Research Article

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EFFICACY OF BRAHMĪDRĀKṢĀDI KWĀTHA IN MILD COGNITIVE IMPAIRMENT

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ABSTRACT

Mild Cognitive Impairment (MCI) is defined as the onset of cognitive impairment beyond that is expected based on education and age of individual, but which are not significant enough to interfere with their daily activities. It is often found to be a transitional state between normal ageing and that of dementia. It is better to provide intervention at an early stage, as studies concluded that there is maximum chance of the condition, to develop to dementia. Brahmīdrākṣādi Kwātha is an Ayurvedic poly herbal formulation, conventionally practised for treating psychiatric disorders and also diseases affecting cognition such as dementia, mental retardation, cerebral palsy etc. It is reported as effective clinically, but no studies have been reported in this regard. An uncontrolled clinical trial was conducted with 30 participants of the age group 55- 65, whose MMSE score lies between 24 ≥28, a score of 3 on GDS and with intact activities of daily living were selected from the Manassanthi OPD, V.P.S.V. Ayurveda College, Kottakkal. They were administered with 15 ml of Brahmīdrākṣādi Kwātha with 45 ml warm water twice daily at 6am and 7pm continuously for 3 months. Brahmīdrākṣādi Kwātha has statistically significant effect in improving general cognitive functions, executive functions, sensory perception, processing and psychomotor functions after the intervention in MCI

Keywords: Mild cognitive Impairment, Brahmīdrākṣādi Kwātha, rasāyana, srotośodhaka, āvarana, MMSE, GDS

INTRODUCTION

Due to the advancements in the healthcare system, the percentage of the old age community is increasing[1] worldwide and their health problems are becoming an imperative public concern. By 2050, the proportion of the world's older adults is estimated to almost double from about 12% to 22%. The physical and mental health problems of the older adults need to be recognized and among which the neuropsychiatric disorders such as dementia, mild cognitive impairment account for 6.6% of the total disability[2]. As per studies, Cognitive impairment and dementia are increasing globally especially in the developing countries[3].

In mild cognitive impairment (MCI), the cognitive deficit is less severe than that of dementia and the activity of daily living (ADL) are generally preserved. It is thought to be a precursor to dementia in up to one third of cases[4]. The prevalence of MCI is estimated as 3%–42% worldwide[5] and in India it is about 4.3%[6]. Two types of MCI are identified i.e. amnestic mild cognitive impairment (aMCI) and non-amnestic (naMCI) or single domain MCI and multiple domain MCI. Longitudinal studies proved[7, 8] that a number of people with MCI progresses to dementia or severe cognitive impairment, a few proportions reverts to normal, while the majority remain unchanged. Those with MCI progress to dementia in higher proportions than the cognitively normal individuals[9]. The annual conversion rate of MCI to dementia is about 7%, among which memory impairments and impairments in multiple domains lead to greater progression and lesser improvement[10].

Cognitive impairment needs to be tackled in the early point in time, because the condition will progress to dementia, which imposes significant economic burden on the country, families, and individuals. Currently, no drug has proven effective in management of MCI. Clinical trials with cholinesterase inhibitor class drugs like donepezil, rivastigmine, galantamine and rofecoxib were conducted. None have demonstrated convincing effects in delaying longer term disease progression or conversion to dementia[11]. Even though they are useful in MCI, adverse effects such as Gastrointestinal disturbances, insomnia, convulsions, bradycardia and even death were reported in post marketing surveillance[12].

Background of study

Last two decades witnessed enhance in number of people using complementary and alternative medicine all over, especially Ayurveda[13]. In the classical textbooks of Ayurveda, there are vast mentioning of measures and modalities for successful aging. The drugs either mentioned as Medhya rasāyanas specifically or other having Medhya activity can be potentially used for prevention and management of age related cognitive decline. The drugs like Mandūkparnī (*Centella asiatica)*, Śankhapuṣpī (*Convolvulus pluricaulis*), Gudūchī (*Tinospora cordifolia*) and Yaṣhtimadhu (*Glycyrrhiza glabra*) are known as Medhya rasāyanas, which directly enhances the cognition[14,15]. A few combinations are clinically proved to be promoting cognition (Medhā*)* by practice. One among them in practise is Brahmīdrākshādi Kwātha.

