Original Article

Improvement of balance in progressive degenerative cerebellar ataxias after *Ayurvedic* therapy: A preliminary report

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Abstract

Background: The treatment options for improving the balance in degenerative cerebellar ataxias are very few. *Ayurvedic* texts have described diverse treatment regimens for this disease. **Aims:** To determine the change in balance indices, if any, by dynamic posturography (Biodex Balance System, USA) in progressive cerebellar ataxia following *Ayurvedic* treatment. **Materials and Methods:** We performed a preliminary open labelled study on ten patients diagnosed with progressive cerebellar ataxia. The patients were treated over a period of one month. Treatment consisted of *Shirobasti* (therapeutic retention of medicament over the scalp) in male patients and *Shirodhara* (pouring of a steady stream of medicament on the forehead) in female patients with *Dhanvantaram tailam* (medicated oil) for 45 minutes daily, followed by *Abhyanga* (methodical massage) with *Dhanvantaram tailam* and *Bhashpa sweda* (steam bath), for 14 days. In addition, the treatment also consisted *Abhyantara aushadha* (oral medicines) of *Maharasnadi kashayam* 15 ml thrice daily, *Dhanvantaram capsules 101* two capsules thrice daily, and *Ashwagandha* tablet 500 mg one tablet thrice daily, for one month. The patients were assessed on the Biodex balance system before and after the treatment. Results were analyzed using paired samples '*t*' test. **Results:** All patients tolerated the treatment well without any adverse events and reported subjective improvement in walking. There was a statistically significant improvement in the overall and anteroposterior balance indices of dynamic stability. **Conclusions:** Over the short period of the present study, *Ayurvedic* therapy was found to be safe and, showed improvement in the balance in patients with progressive degenerative cerebellar ataxia. Further randomized placebo-control double-blind studies are needed to validate the results.

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Introduction

Comprehensive treatment of progressive cerebellar ataxias has remained elusive to a large extent. There is as yet no approved drugs or disease-modifying therapies for this problem[1] and till date, there is no documented Allopathic treatment effective for cerebellar ataxias. *Ayurveda* describes this condition as *kaphavrita vyana vata* (occlusion of *vyana vata* by *kapha dosha*) under *vata vyadhi* (neurological diseases)[2] and specific treatment regimens[2-6] have been described to combat the various symptoms seen in the course of the disease. The aim of this study was to objectively assess the improvement in balance in progressive degenerative cerebellar ataxias following one such mode of treatment.

Materials and Methods

Design and participants

This study was conducted at the Ayurvedic Research Unit at our institute. The *Ayurvedic* treatments used in the present study are in practice in India for many years. The treatment protocol involved administration of *Ashwagandha* tablet, *Dhanvantaram tailam*, and *Maharasnadi*

kashayam, which are routinely used substances in various *vata* disorders in *Ayurveda*. These medicines are *vatahara*, that is, for alleviating neurological disorders that are considered as *vata* disorders in *Ayurveda* and they are also used as *balya* and *pushtiprada*, meant for any degenerative disorders. The therapeutic regimen of *abhyanga* (massage), *svedana* (sudation), *shirobasti*, and *shirodhara* (specific treatments for the head) are routinely used in neurological disorders. Considering the above facts, the institutional ethical clearance was not sought for this study. Only those patients who verbally consented to receive this form of treatment were considered for the study.

For inclusion in this study, patients with chronic degenerative ataxias in the age group of 12–60 years, who had progressive worsening of symptoms despite various Allopathic treatments and were willing to consider *Ayurvedic* treatment, were recruited. Patients with ataxia secondary to tumor, infection, stroke (ischemia or hemorrhage), demyelination, craniovertebro-junction anomalies, alcohol, hypothyroidism, drugs, pregnancy and postpartum period, renal, hepatic, and significant cardiac dysfunctions, and severe dementia were excluded from the study. Ten patients fulfilled the above inclusion and exclusion criteria and were recruited in the study. A detailed neurological examination of all the patients was performed. Genotyping was performed to determine the CAG repeat lengths.

