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Research Article

EFFECT OF *BRAHMISOHALADI SIROLEPA* IN CHILDREN WITH AUTISM SPECTRUM DISORDERS

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ABSTRACT

Autism Spectrum Disorder (ASD) is a neurodevelopmental disorder characterized by impairment in social interaction and communication with restricted interests and repetitive behaviour. The prevalence of ASD has shown an alarming increase in the recent decades ending up to 1 in 90 children. In spite of enormous researches in contemporary medical field, no medicaments have proved to be effective in improving their social behaviour. In Ayurveda, ASD comes under the category of *Unmada* involving derangement of all the three Doshas (*Vishama sannipatha*) with predominance of *Vata* & *Pitha*. Child friendly and effective procedure based therapy in the form of *Sirolepa* (application of medicated paste on scalp) is being tried in children with ASD between 3 and 12 years selected from the outpatient cases of Dept. Of Kaumarabhrithya, Government Ayurveda College, Thiruvananthapuram. The present study empirically analysis the efficacy of *Sirolepa* with *Brahmisohaladi* with its classical reference in *Arogyakalpadruma* in the context of *Unmada*. Children with ASD satisfying the DSM V criteria and having a CARS score above 30 were selected for the study having duration of 28 days. There was an observable improvement in eye contact, attention span and sleep pattern with a marked reduction in hyperactivity. All of the children included in the study were receiving speech as well as psycho therapies and appropriate dietary advice throughout the treatment course. The clinical observation was supported by CARS (Childhood Autism Rating Scale) & ATEC (Autism Treatment Evaluation Checklist) recorded as pre- post evaluation. The changes in CARS and ATEC score were highly significant at 0.05% level ($P<0.0005$). The study provides the first potential evidence that *Brahmisohaladi Sirolepa* may be capable of modifying the core social and cognitive defects associated with ASD.

KEYWORDS: Autism Spectrum Disorder, *Brahmisohaladi Sirolepa*, *Unmada.*

INTRODUCTION

ASD is one among the most enigmatic forms of disability mainly due to the socio behavioural attributes of the diseased. ASD includes Autism, Asperger syndrome, Childhood Disintegrative disorder & Pervasive developmental disorders not otherwise specified.[1] It involves severe difficulties in basic aspects of social behaviour such as eye contact, facial expression, unusual gestures, diminished responsiveness, pragmatic deficits, neologism, lack of emotions in speech, unusual response to sensory stimuli etc.[2] This group of neuropsychiatric disorders show specific delay & deviance in social, communicative & cognitive development with developmental regression, absence of protodeclarative pointing, abnormal reaction to environmental stimuli, abnormal social interests, absence of symbolic play and so on.

Global prevalence of ASD ranges from 0.07% to 1.8%.[3,4] A population study conducted in nine different centres over five zones in India was concluded with a prevalence rate of 1.2%.[5] Male sex and upper socio economic group had a higher risk of Autism when compared to lower socio economic group.[6] Recent decades have witness an alarming increase in prevalence of this disorder all over the world.

Although the exact cause of ASD is still not known, the main findings emphasize the role of genetic and environmental factors in the development of autistic behaviour.[7] Environmental factors are also likely to interact with the genetic profile and cause aberrant change in brain growth, neuronal development and functional connectivity.[8]

Pharmacological therapy in ASD is limited to Respiridone and Aripiprazole. [9] But they are approved by FDA only for managing the irritability associated with the disorder. [10] Selective serotonin receptive inhibitors (SSRIs) are prescribed for the

treatment of conditions often co morbid with ASD such as depression, anxiety and obsessive compulsive behaviour. [11] But the researchers in the field were unable to come up with a statistical evidence to prove its efficacy against the emerging evidence of harm. [12]

Early intervention of ASD with communication DEALL programme (Developmental Eclectic Approach to Language Learning) by providing intensive stimulation for 3-4 hrs per day for 5 days per week over an academic year by a team of speech language pathologists, occupational therapists, developmental psychologists and special educators 1: 4 staff student ratio has come up with statistically significant increase in developmental domains & autism severity as measured by CARS. [13] Only behaviour therapies have proven their efficacy in managing the socio behavioural attributes of ASD. [14,15] But they are very time consuming and it demands one to one training for prolonged duration for 50 to 60 hours per week under the personal guidance of expertise .This type of ideal behaviour therapy is setting out of reach for more than 80% of ASD population.

