



Research Article

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COMPARATIVE CLINICAL EVALUATION OF AN AYURVEDIC REGIMEN IN THE MANAGEMENT OF SENILE DEMENTIA

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ABSTRACT

An enhanced life expectancy in developed countries has been accompanied by an increased number of people suffering from age-associated dementia. Senile dementia is a syndrome due to disease of the brain, usually of a chronic or progressive nature, in which there is disturbance of multiple higher cortical functions, without any impairment in consciousness. Prevalence rates for senile dementia increase essentially with advancing age. The prevalence rate rises to 54.8% in individuals above 95 years of age. So far, efforts to find a cure for Alzheimer Disease (AD) have been disappointing, and the drugs currently available to treat the disease address only its symptoms and with limited effectiveness. Present study was designed to see the efficacy of Saraswata ghrita along with Shirobasti on Senile dementia. A total number of 34 patients of Senile dementia were recruited by using ICD-10 criteria of Dementia and MMSE scores and randomly divided into two groups. Alzheimer's disease assessment scale (cognitive subscale) has been used to evaluate the clinical condition of the patients of Senile dementia. After completion of treatment Saraswata ghrita along with Shirobasti shows statistically significant results on clinical and neuro-cognitive parameters.

Keywords: Senile dementia, Saraswata ghrita, Shirobasti

INTRODUCTION

An enhanced life expectancy in developed countries has been accompanied by an increased number of people suffering from age-associated Dementia. Senile dementia is a syndrome due to disease of the brain, usually of a chronic or progressive nature, in which there is disturbance of multiple higher cortical functions, including memory, thinking, orientation, comprehension, calculation, learning capacity, language, and judgement without any impairment in consciousness¹. Prevalence rates for Dementia increase essentially with advancing age². Persons above 60 years of age show 0.43% prevalence whereas persons aged above 65 years show 2.44% prevalence. The prevalence rate rises to 54.8% in individuals above 95 years of age³. There is a paucity of modern drugs/agents facilitating acquisition, retention, and retrieval of information and knowledge. Nootropic agents such as piracetam⁴, cholinesterase inhibitors like donepezil are being primarily used to improve memory, mood and behaviour. However, the resulting adverse effects associated with these agents have limited their use^{5,6} and it is worthwhile to explore the utility of traditional medicines in the treatment of various cognitive disorders.

Ayurveda, the Indian system of medicine had developed certain dietary and therapeutic measures to delay ageing and rejuvenating whole functional dynamics of the body organs. This revitalization and rejuvenation is known as the 'Rasayana chikitsa' (rejuvenation therapy)⁷. Ayurveda claims that several plants, the "Medhya" plants (intellect promoting) which have been found beneficial in cognitive disorders⁸. Saraswata ghrita mentioned in Bhaisajya

Ratnawali Svarbheda Rogadhikar⁹, is a unique combination of Medhya drugs having high content of Brahmi, which is a well known drug for its nootropic and memory enhancing properties through various researches and clinical studies¹⁰⁻¹².

Since Senile dementia is a disorder due to vitiated Vata especially in old age, snehana is extremely recommended for it and Shirobasti is said to be best in all type of snehana of Moordha¹³. Also Moordha is the palace for Prana vayu and all Indriyas¹⁴. Thus snehana of Moordha will not only pacify the Prana vayu but also give nourishment to the brain.

Medicine to be used in Shirobasti

According to Sushruta and Vagbhata, accordingly to disease, medicated sneha should be poured in Shirobasti^{15,16} and Ghrita is said to be best among the all sneha, and further described as a Yogvahi rasayana means any drug processed with ghrita will possess the quality of added drug¹⁷. With this approach Saraswata ghrita is selected to be used in Shirobasti.

Aims and Objectives

- To evaluate the effect of an Ayurvedic regimen (Saraswata ghrita orally in combination with therapeutic procedure Shirobasti) on clinical symptoms in patients of Senile dementia.
- To evaluate effect of an Ayurvedic regimen (Saraswata ghrita orally in combination with therapeutic procedure Shirobasti) on neuro-cognitive parameters—Alzheimer's disease assessment scale in patients of Senile dementia.