Brahmīdrākṣādi Kwātha is an Āyurvedic polyherbal combination explained in Sahasrayoga jwarādhikara which is exclusively used for treating manasroga, conditions affecting cognition such as dementia, cerebral palsy, ADHD, mental retardation etc in clinical practice but there are no studies reported in this regard. It is Vātahara and cures pain and burning sensation[16]. Clinical Studies conducted with Medhya rasāyanas such as Madhuyaṣti,

Gudūchī in Mild Cognitive Impairment were found to be effective[17, 18].

METHODOLOGY

The protocol was approved by Research Committee and Institutional Ethics Committee (IEC) prior to the commencement. (Approval No: IEC/ doc/13/15; dated 24- 04-2017)

Aim

- To provide a better Ayurvedic management for Mild Cognitive Impairment.
- To improve the quality of life of those affected with Mild Cognitive Impairment.

Objective

To assess the efficacy of Brahmīdrākṣādi Kwātha in Mild Cognitive Impairment.

Materials and methods

Study design: Uncontrolled Clinical Trial
Period of study: 18 months
Sample size: 30
Setting: Manassanthi OPD, VPSV Ayurveda College, Kottakkal

Inclusion criteria

Participants with age group 50 - 65 years, score $\geq$ 24 - 28 in Mini Mental Status Examination (MMSE), score 3 on Global Deterioration Scale (GDS) with intact activity of daily living and having given written consent were included.

Exclusion criteria

In the trial, subjects with cognitive impairment due to head injury, stroke, dementia, cardiac problems were excluded. Those using psychoactive substance, anticonvulsant, psychiatric medication, cognitive enhancers, and thyroid drugs were not included.

Methodology

The drug was purchased from a GMP certified company with batch number 515108**.** Participants were advised to take 15 ml of Brahmīdrākṣādi Kwātha with 45ml warm water at 6am and 7pm daily 1 hour before food, continuously for 3 months.

ASSESSMENT CRITERIA

- Modified Mini Mental State Examination
- Six letter cancellation test
- Digit letter substitution test
- Clock drawing test
- Outcome measure for people with mild cognitive impairment

DATA COLLECTION AND ANALYSIS

Assessment was done at the end of every month till 3 months and a follow up assessment at the end of fourth month. Repeated measures ANOVA were performed to assess difference between observations at various levels of intervention and after one month follow up. Sidak test was done to perform multiple comparisons. Statistical analysis was done by using Microsoft Office 2007 Excel and SPSS Statistics version 16.0.

RESULT

Brahmīdrākṣādi Kwātha has statistically significant effect on total score of 3MS examination, which suggesting the improvement in overall cognitive function. The statistically significant effect on scores of Six Letter Cancellation Test (SLCT) and Digit Letter Substitution Test (DLST), suggests that there was an improvement in sensory perception, processing and psychomotor functions. Brahmīdrākṣādi Kwātha has statistically significant effect on Clock Drawing Test which suggests the improvement in executive function. It has statistically significant effect on improving the Quality of Life (QoL) in Mild Cognitive Impairment.

