

An open label pilot trial of Abhaya Ghrita in autistic disorder

Abstract

Autism is a developmental disorder characterized by impaired social interaction, communication, repetitive behaviors and restricted interests. Autism spectrum disorders (ASD) is a clinically defined behavioral syndrome that manifests in early childhood. In India prevalence rate of ASD is 1.2%. There is a little evidence of any 'cure' for Autism. There is lack of sufficient data regarding *Ayurvedic* strategy of managing this condition. The present study was aimed to assess the efficacy of "Abhaya ghrita", which contains *Brahmi* (*Bacopa monnieri*), *Kushta* (*Saussurea lappa* Clarke), *Vacha* (*Acorus calamus* Linn), *Pippali* (*Piper longum* Linn) etc herbs. In present study, 10 patients with 'Autistic disorder', satisfying the DSM-IV-TR (Diagnostic and statistical manual for mental disorders) diagnostic criteria were selected. *Abhaya ghrita* (with a dose of 5-10ml) has been given orally twice a day for three months. Total three assessments were taken, before starting treatment, after completion of treatment and after follow up. Criteria of assessment were based on the scoring of 'Indian scale for assessment of Autism (ISAA). Paired 't' test was used for statistical evaluation. *Abhaya ghrita* has provided 10.69% of relief on ISAA, which was considered as clinically unsatisfactory.

Keywords: autistic disorder, autism, autism spectrum disorders, *ayurveda*, *abhaya ghrita*, indian scale for assessment of autism

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Introduction

Autism is a developmental disorder which is characterized by impaired social communication, interaction, stereotypic behaviors and restricted interests. Signs and symptoms of Autism are still unclear.¹ Autism spectrum disorders (ASD) is a syndrome which manifests during early childhood. The characteristic features of ASD include abnormal or unreciprocated interpersonal & emotional interactions, disturbed language & communication, and repetitive & stereotypic behavior.² Global prevalence of ASD ranges from 0.07% to 1.8%. In India prevalence rate of ASD is 1.2%. Male gender and upper socio economic status had a higher risk of Autism.³ There is a little evidence of any 'cure' for Autism.⁴ Parents of autistic children mostly prefer alternative therapies for improving developmental progression in language skills and social interactions. People often turn to 'Complementary and alternative medicine' (CAM) when they have a chronic problem that conventional medicine hasn't cured. Certain treatments, diets, behavioral therapies, herbal remedies have shown promising effects on autism patients.⁵

Description regarding Autism is not available in the classical texts of *Ayurveda*, only scattered information about Autism like conditions is available.⁶ Autism and other disorders with autistic features fall under the category of 'Unmada' (psychosis). *Unmada* is characterized by the impairment of *Manas* (mind), *Buddhi* (cognitive functions), *Samgna gnana* (perception), *Bhakti* (desire/interests), *Sheela* (character / personality), *Cheshta* (motor activities) and *Achara* (conduct).⁷ Although outcome for adults with autism has improved, many of them remain highly dependent on others for support. Majority of the children treated for Autism have shown 'poor' (46%) and 'very poor' (12%) outcome.⁸

In present study, "Abhaya ghrita" was selected for treating Autistic disorder (AD). This formulation has been mentioned in '*Kashyapa samhita*'⁹ and '*Ashtanga hridaya*'.¹⁰ *Abhaya ghrita* contains six herbs,

Brahmi (*Bacopa monnieri*), *Siddharthaka* (*Brassica compestris*), *Kushta* (*Saussurea lappa* Clarke), *Vacha* (*Acorus calamus* Linn), *Sariva* (*Hemidesmus indicus*), *Pippali* (*Piper longum* Linn) and *Saindhava lavana* (salt). *Abhaya ghrita* improves speech, vocabulary, language, cognitive functions, memory, intelligence and vision.^{9,10}

Materials and methods

Aim & objective

To evaluate the efficacy of 'Abhaya ghrita' in the management of AD.

Study design

An open label pilot study

Selection of subjects

Total 10 subjects were recruited by following simple random sampling from the OPD (out-patient department) of 'Parul *Ayurveda* hospital'.

Inclusion criteria

Subjects who have fulfilled the 'DSM-IV TR' (Diagnostic and statistical manual of mental disorders, 4th edition, text revision) diagnostic criteria of 'Autistic disorder' (299.00)¹¹ were included in the present study. Subjects belongs to the age group 5–12 years were only included.