MATERIALS AND METHODS

A total number of 34 patients from OPD/IPD of Department of Kayachikitsa and Department of Medicine, S.S. Hospital IMS, BHU, presenting with clinical feature of Senile dementia, were screened for any neuropsychiatric disturbances and assigned into two groups

- Group A - 25 patients – Saraswata ghrita 6gm BD along with Shirobasti (with Saraswata Ghrita).
- Group B - 09 patients - Placebo in the form of Lactulose Cap. in dosage of 500mg BD

The following inclusion and exclusion diagnostic criteria were applied for the selection of cases of Senile dementia. Study was carried out as per the Ethical clearance no. 168. Approved on 13.05.2011.

The Inclusion Criteria

- Patients aged 55 and above up to 85 years.
- The elderly patients who fulfilled the ICD-10 diagnostic criteria for Dementia and who have MMSE score ≤ 23 were included in this study.

The Exclusion Criteria

- Impairment in cognitive functions due to Delirium.
- Impairment in memory without significant impairment in other cognitive functions (i.e. Aphasia, Apraxia, Agnosia or disturbance in executive functioning).
- Multiple cognitive deficits due the effect of substance intoxication or substance withdrawal.
- Cognitive impairment due to any other psychiatric disorder like Schizophrenia, Depressive disorder.
- Normal cognitive decline due to Age.
- Patients aged less than 55 and more than 85 years were excluded.

Dose and administration

- Dosage of trial drug
Saraswata Ghrita 6gm twice a day orally with lukewarm milk
- Total duration of trial
3 Months
- Follow-up
At interval of 1 month each

Schedule of Shirobasti

- Drug used: Saraswata Ghrita

- Quantity: 1 Liter
- Per day Duration: 45 min., daily
- Total Duration: 15 days, every month for three consecutive months (Total 45 days)

Parameters for assessment of therapeutic response

Clinical parameters

The symptomatic relief produced by the trial treatment was assessed on initial visit and on successive follow ups at 1month intervals for entire period of therapeutic trial for three months over the symptoms severity grading scale ranging from 0-4.

Neuro-cognitive parameters

The effect of treatment was also assessed in terms of certain neuro-cognitive factors. Alzheimer’s disease Assessment Scale (ADAS)¹⁸ has been used to quantify the neuro-cognitive parameters.

Assessment of the overall effect of the therapeutic trial

The overall result of the therapeutic trial has been assessed on the basis of changes into total ADAS score and the symptomatology. The reduction into the total ADAS score less than 5 or an increase in ADAS score was considered as no improvement or insignificant improvement, reduction between 5 to 10 and minor changes into the patients clinical condition was considered as mild improvement., while the reduction into the total ADAS score ranging between 10 to 16 was considered as moderate improvement, if also associated with significant changes into the patient’s clinical condition. Excellent improvement has been considered if the total reduction of ADAS score was more than 16 with significant improvement in clinical symptoms.

OBSERVATION AND RESULTS

The observations and results have been presented under the following tables

Table 1: Incidence of age and sex in 34 patients of Senile dementia

Age (in yrs)	Male		Female		Total
	No.	%	No.	%	
60-65	9	26.5%	3	8.8%	12
66-70	9	26.5%	1	2.9%	10
71-75	3	8.8%	1	2.9%	4
76-85	4	11.8%	4	11.8%	8
Total	25	73.6%	9	26.4%	100%

Table 2: Group wise distribution of the patients of Senile dementia according to severity of cognitive impairment based on their MMSE score

Groups	Cognitive Dysfunction						Total
	Mild (MMSE=18-23)		Moderate (MMSE=10-18)		Severe (MMSE<10)		
	No.	%	No.	%	No.	%	
Group A	13	52%	10	40%	2	8%	25
Group B	4	44.4%	5	55.6%	0	0%	9
Total	17	50%	15	44.1%	2	5.9%	34

MMSE = Mini Mental State Examination

Table 3: Effect on clinical symptomatology in 25 patients of Senile dementia treated with Saraswata ghrita in combination with Shirobasti