Effect of Therapy on Various scales by Repeated Measures ANOVA (RM ANOVA)

Table 1: Effect of Therapy on Various scales

Scale	F value	P value
Modified Mini Mental Status (3MS)	6.8	< 0.001
Clock Drawing Test (CDT)	114.81	< 0.001
Six Letter Cancellation test (SLCT)	110.721	< 0.001
Digit Letter Substitution Test (DLST)	56.197	< 0.001

Table 2: Sidak test for Multiple Comparison on of effect on Modified Mini Mental Status (3MS)

Pairs	Mean difference	S.E	P value
BT vs AT1	-9.1	0.85	< 0.001
BT vs AT2	-11.9	0.83	< 0.001
BT vs AT3	-12.5	1.05	< 0.001
BT vs AF	-8.7	1.16	< 0.001
AT1 vs AT2	-2.7	0.62	< 0.01
AT1 vs AT3	-3.4	0.86	< 0.01
AT1 vs AF	0.4	1.16	>0.05
AT2 vs AT3	-0.7	0.57	>0.05
AT2 vs AF	3.1	1.04	>0.05
AT3 vs AF	3.8	1.01	<0.01

BT= Before treatment, AF= After follow up, AT1=After treatment first assessment, AT2=After treatment second assessment, AT3= after treatment 3rd assessment

Table 3: Sidak test for Multiple Comparison on of effect on Clock Drawing Test (CDT)

Pairs	Mean difference	S.E	P value
BT vs AT1	0.43	0.2	> 0.05
BT vs AT2	0.60	0.2	< 0.05
BT vs AT3	0.90	0.2	< 0.001
BT vs AF	0.97	0.2	< 0.001
AT1 vs AT2	0.17	0.1	0.05
AT1 vs AT3	0.47	0.1	< 0.01
AT1 vs AF	0.53	0.1	< 0.001
AT2 vs AT3	0.30	0.1	< 0.05
AT2 vs AF	0.37	0.1	< 0.05
AT3 vs AF	0.07	0.1	> 0.05

Table 4: Sidak test for Multiple Comparison on of effect on Six Letter Cancellation test (SLCT)

Pairs	Mean difference	S.E	P value
BT vs AT1	-1.4	1.4	< 0.05
BT vs AT2	-5.2	1.4	< 0.05
BT vs AT3	-6.2	1.8	.< 0.05
BT vs AF	-2.3	1.2	> 0.05
AT1 vs AT2	-3.8	0.8	< 0.001
AT1 vs AT3	-4.8	1.3	> 0.05
AT1 vs AF	-0.9	1.5	> 0.05
AT2 vs AT3	-1.0	1.0	> 0.05
AT2 vs AF	2.9	1.3	> 0.05
AT3 vs AF	3.9	1.5	> 0.05

Table 5: Sidak test for Multiple Comparison on of effect on Digit Letter Substitution Test (DLST)

	Mean difference	S.E	P value
BT vs AT1	-4.17	1.5	> 0.05
BT vs AT2	-6.57	1.5	< 0.01
BT vs AT3	-9.03	1.8	< 0.001
BT vs AF	-4.33	1.2	<0.05
AT1 vs AT2	-2.40	1.0	>0.05
AT1 vs AT3	-4.87	1.2	< 0.01
AT1 vs AF	-.167	1.2	> 0.05
AT2 vs AT3	**-2.47**	**0.9**	**> 0.05**
AT2 vs AF	**2.23**	**1.2**	**> 0.05**
AT3 vs AF	**4.70**	**1.2**	**< 0.01**

Table 6: Effect of therapy on Practical Domain of Quality of life (QOL) Questionnaire

Source of variation	Sum of Squares	Df	Mean sum of square	F value	P value
Between assessments	12484.444	1	29.180	427.841	< 0.001

Table 7: Sidak test for Multiple Comparison on of effect on Practical Domain of Quality of life (QOL)

Pairs	Mean difference	S.E	P value
0^{th} (BT) vs 90^{th} (AT)	**4.0**	**0.3**	**< 0.001**
0^{th} (BT) vs 120^{th}(AF)	**6.7**	**0.5**	**< 0.001**
90^{th} (AT) vs 120^{th}(AF)	**-2.7**	**0.3**	**< 0.001**

BT= Before treatment, AF=After follow up, AT=After treatment

Table 8: Effect of therapy on Emotional Domain of Quality of life (QOL) Questionnaire