Intervention

Patients were admitted to the Ayurvedic Research Unit at our institute for a period of one month and *Ayurvedic* treatment was administered, which consisted of the following:

Shirobasti (therapeutic retention of oil over the scalp)

This was done to the male patients for 45 minutes daily, for 14 days.[5] The patients' heads were shaven prior to the treatment program. The patients were made to sit comfortably on a chair. A unique hollow cylindrical container made of leather was placed on the head and the area of the container in contact with the scalp was sealed with a paste of black gram powder to prevent leaking of the oil.[2] Two-and-a-half liters of *Dhanvantaram tailam*[2] was warmed on a water bath to 95–100˚F (depending on the patients' tolerance) and cautiously poured into the container. As the oil became cold, it was removed and replaced with fresh warm oil. The same process was repeated over a 45-minute period, maintaining the temperature of the oil constantly between 95–100˚F.[7]

Shirodhara (pouring of a steady stream of oil on the forehead

This procedure was performed in female patients for 45 minutes daily, for 14 days.[5] The patients were made to lie supine on the *Dhara* table (customized unique table) and the eyes were covered with gauze to prevent oil dripping into the eyes. Two-and-a-half liters of *Dhanvantaram tailam* was warmed up to 95–100°F on a water bath and taken in the *Dhara patra* (special vessel with a small hole in the center). A steady stream of the oil was made to fall on the forehead of the patient from a height of three inches. As the oil dripped on to the table, it was collected in a vessel kept underneath the table and reheated. This warm oil was again poured into the *Dhara patra*. Care was taken to ensure a continuous flow of oil.[7]

Abhyanga (massage)

After *Shirodhara* and *Shirobasti*, *Abhyanga* (methodical massage)[7] of the entire body was performed with *Dhanvantaram tailam*.

Svedana (sudation)

Bhashpa sveda variety of *Svedana* was done. The patient was made to sit in a *Bhashpa svedana yantra* (customized wooden box)[7] into which warm vapors were passed. This induced perspiration in the patient. This was continued for 10–15 minutes depending on the patient's tolerance level.

Abhyantara aushadha (oral medicines)

All the patients were administered the following internal medicines for one month.

- *Dhanvantaram capsules*[2] *101* (2 ml): Two capsules t.i.d.
- *Ashwagandha tablet*[6] 500 mg: One tablet t.i.d.
- *Maharasnadi kashayam*:[4] 15 ml t.i.d.

Medicines were procured from The Indian Medical Practitioners Cooperative Pharmacy and Stores Ltd., Chennai, India.

The details of the ingredients of the above *Ayurvedic* preparations are given in the Appendix.

Outcome measures

The study endpoints assessed and analyzed for each patient consisted of objective testing of balance using dynamic posturography (Biodex Balance System (BBS), USA). Patients were tested for dynamic stability and limits of stability (LOS) before and after the treatment by the same coinvestigator in this study. LOS is defined as the area which the subject safely moves without changing the base of support. To test LOS, the patients were asked to shift their center of mass without changing foot position into eight targets positioned in an ellipse, the perimeter of which corresponded to 50% of the LOS. The direction of the target was indicated on the screen by a blinking target which appeared at random

in different directions, each target being selected only once. The maximum movement time allowed was 300 seconds. Postural sway was recorded and the area of sway calculated and expressed as percentage of the patients' LOS. The balance indices which included the overall balance index (OBI), anteroposterior index (API), and mediolateral index (MLI), and the LOS scores as computed and given by the system were collected and used for further analysis.

Statistical analysis

Results were analyzed using paired samples '*t*' test.

Results

There were three women and seven men who participated in the study (mean (SD) age: 24.2 years (9.4), height: 162.6 cm (9.8), and weight: 47.0 kg (7.5)). The mean age at onset of illness was 19.9 ± 10.6 years and the duration of illness 4.4 ± 3.8 years. Genotyping confirmed a diagnosis of SCA1 and SCA2 in two patients each, SCA3 in one patient, and the remaining five patients were negative for SCA1, SCA2, and SCA3. All the patients were able to complete the treatment and no one had any adverse events.

Prior to the treatment, all ten patients had abnormal balance indices. Sixty percent of the patients had abnormal OBI and API, 20% had abnormality of only OBI, 10% had abnormalities of OBI and MLI, and in the rest 10% all the balance indices were abnormal. After the treatment, 40% of the patients had normal balance indices, 30% had abnormal OBI and API, 20% showed abnormality in all indices, and 10% had only OBI abnormality. Figures 1a-1c shows the actual values of all the balance indices of each patient before and after treatment. There was a statistically significant improvement in the mean values of OBI and API balance indices (P = 0.007, P = 0.047, respectively), but not of MLI [Figure 1d].