Exclusion criteria

Subjects who had history of head injury, major systemic illness and who have been taking psychotropic medicines were excluded in the present study. Children who suffered with any other major neurological or psychiatric pathology were also excluded.

Laboratory investigations

Hematological, biochemical and radiological investigations have been carried out according to the necessity to exclude organic pathology in suspected cases only. If any abnormalities found in investigation reports those patients were excluded from the study. In present study no patient is excluded in such a manner.

Ethical clearance

Ethical clearance was obtained from 'Institutional Ethics Committee (IEC)' of Parul Institute of Ayurveda, Parul University (vide ref-PIA/IECHR/2015-16/KB/010 dated 22/10/2016).

Registration

This study is registered in 'Clinical Trial Registry of India (CTRI)' (vide CTRI/2017/05/008454).

Informed consent

An informed written consent was obtained from the parents or guardians of children. The consent form was prepared in accordance with the guidelines of 'World health organization' (WHO)-Research Ethics Review Committee (ERC). The informed consent form used in the present study has two parts: Patient information sheet (included subjects receive a copy) and a certificate of consent (signed by the parents or care taker).

Assessment criteria

Total three assessments were taken, before treatment (1st day), after treatment (90th day) and after follow up (120th day) by using the 'Indian scale for assessment of Autism' (ISAA). ISAA is an objective assessment tool for person with autism and it consists of 40 items rated on 5 point scale ranging from 1 (never) to 5 (always). The 40 items of ISAA are divided under six domains, 'social relationship and reciprocity', 'emotional responsiveness', 'speech, language and communication', 'behavioral patterns', 'sensory aspects' and 'cognitive component'. ISAA score less than 70 is considered as 'normal', 70-106 (mild autism), 107-153 (moderate autism) and score of above 153 is considered as 'severe autism'.¹²

Intervention

Abhaya ghrita was prescribed with the dose of 5-10ml (exact dose was calculated by using 'Young's rule'), twice a day, orally before food for the period of 90 days. Follow up period was kept for 30days after completion of the treatment period.

Statistical analysis

Statistical analysis was done by using "student's paired t-test". Raw data was subjected to statistical analysis in terms of mean difference, standard deviation, standard error, paired 't' test etc. Statistically significance level was kept at, $p < 0.05$.

Observations

In present study total 10 subjects ($n=10$) were recruited and all of them successfully completed the protocol. In present study, 80% subjects were female, 70% subjects belongs to 9-12yrs of age group, all subjects belongs to 'Hindu' religion, 60% were from above poverty line, 80% subjects were from rural area, 60% subjects were from joint family and 90% of parents of the subjects were educated up to higher secondary. Present study showed that 60% parents of the subjects were

'supportive' and have shown 'positive parenting attitude' towards Autistic child. Among parents of Autistic children, 40% were 'over protective', 40% were 'lax in discipline', 10% were 'abusive' and 40% of the parents had alcohol addiction. Out of 10 subjects, 40% of the subjects had shown positive family history for AD and almost all the subjects were suffering from delayed developmental milestones. Only 30% of the subjects were going to Special school.

Out of 10 subjects, 40% of mothers of the AD children had positive ante-natal birth history like anemia, fever, preeclampsia and 40% had positive post-natal history like lower segment cesarean section (LSCS), fetal distress and low birth weight. Almost all the subjects have shown impaired peer relation and learning disorder; only 20% of the subjects were actively participated in school activities, 30% of AD children have shown special interest in singing, drawing etc. Rigid, stereotypic behavior and fixed food habits were found in 60% of the subjects. Present study has shown that almost all the subjects were suffering from impaired social interaction, impairment in communication and impaired peer relation.

Results

Maximum relief, i.e. 16% ($P < 0.005$) found in 'remains aloof' feature which belongs to the 'social relationship and reciprocity' domain. In 'emotional responsiveness' domain maximum relief, i.e. 13.7% ($P < 0.03$) was found in 'shows inappropriate emotional response' feature. In 'speech-language and communication' domain maximum relief, i.e. 19.4% ($P < 0.03$) was found in 'echolalic speech'. In 'behavioral patterns' domain, maximum relief, i.e. 16.1% ($P < 0.01$) was found in 'insists on sameness' feature. In 'sensory aspect' & 'cognitive components' domain, maximum relief, i.e. 18.1% ($P < 0.005$) was found in 'show delay in responding' feature.

