stones, etc., were also observed.

Differences in IQ have also been found between hyperactive boys and their normal siblings.[16] The vast majority of children with ADHD have difficulties with school performance, most often under-productivity of their work. ADHD children frequently fall below normal or control groups of children on standardised achievement tests.[17] The interpersonal behaviours of those with ADHD are often characterised as more impulsive, intrusive, excessive, disorganised, engaging, aggressive, intense and emotional. And so they are "disruptive" of the smoothness of the ongoing stream of social interactions, reciprocity and co-operation that is an increasingly important part the children's daily life with others.[18] In present study, majority of children having the problems, like poor adjustment to school, frequent change of school, poor scholastic performance and poor peer relationships.

In the present study, maximum children were fond of chocolates, bakery items and sweets. Some relationship has been observed with particular food items and ADHD severity. Previous studies reported that, by restricting the items like food dyes, food flavourings, preservatives, monosodium glutamate, chocolate and caffeine from diet along with multi vitamins provided 50% relief in ADHD patients.[19]

Previous study done on *Brahmi* (*Bacopa monnieri*) showed significant improvement in ADHD children over placebo in tests of sentence repetition, logical memory and pair associated learning.[20] Study on *Ginkgo biloba* and *Panax quinquefolius* (American ginseng) also showed beneficial effects in attention and impulsivity of ADHD children.[21] Standardised extract of *Pinus pinaster* (French maritime pine) bark is proved effective in ADHD.[22] However, conclusive findings from large prospective controlled trials on herbal preparations are still awaited.

Naladadi Ghrita, contains the herbs like *Shankhapushpi* (*Clitoria ternata*), *Nalada* (*Nardostachys jatamansi*), *Vacha* (*Acorus calamus*) and *Madhuka* (*Glycyrrhiza glabra*), etc., and it is described as *"Pratibha Rasaayanam" (*Intellect promoter*),* "*Jado api vaagmayee*" (even mute or retarded persons are also becomes talkative) and *"Shrutadhari"* (power of retaining everything whatever attends or listens);[3] based on these qualities it was selected as trial drug of present study. *Kushmanda Ghrita* is known as *tridoshahara* especially *pittahara* and indicated for *cheto vikara's* (psychiatric conditions) and it contains only two herbs, *Kushmanda* (*Benincasa hispida*) and *Yashtimadhu* (*Glycyrrhiza glabra*).[5] Both the trial drug and control drug were purchased from the Good Manufacturing Practice (GMP) certified private *ayurvedic* pharmacy where the study has been conducted.

The main ingredient of *Naladadi ghrita* is *Shankha pushpi* and it is highly regarded as *Medhya* (intellect promoter). *Shankha pushpi* is having neuro protective, intellect promoting, free radical scavenging and antioxidant activity. Ayushman-8 (containing *Shankhpushpi, Brahmi* and *Vacha*) reported to be effective on Manasa-mandata (mental retardation). *Shankha pushpi* proved effective in relieving signs and symptoms of *Chittodvega* (anxiety disorders), anti-depressant in mice and it calms the nerves by regulating the body's production of the stress hormones, adrenaline and cortisol. *Vacha* has been used to cure diseases of CNS. It has been proved for its analgesic and anti-convulsant, anti-oxidant, sedative and hypothermic effects. Good in clearing speech to the children and useful in schizophrenic psychosis. Roots and rhizomes of *Jatamansi* are used to treat hysteria, epilepsy and convulsions. The decoction of the drug is also used in neurological disorders, insomnia. It is proven to improve learning and memory in mice and it has shown significant inhibition of benzoyl peroxide-induced cutaneous oxidative stress and toxicity.[23] The relief found in trial group is because of the synergetic action of all these drugs present in *Naladadi ghrita*.

Kushmanda (*Benincasa hispida*) shows presence of alkaloids, flavinoids, saponins and steroids. It serves as reactive oxygen species scavenger and an antioxidant agent. It has a tissue protective preventive effect on colchicine-induced Alzheimer's disease. *Kushmandadi Ghrita* showed significant results in the management *Chittodvega* (anxiety disorders). *Yashtimadhu* (*Glycirrhiza glabra* Linn.) is also a *Medhya* drug having multi-dimensional activities because of the contents like glycyrrhizine and flavonones. The roots and rhizomes of *Yashtimadhu* have been studied with respect to

spatial learning and passive avoidance, preliminary free radical scavenging, cerebral ischemia and anti-oxidant capacity towards low-density lipoprotein (LDL) oxidation. It acts as brain tonic, increases the circulation into the CNS and balance the sugar levels in the blood. Liquorice has significant action on memory enhancing activity in dementia and it significantly improved learning and memory on scopolamine induced dementia.[23] *Kushmanda ghrita* provided encouraging results in the present study because of the synergetic action of its contents.

In trial group, maximum relief was observed in the items like, "often shifts from one un completed activity to another", "often engages in physically dangerous activities without considering consequences", "has difficulty following instructions", etc.; these improvement may be because of the *"medhya rasayana"*, "*shrutadhaari*" properties of *Naladadi ghrita*. In the control group, maximum relief was observed in items like, "often does not seem to listen", "often loses things necessary for tasks", "often engages in physically dangerous activities without considering consequences", "often fidgets and squirms in seat", "has difficulty following instructions" and "has difficulty sustaining attention to tasks". These actions may be because of "*vatapittahara"* and *"cheto vikara prashamana*" properties of *Kushmanda ghrita*.

Both the trial drug and control drug provided "mild improvement (≥35% relief)" on total score of ADHD rating scale individually. There was no significant difference ($P > 0.05$) found in between the two groups.

Maximum numbers of patients, that is 70% were having combined subtype of ADHD in trial group, whereas in control group maximum children, that is 60% were predominantly having inattentive subtype of ADHD. Further studies are required to sort out whether *Naladadi ghrita* is more effective in combined subtype of ADHD compared to others and *Kushmanda ghrita* is more effective in inattentive subtype of ADHD compared with other subtypes of ADHD.

CONCLUSION

Individually both of the drugs, *Naladadi ghrita* and *Kushmanda ghrita* were found effective in the management of ADHD. There was no significant difference found between the two drugs.

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