Prior to the treatment, eight patients were able to complete the LOS test in the stipulated time. The two patients who were unable to complete the LOS test before treatment were able to do so after the treatment. However, one

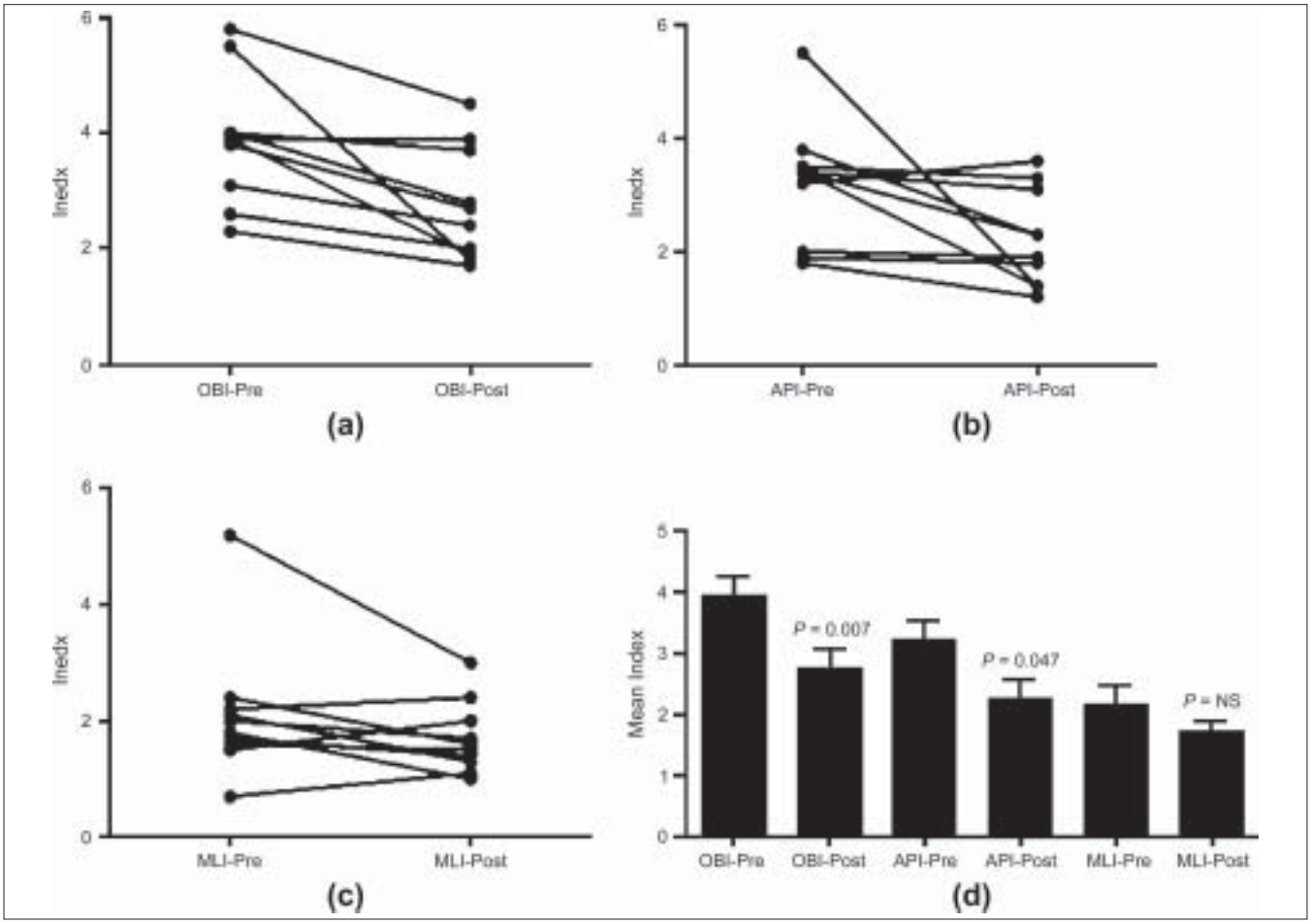

Figure 1: (a) Improvement in overall balance index (OBI) of individual patients following *Ayurvedic* treatment; (b) Improvement in anteroposterior index (API) of individual patients following *Ayurvedic* treatment; (c) Mediolateral index (MLI) before and after *Ayurvedic* treatment; (d) Mean values of OBI, API, and MLI before and after treatment

patient who was able to perform the assessment before treatment was unable to do so following the treatment. The mean time taken for completing the test reduced from 237.6 ± 59.7 seconds to 215.7 ± 85.0 seconds. However, there was statistically no significant change in any of the parameters of LOS following treatment.