The multiple developmental and behavioral problems associated with ASD necessitate multidisciplinary care, coordination of services, and advocacy for individuals and their families. Early and sustained intervention with the help of multiple treatment modalities is always indicated.[16,17] Here lies the importance of highly economical, child friendly and easily implementable *Sirolepa* with no drug interactions or side effects.

Ayurveda has viewed ASD as a behavioural abnormality with its roots embedded in the defective neuropsychological platform and derangement in digestive and metabolic system. *Unmada* is a spectrum of neuropsychological disorders affecting the smooth functioning of *Manas* (mind), *Budhi* (intellect), *Samnja* (consciousness), *Jnana* (know-ledge), *Smriti* (memory), *Bhakthi* (desire), *Seela* (manners), *Chesta* (behaviour) and *Achara* (conduct).[18] The acquisition of knowledge (*Jnanot-pathy*), one among the important functions of *Manas* is disturbed in *Unmada*. *Jnanotpathy* happens only when *Manas* is in tune with *Atma* (soul), *Indriya* (sense organ), *Indriyartha* (objects).[19] So even if there is no defect in hearing capacity, they are unable to comprehend the speech and act accordingly. They can appreciate the tone, pitch and modulation of sound, but in no way can help in language reception.[20] Similar is the condition with other senses also. Inability in sharing of emotions like joy or sorrow, feeling of empathy, emotional reciprocity etc point towards the involvement of *Manas* in the pathology of disease. The concept of genetic defects (*Beeja dushti*), antenatal psychological stress, non congenial dietetics (*Virudha ahara*) disturbing the metabolism (gut brain axis), defective parental psychological back ground (parental genetic makeup) and faulty child rearing system (refrigerated parentage, neglected childhood, monitor addiction) have the key role in the etiopathology of *Unmada* and ASD.[21] Uneven development of functional areas of brain, unstable neurotransmitter level controlling the brain functions etc. have been incorporated in framing the treatment outline.

The present study empirically analysis the efficacy of *Sirolepa* with *Brahmisohaladi* in managing the sociobehavioural attributes of ASD. Application of medicated paste on shaved scalp form the base of *Sirolepa*. *Balasohaladi Sirolepa* has its classical reference in Arogyakalpadruma in the context of *Unmada*. [22] *Brahmisohaladi Sirolepa* is an alteration in the ingredients of *Balasohaladi Sirolepa* with a view to address the behavioural attributes of ASD, due to the functional derangement of the *Pitha*. *Bala* leaves in *Balasohaladi Sirolepa* were replaced with fresh *Brahmi* leaves having more *Pithasamana* and *Medhya* property, forming *Brahmisohaladi Sirolepa.*

MATERIALS AND METHODS

Contents of *Brahmisohaladi Sirolepa*

1. Fresh whole plant of *Brahmi* – 50g
2. Fresh whole plant of *Sohala* – 50g
3. Powder of *Mustha* - 12g
4. Powder of *Jeeraka* - 12g
5. *Panchagandha churna* (*Hreebera, Sevya, Kushta, Yashti, Rakthachandana*)- 60g
6. *Navaneetha* (salt less butter) – 48g
7. Cow's milk – 50 ml (as required to make a smooth paste)

Table 1: Chemical Constituents of the ingredients of *Brahmisohaladi Sirolepa*

S.No.	Sanskrit/English name	Botanical name	Part used	Chemical Constituents [23]
1	*Brahmi*	*Bacopa monnieri*	Whole plant	Brahmine, Herpestine, Alanine, Hersaponin, Monnierin, Octacosane, Bacogenins
2	*Sohala*/ Common purslane	*Portulaca oleracea* Linn.	Whole plant	Norepinephrine, Oleracein, Hesperidin, Caffeic acid , Alanine,