Source of variation	Sum of Squares	Df	Mean Sum of square	F value	P value
Between assessments	13813.61	1	43.72	315.91	< 0.001

Table 9: Sidak test for Multiple Comparison on of effect on Emotional Domain of Quality of life (QOL) Questionnaire

Pairs	Mean difference	S.E	P value
0^{th} (BT) vs 90^{th} (AT)	3.6	0.5	<0.001
0^{th} (BT) vs 120^{th}(AF)	5.3	0.5	<0.001
90^{th} (AT) vs 120^{th}(AF)	1.6	0.5	<0.001

Table 10: Percentage relief on various scales

Scales	% of Relief	
	After intervention	After follow up
3MSE	16.78%	11.71%
CDT	32.14%	34.27%
SLCT	26.92%	10.11%
DLST	46%	22.10%

DISCUSSION

This study verified that internal administration of Brahmīdrākṣhadi Kwātha for a period of 3 months improved cognitive performance in subjects with MCI.

Effect of Therapy on Modified Mini-Mental State (3MS)

3MS is a modified version of the Mini-Mental State (MMS) examination, a screening test for dementia. The 3MS is designed to sample a broader variety of cognitive functions, cover a wide range of difficulty levels, and enhance reliability and validity in order to sample a broader variety of cognitive functions, cover a wider range of difficulty levels, and enhance the reliability and validity of the test scores. 3MS test has a score range of 1–100. It provides an estimated score of the MMSE and can also be used to monitor cognitive change over time. Studies have proved the usefulness of the 3MS test in both research and clinical studies[18].

The primary cognitive outcome 3MS Examination showed a significant improvement noticed after first month intervention sustained till three months and was not maintained as such in the follow up. This is in accordance with a previous study of Gudūci satva[19] in which improvement was observed at 4 weeks. In a recent study, the relation between change in 3MS score and clinically noticeable changes has been explored in community-dwelling elderly people. A change equal to 1 or more than 1 point in 3MS score was clinically detectable[20]. It is inconsistent with a study conducted by P Newhouse et al. which observed improvement in primary cognitive out come only after 3 months of intervention[21].

Effect of Therapy on Clock Drawing Test (CDT)

CDT is a simple tool that is used in the assessment and monitoring of progressive dementia in the community. It is often used in combination with other screening tool, but even when used by itself; it provides helpful insight to person's cognitive ability[22]. It is useful in detecting problems in executive functioning even when someone scores well on the 3MSE. Executive functioning can be impaired before any memory problems are evident in the case of non- amnestic MCI (naMCI)[23]. .

There were trends for improvement in the CDT during intervention. The change that observed only after 2 months of intervention, gradually increased and at the time of follow up the changes sustained. It is quite different from the study conducted by Avinash *et al* in 2014 which didn't detect any change in executive functions on assessment by CDT[18]. In present study change in executive function maintained at the time of follow up. It is positive with a study conducted by Owns worth et al[24] stating that improvement in executive functions were maintained at 6 months.

Effect of Therapy on Six Letter Cancellation Test (SLCT)

Six letter cancellation test (SLCT) is a psychomotor function test in which perceptual processing of sensory information can be readily assessed[25]. The letter cancellation task provided a measure of speed of information processing speed. The measure was the number of letters searched during the specified time. This is a test of attention, visual search and mental speed[26]. In those with MCI, psychomotor slowing specially for choice reaction time is noted[27]. In the present study effect of intervention in psychomotor speed assessed by SLCT, changes were observed after 2 months of intervention and sustained till 3 months of therapy but was not maintained on follow up. It is in not in accordance with study on the effect of nicotine in MCI, which got improvement on SLCT by 3 months[21]. In a preventive trial on Progression of MCI by Guduchi Satva, it was observed that changes in psychomotor speed was attained by SLCT with one month of therapy[18].