Symptoms	Mean Score ±SD		Difference	Relief %	t value	p	Results
	BT	AT					
Forgetfulness	3.00±.764	2.64±.995	0.36	12%	3.674	<.01	HS
Impaired attention	2.72±.737	1.96±1.060	0.76	28%	7.268	<.001	HS
Object mislaid	3.56±.651	2.68±1.030	.88	24.7%	6.063	<.001	HS
Name forgotten	3.20±.957	2.16±.987	1.04	32.5%	11.438	<.001	HS
Number forgotten	3.52±.714	2.80±.913	0.72	20.4%	6.641	<.001	Hs
Difficulty in recognising family members and surroundings	2.32±1.376	1.68±1.345	0.64	27.5%	6.532	<.001	HS
Disturbed speech	1.92±1.187	1.52±1.229	.40	20.8%	3.162*	<.01	HS
Assistance in personal care	2.28±.980	1.96±1.060	0.32	14%	3.367	<.01	HS
Making mistakes in accounts	3.40±1.000	2.32±1.030	1.08	31%	9.448	<.001	HS
Delusional thoughts	1.60±1.443	1.24±1.000	0.36	22.5%	3.00*	<.01	HS
Irritability	3.08±.997	1.24±1.128	1.84	59.7%	13.37	<.001	HS
Disturbed sleep	2.24±1.200	1.04±1.060	1.2	53.5%	10.392	<.001	HS
Tremors	2.04±1.428	1.84±1.491	0.20	9.8%	2.236*	<.05	S
Disturbed gait	1.96±1.098	1.52±1.295	0.44	22.4%	4.34	<.001	HS
Anxiety	1.88±1.013	.72±.678	1.16	61.7%	4.284*	<.001	HS
Sad mood	1.36±1.319	.92±1.077	.44	32%	4.34	<.001	HS
Feeling of Weakness	2.36±.757	1.52±.872	0.84	35.6%	8.887	<.001	HS

BT= Before Treatment; AT= After Treatment. *values are calculated by using wilcoxon signed test due to SD was more than half of mean score

Table 4: Effect on Alzheimer's Disease Assessment Scale (ADAS-cog subscale) score in 25 patients of Senile Dementia treated with Saraswata Ghrita in combination with Shirobasti

Tasks	Mean Score ± SD		Difference	Relief %	t value	p	Results
	BT	AT					
Word recall task	7.56±1.87	5.16±2.19	2.40	31.47%	10.39	<.001	HS
Naming object task	2.56±1.04	1.60±1.22	0.96	37.5%	8.913	<.001	HS
Commands	2.24±1.48	1.48±1.47	0.76	33.9%	3.58*	<.001	HS
Constructional praxis	2.92±1.52	2.48±1.47	0.44	15%	3.773	<.01	HS
Ideational praxis	3.68±1.180	3.08±1.552	0.60	16%	4.648	<.001	HS
Orientation	4.92±1.352	3.08±1.382	1.84	37.3%	14.73	<.001	HS
Word recognition task	9.44±1.294	6.60±1.958	2.84	30%	11.381	<.001	HS
Remembering task	3.72±.936	2.64±1.036	1.08	29%	13.50	<.001	HS
Spoken language ability	3.08±1.038	2.72±1.329	0.36	11%	3.674	<.01	HS
Word finding difficulty in speech	3.04±.841	2.84±.987	0.20	6.5%	2.449	<.05	S
Comprehension	3.16±.850	2.84±1.06	0.32	10%	3.361	<.01	HS
Total ADAS score	46.28±11.17	34.48±13.69	11.80	25.5%	15.319	<.001	HS

*values are calculated by using Wilcoxon signed test due to SD was more than half of mean score

Table 5: Effect on clinical symptomatology in 9 patients of Senile dementia treated with Placebo