Discussion

In this study, we have reported our preliminary observations of the effect of *Ayurvedic* treatment in patients with degenerative cerebellar ataxia. Though molecular genetic research has completely revolutionized the way in which the progressive cerebellar ataxias are classified and diagnosed, it is yet to produce effective gene-based, neuroprotective, or neurorestorative therapies.[8] With due acknowledgement of the limitations of open-label study on a small heterogeneous group of progressive degenerative ataxias, we report encouraging observations in treatment of this debilitating disorder for which there is no effective therapy till date. Though *Ayurvedic* treatment has been reported to be effective in other neurodegenerative conditions, such as Parkinson's disease,[9] to the best of our knowledge, there are no reports of similar beneficial treatment in progressive degenerative cerebellar ataxias.

Dynamic posturography and BBS have been validated in earlier studies.[10-12] In our study, there was an objective improvement in balance after one month of *Ayurvedic* therapy. While before treatment all the patients had one or more abnormal balance indices, following treatment, 40% of patients showed normal balance indices (all three). The mean values of OBI and API also significantly improved after treatment. The MLI was normal in eight patients prior to the treatment. In the remaining two patients, the mean MLI improved after treatment (3.8 ± 1.98 to 2.3 ± 0.99). On the contrary, we did not observe any significant change in the LOS parameters.

Ayurveda stresses on a holistic approach to diseases, and hence, treatment is aimed at both the *dosha* (causal factor) and the *vyadhi* (disease). The *Ayurvedic* treatment administered in the present study is also on similar lines. Predicting the exact mode of action of the treatment is not feasible due to the complexity of the treatment regimen. However, a hypothesis on the possible mode of action has been postulated based on the descriptions in *Ayurvedic* classics and existing literature on these therapies.[13-21]

Shirodhara, *Shirobasti*, *Abhyanga*, and *Svedana* are *balya* (promote strength) and *vatahara* (pacify morbid *vata*). *Svedana* also aids *kaphaharana* (pacifies morbid *kapha*). This promotes *samprapti vighattana* (undoing the pathogenesis) and plays a crucial role in bringing about the desired result. Therapeutic oil massage is known to promote growth and development in neonates via transcutaneous absorption of the nutrients.[13-15] These therapies enhance muscle power and thus may have contributed to the improved performance in the balance parameters. Oxidative stress plays a vital role in the pathogenesis of such degenerative disorders of the brain.[16] Thermal therapy is known to enhance antioxidant functions such as the activities of superoxidase dismutase.[17] Hence, *Svedana* procedure may also have facilitated a similar action. *Shirodhara* has been shown to have anxiolytic, sympatholytic, and immunopotentient effects on patients of anxiety.[18,19] A possible reduction in the anxiety coupled with other effects may have resulted in better performance. *Ashvagandha (Withania somnifera Linn.)*, *Bala (Sida cordifolia Linn.)*, and other ingredients in *Maharasnadi kashayam* are known antioxidants,[20] and thus may contribute to prevent and/or revert the pathogenesis. *Bala* is also the chief ingredient of *Dhanvantaram tailam*. Krishnamurthy and Telles reported improvement in the mobility, as assessed by timed up and go (TUG) test in older people (60–95 years), after treatment with a polyherbal formulation containing *Ashwagandha* and *Bala*.[21] The authors attributed this to a possible improvement in the muscle strength, similar to that reported in *Ayurvedic* classics.

In summary, the present study is a preliminary report of the objective evaluation of the efficacy of *Ayurvedic* therapy in improving balance. The results are encouraging and warrant further structured studies to objectively assess the efficacy of different modalities of *Ayurvedic* treatment in degenerative ataxias where till date contemporary medicines do not have much to offer.