				Catechol[24]
3	*Musta* / Nut grass	*Cyperus ritundus* Linn	Root	CyperenI& II, Cyperenone, Cyperol, Sugenol, β-Sitosterol, Mustakone. [25,26]
4	*Jeeraka*/ Cumin seeds	*Cuminum cyminum* Linn	Seeds	Cuminin, Diacyl glycerol, Imperatorin, Apigenin, Cuminaldehyde.
5	*Hreebera*	*Plectranthus vettiveroides*	Whole plant	Androstan, Spathulenol, Z-valerenyl acetate, myrtenol,1naphthalenol
6	*Sevya* / Cuscus grass	*Vetiveria zizanoides* Linn.		Eugenol, Vetiverol, Zizanol, Khusimene, Sesquiterpenes[27]
7	*Kushta*/ Costus root	*Saussarea lappa*	Root	Costol, Costunolide, Sitosterol
8	*Yashtimadhu*/ Liquorice root	*Glycyrrhiza glabra* Linn.	Root	Glycyrrhizin, Liquirtin, Glabrene, Isoliquiritogenin[28,29]
9	*Rakta chandan*/ Red sandal wood	*Pterocarpus santalinus* Linn.	Heart wood	Pterocarpol, Santalin A,B, Lapenediol

***Brahmisohaladi Sirolepa* –**

Preparation and application

The fresh whole plant of *Brahmi* and *Sohala* were taken in the mentioned quantity and washed well and made in to a paste without adding water. To this paste, 60 gram of *Panchagandha choorna,* 12 gram each of *Mustha* and *Jeeraka* were added. The mixture was made in to paste by adding butter and required amount of milk. An earthen vessel was used to mix the ingredients. The medicinal paste was rubbed well in that earthen vessel for about 5 minutes. After that the medicinal paste with thick consistency was obtained. *Brahmisohaladi Sirolepa* was applied all over the scalp in anticlockwise pattern ensuring a uniform thickness of 0.5cm. The duration of *Sirolepa* was one hour on the first day. It was advised to increase the time period 30 minutes per day till 14th day .The maximum time of keeping the *Sirolepa* on scalp was 7.30 hour on day 14. The same time period repeated on day 15. From day 16 onwards, the duration gradually decreased by half hour. Thus by the 28th day the time period was reduced to 1 hour. It was advised to do the Sirolepa after 8 am and finish before 6pm. Scalp was cleaned with a dry cloth and advised to take bath in water boiled with leaves of *Sida retusa* and *Panchagandha choorna*.

Methodology

The study was conducted at Dept. of Kaumarabhrithya, Government Ayurveda College, Thiruvananthapuram in ASD children between 3 and 12 years selected from the outpatient cases. Those children satisfying the DSM V (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition) criteria and having a CARS (Childhood Autism Rating Scale) score above 30 was selected for the study.[30,31] Children having intractable seizures and recurrent upper respiratory tract infections were excluded from the study for fear of drug interactions and chances of exacerbation of respiratory infection during the treatment phase. Evaluation of the cases was done with Internationally accepted assessment tools like CARS and ATEC (Autism Treatment Evaluation Checklist).[32] Evaluation of the efficacy of the treatment in the different aspects of ASD like speech and language, sociability, sensory /cognitive awareness and behavioural domains could be made possible by subscales of ATEC. Blinded evaluation of cases before and after the treatment duration of 28 days was done by a psychologist.

Ethical Consideration

Ethical considerations were satisfied throughout the study. The treatment used in the study was time tested and safe as per the professional experience of the department. The parents of the children were explained about the details of the study and an informed consent was obtained from them before recruiting him/her into the study. The parents were allowed to withdraw their children from the study at any time at their will. The information about the patients was kept confidential.