Effect of Therapy on Digit Letter Substitution Test (DLST)

The Digit Letter Substitution Test (DLST) can be used in clinical or research setting when information processing speed is to be measured. The simple responses generated in substitution tests depend on the integration of complex neuropsychological processes, including visual scanning, mental flexibility, sustained attention, psychomotor speed, and speed of information processing[28]. The speed of information processing assessed by DLST, gives an idea about the tendency of improvement. Alterations in DLST were identified after 2 months of intervention and gradually increased till the 3rd month but didn't sustain on follow up. In a study conducted by Avinash et al[18], change in speed of information was detected by one month of intervention itself.

Effect of Therapy Quality of Life (QOL) of People with MCI

The MCI Questionnaire (MCQ) is a self-report, 13-item PRO (patient reported outcome measures) developed to assess quality of life (QOL) in people with MCI. The MCQ taps into two domains of quality of life, namely Emotional Effects (6 items) and Practical Concerns (7 items). The MCQ has been developed in such a manner that it can be used to assess outcomes following intervention either in pharmacological or in non-pharmacological manner. The domain with practical concern deals with practical difficulties faced by people suffering from MCI. They are conversation, sentence making, memory, psychomotor activity, and dependency. The domain deals with emotional effects had questions on mood, feelings, worries and irritations they are facing[29]. In the trial, significant response was noticed in both domains of QOL from one month itself which was sustained till follow up. It is due to the fact that improvement in cognition definitely reflects in QOL.

Probable mode of action of drug

Brahmīdrākṣādi Kwātha is conventionally used in the management of various diseases affecting cognition, in clinical practice. It alleviates Vātha and *also* cures pain and burning sensation[17]. All the reported cognitive changes are attributed to medhya properties (nootropic activities) of ingredients. Most of the ingredients of Brahmīdrākṣādi Kwātha have nootropic property, anti-cholinesterase, anti-inflammatory, and antioxidant property with ground evidence from several experimental studies.

As MCI is a neurodegenerative disorder, free radicals play a contributory role in its aetio pathogenesis[30]. The herbs that inhibit acetyl cholinesterase (AchE) and rich source of antioxidants are reported as effective for several neurodegenerative diseases. Anti-inflammatory herbs are also potent in the neurodegenerative diseases, by reducing inflammation of the brain tissues[31]. The ingredients such as Brahmī, Drākṣā, Harīthakī and Śatāvarī possess nootropic property. Components like Kāśmarī, Āmalakī, Śāliparṇī Āragwadha, Śuṇṭhī and Vacā have AchE inhibitor property. Āmalakī, Bala, Daśamūla and Vacā are of anti-inflammatory and antioxidant in nature. Vacā and Brahmī are medhya (nootropic). All this contributed to the observed action of the kwatha in MCI.

Brahmīdrākṣādi Kwātha is Vātapittahara (alleviate vata and pitta. It is a combination with ingredients having heterogeneous properties. Medhya drugs (intellect promoting drugs) in this preparation are Vaca and Brahmī. Vyosha is a combination that enhances the bioavailability. Triphala, the most proven rasāyana (rejuvenator) also present in this combination. MCI is condition with altered doshas resulting from the occlusion of the srotas (channels), predominantly Kapha. Drugs having the property to remove occlusion and improves patency in channels (Srotośodhaka), like Triphala and Vyoṣha removes kapha occlusion and thus alleviates and normalises the three doshas, thereby reversing the pathology.

CONCLUSION

Brahmīdrākṣādi Kwātha is effective in Mid Cognitive Impairment and thus hopes to prevent the progression of cognitive decline and to improve QOL in older people. It removes srotorodha (blockage in channels) and normalizes vata, which plays an important role in pathogenesis of MCI. The efficacy can be enhanced with the prior sodhana followed by administration of Medhyarasayanas (herbal intellect rejuvenators), further studies are the need of the hour so as to help the affected.

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