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Appendix: List of ingredients

Dhanvantaram tailam[2]

Sanskrit name	Latin name	Sanskrit name	Latin name
Bala	*Sida cordifolia Linn.*	*Sariva*	*Hemedismus indicus L.*
Ksheera	Milk	*Kushta*	*Saussurea lappa C.B.Cl*
Yava	*Hordeum vulgare Linn.*	*Tagara*	*Valeriana wallichii DC*
Kola	*Zizyphus jujuba*	*Saindhava*	*Rock salt*
Kulattha	*Dolichos biflorus Lamk.*	*Shaileya*	*Parmelia perlata*
Shalaparni	*Desmodium gangeticum Linn.*	*Vacha*	*Acorus calamus Linn.*
Prishnaparni	*Uraria picta Sesv.*	*Aguru*	*Aqualaria agallocha Roxb.*
Brihati	*Solanum indicum Linn.*	*Punarnava*	*Boerhavia diffusa Linn.*
Gokshura	*Tribulus terristris Linn.*	*Ashvagandha*	*Withania somnifera Linn.*
Kantakari	*Solanum xanthocarpum Linn.*	*Vari*	*Cyperus rotundus Linn.*
Shonaka	*Oroxylum indicum Linn.*	*Kshirashukla*	*Ipomea digitata Linn.*
Kashmari	*Gmelina arborea*	*Yashti*	*Glycerrhiza glabra Linn.*
Patala	*Stereospermum suaveleons DC.*	*Haritaki*	*Terminalia chebula Retz. and Willd*
Bilva	*Aegle marmelos Linn.*	*Vibhitaki*	*Terminalia bellerica Roxb.*
Agnimantha	*Premna integrifolia Linn.*	*Amalaki*	*Phyllanthus emblica Linn.*
Meda, Mahameda substituted with Shatavari	*Asperagus racemosus Willd.*	*Shatahva*	*Anethum sowa Kurz.*
Jivaka, Rishabhaka substituted with Vidari	*Pueraria tuberosa DC*	*Shurpaparni*	*Phaseoulus trilobus Ait.*
Daru	Berberis aristata DC.	*Tvak*	*Cinnamomum zeylanicum Blume*
Manjishta	*Rubia cordifolia Linn.*	*Ela*	*Eletteria cardamomum Linn.*
Kakoli, Kshirakakoli substituted with Ashwagandha	*Withania somnifera Linn.*	*Patra*	*Cinnamomum tamala Nees and Ebum*
Chandana	*Santalum album Linn.*	*Tila taila*	*Oil of Sesamum indicum Linn.*

Dhanvantaram capsules 101[2]

Same oil as above, processed repeatedly for 101 times.

Maharasnadi kashayam[4]

Sanskrit name	Latin name	Sanskrit name	Latin name
Rasna	*Pluchea lancelota Linn.*	*Punarnava*	*Boerhavia diffusa Linn.*
Vatari	*Ricinus communis Linn.*	*Ashwagandha*	*Withania somnifera Linn.*
Vasaka	*Adhatoda vasica Nees.*	*Amruta*	*Tinospora cordifolia Willd.*
Duralabha	*Tragia involucrate Linn.*	*Krishna*	*Piper longum Linn.*
Shati	*Kaempferia galanga Linn.*	*Vriddhadaru*	*Argyreia nervosa Burm.f.Boj*
Daruharidra	*Berberis aristata DC.*	*Shatavari*	*Asperagus racemosus Willd.*
Bala	*Sida cordifolia Linn.*	*Vacha*	*Acorus calamus Linn.*
Musta	*Cyperus rotundus Linn.*	*Sahachara*	*Barleria cristata Linn.*
Nagara	*Zingiber officinale Rosc.*	*Chavika*	*Piper chaba W.Hunter*
Ativisha	*Aconitum heterophyllum Well*	*Brihati*	*Solanum indicum Linn.*
Abhaya	*Terminalia chebula Retz. and Willd.*	*Kantakari*	*Solanum xanthocarpum Linn.*
Svadamshtra	*Tribulus terristris Linn.*	*Shunti*	*Zingiber officinale Rosc.*
Vyadhighata	*Garcinica indica Roxb.*	*Alambusha*	*Biophytum sensitivum Linn.*
Misi	*Anethum sowa Kurz.*	*Ajamoda*	*Trachyspermum roxburghianum DC.*
Dhanya	*Coriandrum sativum Linn.*	*Jala*	*Water*

Ashwagandha tablet[6]

Fine powder of *Ashwagandha* (*Withania somnifera Linn.*)