Statistics

Table 2: Pre-post evaluation with CARS and ATEC

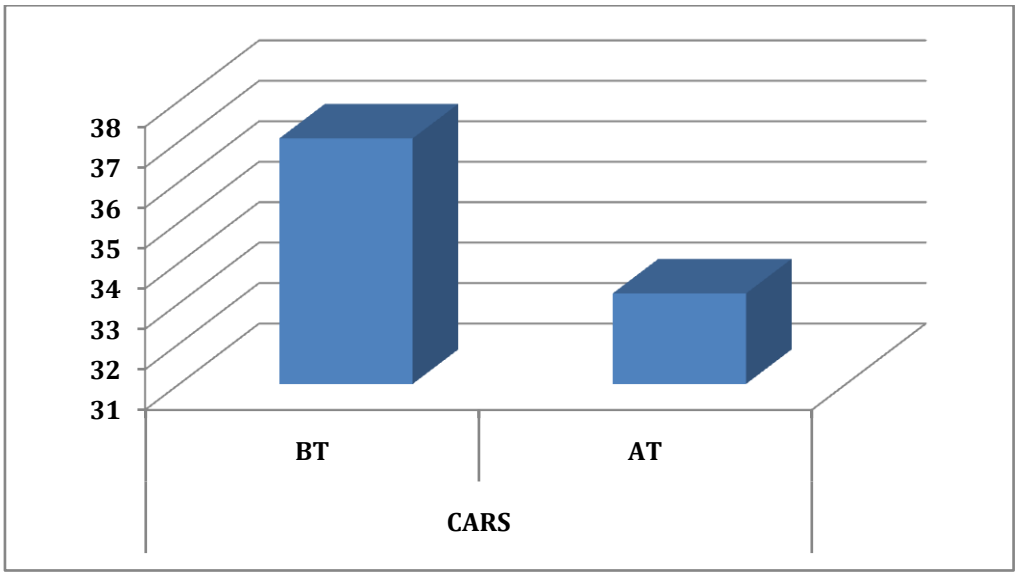
	CARS		ATEC	
Case No	**Before Rx**	**After Rx**	**Before Rx**	**After Rx**
1	38	36	98	84
2	37	34.5	95	79
3	37	34	84	70
4	34.5	31	88	72
5	44	39	122	103
6	30.5	27	74	60
7	32	29.5	79	65
8	39	35.5	104	83
9	35.5	32	96	81
10	40	35.5	112	94
11	33	29	83	69
12	38	34	94	76
13	42	36.5	117	98
14	46	40.5	134	104
15	32	29	84	69
16	40	35.5	106	88
17	35	31.5	89	71
18	38	33.5	92	74
19	31	28.5	68	55
20	44	39.5	126	103
21	32	26.5	72	61

The Paired Samples *t* Test compares two means that are from the same cases. The two means typically represent two different times (e.g., pre-test and post-test with an intervention between the two time points. The purpose of the test is to determine whether there is statistical evidence that the mean difference between paired observations on a particular outcome is significantly different from zero. Statistical analysis of the pre and post test results revealed a highly significant response in the reduction of severity of ASD in CARS (p 0.000) and ATEC scores (p 0.000). Hyperactivity, temper tantrums, repetitive movements, shouting/screaming, oversensitivity to sound and sleep issues showed remarkable response in clinically notable level.