Symptoms	Mean Score ± SD		Difference	Relief %	T	p	Results
	BT	AT					
Forgetfulness	3.22±.667	3.33±.707	-0.11	--	-1.000	>.05	NS
Impaired attention	2.56±.527	3.00±.707	-0.44	---	-2.530	<.05	S
Object mislaid	3.33±1.000	3.22±1.093	-0.11	--	1.00	>.05	NS
Name forgotten	3.22±.833	3.56±.527	-0.34	---	-2.00	>.05	NS
Number forgotten	3.44±.726	3.44±1.014	--	--	.000	>.05	NS
Difficulty in recognising family members and surroundings	2.44±.726	2.89±.782	-0.45	--	-2.530	<.05	S
Disturbed speech	1.89±.782	2.00±.866	-0.11	--	-1.00*	>.05	NS
Assistance in personal care	2.22±.972	2.67±1.000	-0.45	--	-2.530	<.05	S
Making mistakes in accounts	3.44±.726	3.78±.441	-0.34	--	-2.00	>.05	NS
Delusional thoughts	1.67±1.414	1.89±1.364	-0.22	--	-1.41*	>.05	NS
Irritability	2.56±.726	2.89±.928	-0.33	--	-1.414	>.05	NS
Disturbed sleep	2.22±.833	2.56±.527	-0.34	--	-1.414	>.05	NS
Tremors	1.78±.833	1.78±.972	---	--	.000	>.05	NS
Disturbed gait	1.89±.928	2.11±.782	-0.22	--	-1.512	>.05	NS
Anxiety	1.67±1.000	1.78±1.202	-0.11	--	.333*	>.05	NS
Sad mood	1.44±1.014	1.56±1.130	-0.12	--	.555	>.05	NS
Feeling of Weakness	2.22±.667	2.78±.833	-0.56	--	-2.294	>.05	NS

*values are calculated by using wilcoxon sign test due to SD was more than half of mean score

Table 6: Effect on Alzheimer’s Disease Assessment Scale (ADAS-cog subscale) score in 9 patients of Senile Dementia treated with Placebo

Tasks	Mean Score ± SD		Difference	Relief %	t value	p	Results
	BT	AT					
Word recall task	7.00±1.58	7.78±1.85	-0.78	--	-5.292	<.05	S
Naming object task	2.89±1.05	2.89±1.05	--	--	.000	>.05	NS
Commands	2.00±1.22	2.11±1.36	-0.11	--	1.000*	>.05	NS
Constructional praxis	2.67±1.34	2.67±1.34	--	--	.000	>.05	NS
Ideational praxis	3.22±1.202	3.33±1.32	-0.11	--	-1.00	>.05	NS
Orientation	4.44±1.333	4.89±1.364	-0.45	--	-2.53	<.05	S
Word recognition task	8.67±1.803	9.44±1.878	-0.77	--	-5.292	<.05	S
Remembering task	3.33±1.225	3.56±.882	-0.23	--	-1.512	>.05	NS
Spoken language ability	2.56±1.014	2.56±1.014	--	--	.000	>.05	NS
Word finding difficulty in speech	2.67±1.000	2.67±1.000	--	--	.000	>.05	NS
Comprehension	2.78±1.093	2.78±1.093	--	--	.000	>.05	NS
Total ADAS score	42.22±12.15	44.67±12.05	-2.45	--	-13.91	<.01	HS

*values are calculated by using wilcoxon sign test due to SD was more than half of mean score

Table 7: Overall result of the therapeutic trial among the all groups in the patients of Senile dementia

Result	Group A		Group B		Total
	No.	%	No.	%	
Mild improvement	6	24%	0	0%	6
Moderate improvement	13	52%	0	0%	13
Excellent improvement	3	12%	0	0%	3
No/insignificant improvement	3	12%	9	100%	12
Total	25		9		34

DISCUSSION

Interest in the study and care of patients with dementia has greatly been increased, as at present it is the burning problem of the presenile and senile age. At present time, no treatment is available to alter the relentless deterioration of the disease. A number of attempts have been made for neurotransmitter replacement therapy in Alzheimer's type dementia, but the overall management was very difficult and frustrating as there is no specific treatment available. Therefore, an attempt has been made to manage this disease by an Ayurvedic regimen.

The study related with incidence of age and sex revealed that maximum number of patients was found to be between age group of 60-70 yrs (64.7%) with predominance of Male patients (73.6%). Observations regarding the level of cognitive impairment in these patients, based upon MMSE scores revealed that, 50% patients were found to be have mild cognitive impairment, 44.1% have moderate, and only 5.9% have the severe impairment. After completion of the trial patients of Group A showed statistically highly significant changes in all the symptoms except in tremor. Patients also have performed very well in different component of ADAS scale in consecutive follow ups . In patients of Group B, no statistically significant difference was found in any of the symptoms. They also performed very poorly in ADAS scale in consecutive follow-ups.

