EFFICACY OF AMALAKYADI GHRITA ALONG WITH VACHADI GHrita NASYA (PRATIMARSHA) ON SENILE DEMENTIA – A CLINICAL EVALUATION

VD.KUNDAN CHAUDHURI
Reader
Panchakarma Department
G.J.Patel Ayurved College
Anand

DR.H. M. CHANDOLA
Ex. Director of Ch. Brahm Prakash Ayurved Charak Sansthan, Delhi
INTRODUCTION

- Dementia is a progressive degenerative disease of the brain and affects mainly elderly persons. Memory impairment is the essential feature of this disease. The other cognitive functions that can be affected in dementia include general intelligence, learning, language, problem solving, orientation, perception, attention and concentration, judgment and social abilities. The personality is also affected. Agitation or withdrawal, hallucinations, delusions and insomnia are also common.

- Dementia has become a burning problem all over the world. Worldwide, more than 35 million people are currently estimated to have dementia. There are already approximately 1.5 million people affected by dementia in India. Senile dementia is not described as a separate disease entity in Ayurveda. It can be interpreted as Jarajanya smritibhramsha in Ayurveda.

- No direct therapy in modern allopathy system, is available which can reverse or retard the pathophysiological processes permanently. Amalakyadi ghrita, a newly formulated ghee-based ayurvedic medicine which contains amalaki, haridra and rasona, was found effective in senile dementia when taken orally along with Vachadi ghrita nasya (Pratimarshya). The study reveals that most of the patients had disturbed sleep, tendency to indulge in defective dietary habits and taken kapha vitiating dietetics and had improper life style. The Hamilton Anxiety Rating Scale, Hamilton Depression Rating Scale and Brief Psychiatry Rating Scale showed that most of the patients had anxiety, tension, depression, difficulty in concentration and memory, somatic concern and tension etc. The data reflects that unwholesome diet and disturbed mental health plays an important role in etiopathogenesis of senile dementia.
Neurofibrillary tangles

Normal aged brain

Alzheimer’s patient’s brain

Senile plaques

PET scan of brain of patients with AD shows loss of function in the temporal lobe.

Enzymes act on APP and cut it into fragments (beta amyloid).

Changes in tau protein lead to disintegration of microtubules in brain cells in AD.

PATHOLOGICAL CHANGES IN BRAIN OF ALZHEIMER’S PATIENTS
Purpose

• The present study is aimed at evaluating the efficacy of Amalakyadi ghrita taken orally along with Vachadi ghrita pratimarsha nasya in the patients suffering from Senile dementia.

• To find a safe, toxicity free and cost-effective drugs for the patients suffering from Senile dementia.
Methods:

• Method of study:
  The diagnosed demented patients were subjected to the clinical trial. Before registering the patients, written consent was taken and the study was cleared by Institutional Ethics Committee. The study was conducted as a randomized single blind clinical trial.

• Material and Methods:
  Total 56 patients with signs and symptoms suggestive of Senile dementia were registered out of whom 42 patients completed the 3 months’ treatment course.
• **Inclusion criteria:**

Patients aged within 60 – 90 years attending the OPD of Kayachikitsa Department, I.P.G.T. & R.A, Hospital Jamnagar were screened and those fulfilling the clinical features of Senile dementia based on both Ayurvedic and modern descriptions, were selected.

• **Exclusion criteria:**

Patients who were out of the above age group and suffering from psychiatric and neuropsychiatric conditions like Schizophrenia, Parkinsonism, Huntington’s disease, Pick's disease etc, persistent endocrine disorders, any other chronic systemic disorders and persons taking psychotropic drugs and alcohol were excluded.
Methods contd..

• **Drug, Dose, Duration & Diet:**
  
The dementia patients were prescribed Amalakyadi Ghrita, 10 gms twice daily in morning & evening for 3 months in empty stomach with lukewarm water.
  
  Vachadhi Ghrita pratimarsha nasya two bindus in each nostril twice a day in the morning and evening were also administered for 3 months. Before taking the medicine, patients were advised to take Haritakichurna in a dose of 3-4 gms at bed time for 3-7 days for koshthasuddhi. All the patients were advised to follow appropriate diet as per their Prakriti. They were advised to take sattvikaahara, to correct their dietary habits and to avoid unhygienic and stale food.

• No adverse effect of the drugs was observed during clinical trial.

