

Study the Efficacy of Medhya Rasayan in Senile Dementia

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Abstract

Background: Dementia is a condition in which one's thinking and remembering ability gradually hampers. According to The World Health Organization (WHO), in developing countries, the number of people who are 60 years aged and above will be approximately 75% among 1.2 billion as estimated. According to prediction, every 20 years, percentage of dementia almost doubles. Growth rate of dementia will be increased in countries like India, China, and South Asia and Pacific regions. However, lower in developed countries. According to various studies of DSMIV or ICD10 in Indian, Dementia prevalence varies from 0.9% to 4.8% in urban areas and 0.6% to 3.5% in rural areas. Dementia gradually decreases one's strength, physical abilities, unable person to maintain a steady gait as it affects brain areas which controls movement and balance results in causing a risk for safety. These deteriorates the potential capacities like troubles in remembering things, thinking clearly, communicating with others, mood swings, changes in personality and behavior, may decrease a person's quality of life. Till today, there is no complete cure for senile dementia, only symptomatic relief is there with Acetyl Cholinesterase Inhibitors (AChEI) (donepezil, rivastigmine and galantamine) and memantine, which is an N-methyl-Daspartate partial antagonist. Approximately 40-50% of people with Alzheimer's disease respond this symptomatically treatment. There are many side effects of this modern treatment are noted. There are very less work in Ayurveda on senile dementia. Hence this study is planned.

Objectives: To evaluate the efficacy of Medhya Rasayan on MMSE.

Methodology: Eligible Patients will be divided in two groups by lottery method and medicine will be given according to group and outcomes will be assessed on 30th, 60th, and 90th day.

Results: If the proposed study results in the positive outcome, this treatment can be given in cure as well as prevention purpose of senile dementia.

Conclusion: It will be drawn from statistical analysis.

Keywords

Dementia; Medhya Rasayan; Acetyl Cholinesterase Inhibitors; Alzheimer's disease

Introduction

Among the World population of the percentage of elders is increasing and up to the year 2050, 20 percent of global population will be comprised of adults older above 65 years age group. 89 out of 1000 geriatric population experiences cognitive deficits. This increasing percentage of cognitive impairments among geriatric population demands very precise and careful planning and proper plan of health services to the elders to initiates a healthy life.

Dementia is a condition in which one's thinking and remembering ability gradually hampers. There is no specific classification of Dementia related to old age, but in Alzheimer's disease, dementia is cardinal feature. Soon, there will be increasing number of old age people in our population. This is significant that there are sudden changes or increasing number of our old

age population in steady manner, especially without any destination along with economic development is observed. This makes very challenging and difficult to fulfill the needs of older people, which is the need of hour. Effect of Dementia varies person to person. It totally depends on one's personality, way of living, significant relationships and physical health before the disease.

According to The World Health Organization (WHO), in developing countries, the number of people who are 60 years aged and above will be approximately 75% among 1.2 billion as estimated [1]. According to prediction, every 20 years, percentage of dementia almost doubles. The increased number of cases will be the found more in India, China, South Asia, and western Pacific regions, in Latin America and Africa, and found less in developed regions [2]. According to WHO and World Bank, among all causes of disability-adjusted life years, percentage of dementia is 4.1% [3]. According to various studies of DSMIV or ICD10 in Indian, Dementia prevalence varies from 0.9% to 4.8% in urban areas and 0.6% to 3.5% in rural areas [4]. Dementia gradually decreases one's strength, physical abilities, unable person to maintain a steady gait as it affects brain areas which

controls movement and balance results in causing a risk for safety. This gradual decrease in physical ability and steady gait makes person relying on others and disturbs person's physical wellbeing. This immobility can lead to more physical problems such as impairs bowel movements i.e. constipation, which is the result of immobility [5].

These deteriorating functional abilities such as memory difficulties, thinking abilities, communication skills, mood swings, personality changes and behavior, results in decreasing person's quality of life [6].

The most common causes of Senile dementia are Alzheimer's disease, vascular causes, Parkinson's disease, drug intoxications, alcoholism and least common causes are Endocrine and other organ failure (Hypothyroidism, Adrenal insufficiency and cushing syndrome, Hypo and Hyperparathyroidism, renal failure, liver failure, pulmonary failure), vitamin efficiencies (Vitamin B₁, B₁₂, Nicotinic acid), tuberculosis, papova virus, etc., neoplastic diseases of brain, psychiatric diseases, degenerative disorders of brain head trauma and head damage.

Till today, there is no complete cure for senile dementia, only symptomatic relief is there with Acetyl Cholinesterase Inhibitors (AChEI) (donepezil, rivastigmine and galantamine) and memantine, which is an N-methyl-Daspartate partial antagonist. Approximately 40-50% of people with Alzheimer's disease respond this symptomatically treatment. So, these medications are important management options of dementia in Alzheimer's disease. But, there are many well-known gastrointestinal side effects noted by physicians of "second-generation" AChE Is like nauseating feeling, vomiting, watery stool, and loss of appetite [7].