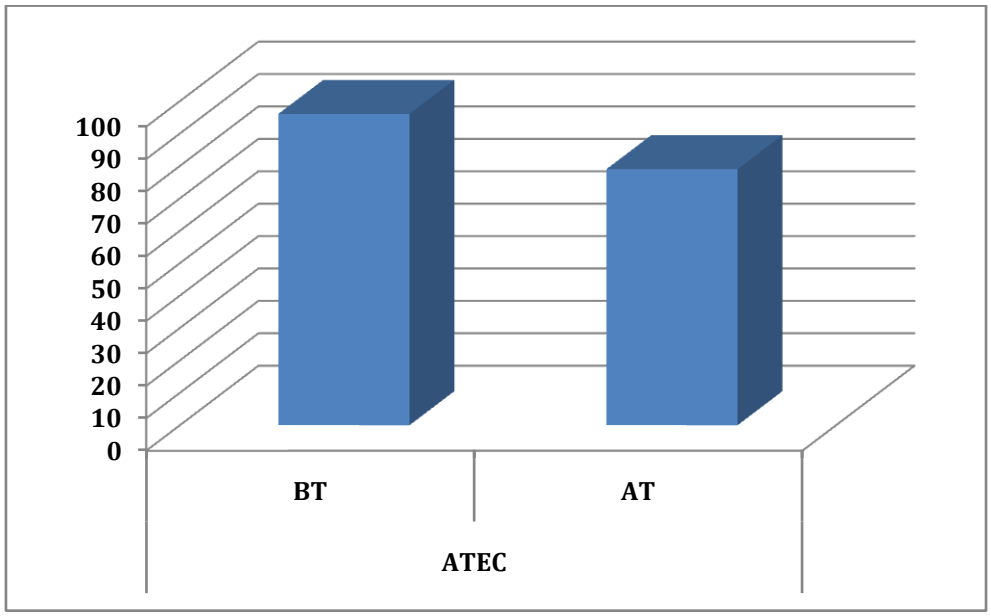
Table 3: Data and test of significance (paired t test) on effectiveness of treatment

Variable	Time	Mean	N	Std. Deviation	T	df	p
CARS	BT	37.071	21	4.5312	16.686	20	.000
	AT	33.238	21	4.0485			
ATEC	BT	96.05	21	18.178	18.921	20	.000
	AT	79.00	21	14.789			

Graph 1: Efficacy of treatment in CARS



Graph 2: Efficacy of treatment in ATEC



DISCUSSION

Children satisfying the inclusion criteria of CARS 30 were exhibiting derangements in the functional level of both *Vata* and *Pitha* with a marked predominance of *Pitha* attributes like irritability, temper tantrums, inflicting self injury and hurting others, hyperactivity, excessive thirst and appetite, insomnia, affinity towards playing with water and desire for cool climatic conditions. As the functional derangements in the activity of brain was evident, *Vathapitha samana* treatment was opted to be done at *Siras* (*Rogadhishtana*). Even if the treatment principles of *Unmada* comprises of many procedure based therapies and detoxification procedures including digestive correction , these special kids would rarely cooperate with these therapies at this stage of irritability and hyper activity. So a child friendly procedure like Sirolepa was selected based on the classical references. Clinical results observed with *Brahmi Sirolepa* in ASD cases was the base for replacing *Bala* leaves of *Balasohaladi Sirolepa* with *Brahmi*. Moreover *Brahmi* is known to have more *Rasayana* property with *Medhya prabhava*. Paste of fresh leaves of *Brahmi* was found to have more *Pitha Samana* property. All other drugs in the formulation were having *Vatapitha samana* property and could be made into a smooth paste with milk and butter. Covering the *Sirolepa* with fresh lotus leaves (like a medicated cap) ensured the retention of the cooling effect of the *Sirolepa* without drying for longer duration. It was noted that that there was not a single drop our during the treatment plan. Two children had one episode each of rhinitis which subsided without medical management within a few days. *Sirolepa* was restricted during this period.

The results showed that there is statistically significant (p 0.000) improvement in the severity of

Autism. The period of intervention was very short (28 days). So we couldn't find any remarkable change in language skills.

CONCLUSION

Symptoms of ASD attributed to *Pitha* derangements showed statistically significant (p 0.000) changes after the treatment. Temper tantrums, irritability, insomnia, self injurious behaviour and hyperactivity reduced considerably in the CARS and ATEC score sheets. During and after the intervention the children were more cooperative for speech and behavioural intervention which reflected in the social behaviour and language acquisition skills. The study drug, *Brahmisohaladi Sirolepa*, is only one among the vast treatment schedules elaborated for managing *Unmada*. Clinical expertise in the field has shown the Ayurveda intervention has the potential to revert the pathology of ASD bringing back to the normal life.

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