After completion of the therapeutic trial, on the bases of overall improvement, in patients of Group A treated with Saraswata ghrita and Shirobasti, only 3 (12%) patients were having no/insignificant improvements, while rest of the patients demonstrated statistically significant improvement on clinical symptoms and neuro-cognitive parameters of ADAS scale. In the patients of group B treated with Placebo, none of the patients showed any significant improvements. Instead of getting

improvement, some patient with advance disease showed more poor performance on clinical scales after completion of trial. This finding is consistent with the progressive nature of the disease.

Senile dementia is not described as a disease moiety in separate chapters of Ayurvedic classics, however, The symptoms of Senile dementia can be correlated with Buddhi bhransha which has been described by Charaka in Sharira sthan¹⁹. Since Smriti is closely interrelated with Buddhi,²⁰ so any derangement of Buddhi leads to disturbance in Smriti and its other component like Dhi, Dhriti and the vice-versa.

Ayurveda describes Rasayana therapy which is the unique therapeutic modality to rejuvenate the body and mind²¹. Further, Rasayana drugs acts by enhancing the digestion and metabolism, the nutritional quality of nutrient plasma (Rasa) and micro-circulation of nutrient materials to the different basic body tissues²². Medhya Rasayans specially improves the mental functions like memory, intellect etc. along with quality of life²³.

Saraswata Ghrita is a unique combination of such type of Medhya and Rasayana drug described in Bhaishajya Ratnavali,⁹ having high contents of Brahmi which is well known drug for its nootropic properties and has been proven through various clinical and experimental study¹⁰⁻¹². Saraswata ghrita also contain Rasayana drug like Haritaki and Amlaki, which have been said to be best among all “Vayasthapana dravya”.^{24,25} Ghrita is enriched with drugs like Haridra, Vidanga and Pippali, and Vacha which are having Shirovirechana property which removes the vitiated Doshas for Shiras²⁶. The whole formulation is in Ghrita form, it improves Memory, Complexion, Intelligence, Voice, and Oja the body. It is Vitalising, Rejuvenating, Vrishya, Medhya and Vayasthapana, promoter of long life and it removes toxic substances from the body²⁷. Moreover lipophilic action of Ghrita

facilitates transportation of drug to a target organ and final delivery inside the cell, because cell membrane also contains lipid. When herbs are mixed with Ghrita, their activity and utility is potentiated many times²⁸. Shirobasti is specifically selected here to study its efficacy on Senile dementia as it belongs to Snehana, especially Bahyasneha and it is suggested as line of treatment of vitiated Vata in almost all Ayurvedic texts. Shirobasti is a snigdha sweda yukta procedure i.e it has dual benefits of both Snehana and Swedana. Thermal therapy is known to enhance antioxidant functions²⁹ hence swedana procedure may also facilitates a similar action. In Shirobasti, there is retention of oil in lukewarm state for a specific period of time on scalp of head region, which is a main seat of Prana Vata and all Indriyas are also attached to Moordha¹⁴. Thus, virtues of Sneha can be obtained here to its best. This is also supported by Ashtanga Hridaya, i.e., Shirobasti is the most effective of all type of Moordha taila¹³. Study suggests that drug if suitably formulated can be delivered directly to the brain via transcranial route³⁰. As the nervous system is mainly composed of lipid tissue, the Ghrita being lipid in nature is quickly absorbed due to the rich vasculature of the scalp and gets distributed to different parts of the brain through the communicating veins (extracranial to intra cranial), exerting its influence on various centres, including the limbic system and the hypothalamus.

CONCLUSION

Based on the findings of the present clinical trial, it can be concluded that the combination of the Saraswata Ghrita and Shirobasti therapy is one of the most effective therapy for the management of the Senile Dementia without any adverse and side effects, instead promoting a greater degree of relief in the symptoms. It has been observed that the improvement of the patients largely depends on their level of cognitive impairment, greater the level of impairment the more difficult it becomes to treat, as the disease becomes intractable with time. Thus the therapeutic combination of Saraswata ghrita orally along with Shirobasti therapy can be judiciously used in the intractable and progressive disorder of Senile dementia with significant clinical benefits and improvements in quality of life of these patients.

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