Also side effects like hallucinations, aggressive behavior, and agitation are reported there but they get settled down on dose reduction or discontinuation of medicine. Management with the medicine like rivastigmine also reported side effects like Esophageal rupture followed excessive vomiting.

In Ayurveda, Jara is included in Ashtang Ayurveda [8].

The term jara means old age. There is no specific terminology for Dementia in Ayurveda, but reference for Medhya Rasayan is given in which it is given that it helps to rejuvenate smrti (Memory).

The mental health is the challenging thing for today's scientific society. Ayurvedic literature is having abundance knowledge regarding keeping physical health, mental health and balance between them. "Medhya Rasayan" is one among the concept describe in Ayurveda to keep the balanced state of mind. Medha means intellect and Rasayana means which helps to increase the rasa, raktadi dhatu (Lymphatics and other physical states). It can be a stronger solution to keep society free from psychosomatic problems.

The increasing age is the factors to deteriorate the physical and psychological health of a person, so to help in this matter "Medhya Rasayan" can be used in today's era, as it is well said that, Precaution is better than cure. However, this rasayana can also be used in old age as a cure of disease. According to developed science, the Medhya Rasayanas have proven beneficial in delaying jara related buddhimandiyatva or the deteriorating conscious intellectual activity in old age. So, proper assessment of these drugs helps to prevent deterioration of cognitive changes in old aged people.

Multiple health deteriorating conditions are more likely to found in old age persons. These mental and cognitive disorders can also

affecting different organ systems results in multiple chronic physical diseases.

The dementia affects the quality of life of the older person which results in indicative physical inabilities, impaired daily activities. Interventions might prevent or longer the duration of early impairment and helps in longevity of life.

Dementia affects the parson's health, impairs quality of life and reduces life expectancy. It also impacts on person's overall family. Dementia also affects family's quality of life as the family is the support and care for the parson with dementia. The person also faces social burden of many things like expenditure and monetary costs. As there are increasing cases of dementia, there is need to explore more and found some alternative medicine to overcome the disease. So require more researches in this aspect of disease.

Rationale of study

Senile dementia is increasing day by day, though it is not life threatening but it significantly hampers quality of life of patient as well as family members. There are very less work in Ayurveda on senile dementia. Hence this study is planned.

Aim: Evaluation of Efficacy of Medhya Rasayan in Senile Dementia.

Objectives:

- To evaluate the efficacy of Medhya Rasayan on Orientation and Registration.
- To evaluate the efficacy of Medhya Rasayan on Attention and calculation.
- To evaluate the efficacy of Medhya Rasayan on recall and language.

Trial design:

- It is a Interventional study.
- Randomized control trial.
- Including 2 groups with equivalent 50 patients in each group.

Research gap: In the search of literature, no any specific terminology for senile dementia is found in Ayurveda. Number of herbal drugs is described as Medhya. Specific medhyarasayanas are also described but the researches in this regard are very few. So there is a need to evaluate the effect of well described "Medhya Rasayan" in Senile Dementia.

Previous work done

In the search of literature, one study has been found in Ayurveda on Rasayan in Senile memory impairment and other two studies has been found on memory improvement in school going children are as follows

- Effects of Medhya Rasayana and Yogic practices in improvement of short-term memory among school-going children by Sarokte [9].
- Clinical efficacy of Guduchyadi Medhya Rasayana on Senile Memory Impairment by Kulatunga RD [10].
- Randomized controlled trial on the efficacy of medhya rasayana tablet on academic stress and performance in school children by Kulkarni [11].

Toxicity studies

Mandukaprni: In this study conducted by Pingale, it is observed that no fatality recorded even at highest dose i.e. 7 g/kg bd.wt. and also bd.wt. Food and water consumption is as it is by the animals from all

dose groups; it proves that there are no any particular toxic effects due to *Centella asiatica* plant powder [12].

Guduchi: In this study conducted by Pingale, it is observed that no fatality recorded even at highest dose i.e. 9 ml/Kg for decoction and 8 gm/kg for whole plant powder of *Tinospora cordifolia*, and also bd.wt. Food and water consumption is as it is by the animals from all dose groups [13].

Shankhapushpi: In this study conducted by Agrawal, it is observed that due to dose of *C. puricaulis* extract upto 5000 mg/kg for duration 72 hours, there was no fatality found amongst the graded dose groups of albino wistar rats. So it can be said that at the doses used for this study in albino wistar rats, *C. puricaulis* extract are relatively safe or non-toxic [14]. Grading of TMD is by using Helkimo index.

Materials and Methods

Literary source

Study will be properly assessed with the help of information collected from various modern medicine books and ayurvedic classical texts i.e. samhita.

Clinical source

The subjects with Senile Dementia will be selected from Kayachikitsa OPD, Geriatric OPD and IPD of MGACH and RC and from specialized peripheral camps.