Maximum relief, i.e. 13.08% ($P < 0.001$) found in 'sensory aspects' and 'cognitive components' of ISAA followed by 'emotional responsiveness' 10.52% ($P < 0.013$) and 'social relationship & reciprocity' 9.35% ($P < 0.001$) (Table 1). Similar findings were observed after completion of follow up period also (Table 1). Overall relief on total score of ISAA after treatment was 10.69% ($P < 0.001$) and after follow up also similar findings were observed (Table 2). Overall effect of therapy based on ISAA scoring has revealed that only in 20% of the subjects mild improvement (25-50% of score reduction in ISAA) was found. Maximum number of the subjects (80%) didn't get satisfactory relief (<25% of score reduction in ISAA).

Discussion

ASD is a spectrum which includes profound mental retardation and impaired speech as well as communication. ASD is a neuro-developmental syndrome characterized by deficits in social reciprocity & communication, and by abnormal, restricted & stereotypic behaviors.¹² Most of the children with Autism have remained highly dependent on their families or other support services during adulthood. Impaired communication, poor reading, spelling abilities and stereotyped behaviors or rigid interests frequently persisted into adulthood.⁸ Autism can be managed effectively through the rational utility of certain *Ayurvedic* drugs and procedures.⁷ '*Abhaya ghrita*' is mentioned in '*Lehyadhyaya*' of '*Kashyapa samhita*' and '*Baalopacharniya adhyaya*' of '*Ashtanga hridaya*'.^{9,10} It is indicated for improving various cognitive functions, memory, intelligence, speech and language skills, and vocabulary. Based on these reasons *Abhaya ghrita* was selected to treat Autism in present study.

Abhaya ghrita contains various herbs which are well documented for treating various psychiatric conditions. *Kushta* has the properties like, *vedanasthapana* (analgesic), *rakshoghna* (protective/enhancing immunity), *vajikarana* (tonic/aphrodisiac), *avasada hara* (anti-depressant) and *aksheepashamaka* (anti-convulsant); it has been found useful in treating various psychosomatic disorders. *Vacha* has shown the properties like, *medhya* (intellect promoting), *shamaka* (depressant), *vedanasthapana* and *aksheepashamana*. It is used as a sedative, anxiolytic, tranquilizer and rejuvenator. *Vacha* is also used to reduce fatigue and to improve memory. *Vacha* has memory enhancing and behavior modifying properties. *Vacha* also improves learning performance.¹³ *Brahmi* has shown properties like, anxiolytic, anti-depressant, muscle relaxant, anti stress adaptogen, *medhya rasayana* (neutraceutical) and *unmada hara* (anti psychotic). *Pippali* is having *deepana* (stomachic) and *paachana* (digestant) properties which improves the drug absorption and bioavailability.¹⁴ In present study *Abhaya ghrita* has not provided satisfactory relief. After treatment period on total score of ISAA, only 10.69% relief ($P < 0.001$) was observed.

Reasons for limited efficacy

Duration of treatment in the present study was three months. Previous studies on *Ayurvedic* management of Autism have suggested long term intervention.⁶ We suggest that future studies should consider longer duration (more than 3months). The prognosis of Autism for everyday life adaptation is extremely variable.¹ Individuals with Autism, who has shown childhood performance IQ (intelligence quotient) of at least 70 had a significantly better outcome than those with an IQ level below this. IQ proved to be consistent prognostic indicator in Autism.⁸ In present study all the patients (100%) had history of delayed milestones, which may be one of the causes for poor outcome. Treatment in the early years can play a significant role in enhancing functioning in later life in Autism children.⁴ Most of the subjects (70%) in present study belong to 9-12years age group which indicates chronicity of the condition and also late intervention. Chronicity and late intervention might be the underlying factors for poor outcome in present study. By considering the above facts it seems that, shorter duration of treatment, low IQ and/or delayed milestones, chronicity, late intervention, comorbid conditions and lack of special education etc factors all together might have influenced the outcome in present study.

Conclusion

'*Abhaya ghrita*' has shown limited efficacy in the management of 'Autistic disorder'.

Acknowledgments

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Conflict of interest

Author declares there is no conflict of interest.

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