Drug source

1. Raw drug will be procured from ‘Manas Ayurveda shop’ and its authentication will be done at dravyaguna department at MGACH and RC.

2. Medhya Rasayan Ghrita will be prepared at Dattatray Rasa shala, MGACH and RC. The ingredients of Medhya Rasayan are:

Drug	Latin name
<i>Mandukaparni</i>	<i>Centella asiatica</i>
<i>Guduchi</i>	<i>Tinospora cordifolia</i>
<i>Shankhapushpi</i>	<i>Convolvulus pluricaulis</i>

Table 1: Drug and their latin name.

Study design

Randomized control trial.

Type of study

Interventional

- Eligibility criteria
- Inclusion criteria

Patients of age group 65 years to 75 years.

Patients with controlled hypertension.

Case definition: 1. Cardinal features of mild cognitive Dementia like some memory troubles and trouble finding words, but they solve everyday problems and handle their own life affairs well.

2. MMSC scoring 18-23 (Mild cognitive impairment)

Exclusion criteria: 1. Patients with evidence of delirium, confusion or other disturbances of consciousness, Parkinson’s disease, stroke, intracranial hemorrhage, brain tumors, history of alcoholism or drug dependence, use of any psychotropic drug, diabetes mellitus, etc.

2. Patients with physical impairment, such as walking, sitting, and holding one’s head up and eventually, results in difficulty in swallow, unable to control the micturition and feces.

3. Patients with loss of ability to communicate.

Interventions: Group A-Medhya Rasayan Ghrita-15 ml twice a day before meal with luke warm water for 3 months [15].

Group B-Go ghrita-15 ml twice a day before meal with luke warm water for 3 months.

Criteria for discontinuing: 1. If complicated features of hypothyroidism occurs during treatment.

2. If patient is no more willing to continue the treatment.

3. If there are any side effects of given medicine.

Outcomes: Efficacy will be assessed with mini mental scale examination under the heads of orientation, registration, attention, calculation, recall, language.

Participants timeline:

- Total 70 patients who fulfill the inclusion criteria will be taken from the OPD and IPD of MGAC and RC, Salod (H), Wardha.
- On first day of visit, patient will be checked for criteria according to case definition, if patient is eligible for study, the patients will be divided randomly by lottery method into two groups of 35 patients in each group including drop outs.
- Group A will be given standard treatment i.e. Medhya Rasayan Ghrita.
- Group B will be given Go ghrita.
- Both groups A and B will be given medicine for continuous 90 days.
- Before starting the medicine, Inform consent will be taken from each patient.
- Each patient will be followed-up on 30th, 60th and 90th day.

Sample size

$$Z_{\alpha/2} \times P \times (1-P)/d^2$$

Where;

$Z_{\alpha/2}$ is the level of significance at 5% i.e.95% confidence interval=1.96

$$P=\text{prevalence of Dementia}=4.1\%=0.041$$

$$d=\text{Desired error of margin}=7\%=0.07$$

$$n=1.96^2 \times 0.041 \times (1-0.041)/0.07^2$$

$$n=30.82 \text{ (therefore 35 patients needed in each group in this study)}$$

Data collection

Assessment will be done by MMSE (Table 1)

Data will be collected from scoring of scale (primary, secondary outcomes) and conclusion will be drawn according to statistical analysis results.

Ethics and dissemination

This study is Institutional Ethics Committee approved. Protocol amendment, if there any changes in protocol modifications, it will be informed to IEC and permission will be taken.

Consent-Before starting the medicine inform consent will be taken from each patient in patient's language.

Confidentiality patients will be maintained by not reviling their personal information in any manner.

Declaration of interest-This study will be self finacilaised.

Ancillary and post-trial care-Patients consent will be taken by giving them all the information regarding study and possibilities. Post-trial harms (if found) care and management will be done.

Results and Discussion

There are very few researches in Ayurveda regarding Dementia. So there is a need to correlate Senile dementia with related diseases describe in Ayurveda and to evaluate the effect of well describe "Medhya Rasayan" on Senile Dementia.

Numerous Rasayan preparations are mentioned in Ayurveda. According to Ayurveda, rasayan helps to keep longevity of life, sharp memory, increases perception power, keeps person healthy, improves complexion, and increases mental and physical strength.

According to Ayurveda, health is balanced manasik, bouddhik, sharirik bliss. It is stated that, this state of mental harmony is deteriorates with increasing age results in degenerative disorders. Ayurveda says that, with increasing age, Medhanash and Balanash are there. Ayurveda helps to keep mental health and reduces stress. Medhya rasayan is specifically mentioned to keep mental health. There are few studies done in Ayurveda on Senile Dementia.

Conclusion

Medhya rasayana is good combination of medhya drugs which are preferably used as rasayan. As this study is clinical, further discussion

will be done according to results. It will be drawn from statistical analysis. If the proposed study results in the positive outcome, this treatment can be given in cure as well as prevention purpose of senile dementia.

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