• **Follow up study:** After completion of treatment, patients were observed for 1 month and all parameters of assessment were assessed.
Methods contd…

Criteria for assessment:

• Subjective criteria: CT scan (if affordable), Mini-mental state examination (questionnaires), Bender Gestalt Motor Visual Test, Hamilton Anxiety Rating Scale, Hamilton Depression Rating Scale, Improvement in clinical features, Brief Psychiatry Rating Scale.

  Chief complaints of Senile dementia and other symptoms related to specific rating scales such as Hamilton Anxiety Rating Scale etc., were assessed by 0-4 gradations according to the severity. Visual memory was assessed by Bender Gestalt Motor Visual Test by grading from 0-3 on the basis of severity.

• Objective criteria: Serum Choline esterase estimation, Routine haematological and bio-chemical investigation, Urine and stool examination.
## Effect of therapy on chief complaints

<table>
<thead>
<tr>
<th>Signs &amp; symptoms</th>
<th>% of improvement</th>
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<th>% of improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suicidal thoughts</td>
<td>33.33%</td>
<td>Losing valuables</td>
<td>53% P&lt;0.001</td>
<td>Forgetting food cooking on stove</td>
<td>33.33%</td>
</tr>
<tr>
<td>Irritability</td>
<td>52.63% P&lt;0.001</td>
<td>Impaired attention</td>
<td>39.70% P&lt;0.001</td>
<td>Difficulty in preparing food/meals</td>
<td>28.57%</td>
</tr>
<tr>
<td>Intentional tremor</td>
<td>38.09% P&lt;0.05</td>
<td>Forgetting names</td>
<td>46.96% P&lt;0.001</td>
<td>Recognition of family faces and surrounding</td>
<td>46.51% P&lt;0.001</td>
</tr>
<tr>
<td>Assistance in personal care</td>
<td>50% P&lt;0.05</td>
<td>Forgetting numbers,</td>
<td>55.03% P&lt;0.001</td>
<td>Forgetfulness</td>
<td>43.42% P&lt;0.001</td>
</tr>
<tr>
<td>Disturbed sleep</td>
<td>63.07% P&lt;0.001</td>
<td>Decreased efficiency in household tasks</td>
<td>16.21% P&lt;0.05</td>
<td>Gait difficulty</td>
<td>41.86% P&lt;0.001</td>
</tr>
<tr>
<td>Mislaying of objects</td>
<td>58.67% P&lt;0.001</td>
<td>Making mistake in accounts</td>
<td>42.85% P&lt;0.001</td>
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</tbody>
</table>
• **Effect of therapy on chief complaints:** Totally, Amalakyadi ghrita orally with Vachadighrita nasya showed mild improvement in most patients (92.85%) and moderate improvement in 2.38% patients. This finding is the proof for psycho activity of the Ayurvedic formulation.

• **Effect of therapy on doshavriddhi lakshana:** Amalakyadi ghrita with Vachadighrita provided 53.33% improvement in kaphavriddhilakshanas which is statistically highly significant, because most of the drugs of Amalakyadi ghrita have vata and kaphashamak properties and also has katu, tikta rasa predominance.
**Effect of therapy on Manasikabhava:** The improvement in bhaya, krodha, medha and smriti are found statistically highly significant (p<0.001) whereas in Shoka it was statistically significant (p<0.05). Total 21.42% were mildly improved.

<table>
<thead>
<tr>
<th>Manshikbhava</th>
<th>% of improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bhaya</td>
<td>45.65%</td>
</tr>
<tr>
<td>Krodha</td>
<td>37.25%</td>
</tr>
<tr>
<td>Shoka</td>
<td>26.66%</td>
</tr>
<tr>
<td>Medha</td>
<td>43.24%</td>
</tr>
<tr>
<td>Smriti</td>
<td>40.84%</td>
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</tbody>
</table>
Effect of therapy on Brief Psychiatry Rating Scale: All the signs and symptoms improved in statistically highly significant manner (p<0.001 each).

<table>
<thead>
<tr>
<th>Signs and symptoms</th>
<th>% of improvement</th>
<th>Signs and symptoms</th>
<th>% of improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatic concern</td>
<td>48.14%</td>
<td>Tension</td>
<td>43.75%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>47.50%</td>
<td>Depressed mood</td>
<td>46.66%</td>
</tr>
<tr>
<td>Emotional withdrawal</td>
<td>66.66%</td>
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Effect of therapy on Mini Mental State Examination: On Mini Mental State Examination (MMSE), 6% increase was found in Scores in MMSE which is statistically highly significant. Therapy successfully improved the orientation, attention, calculation, immediate and short term memory, corrected the language problem and increased the ability to follow the simple commands with statistically significant results. All the drugs have memory enhancing, antioxidant and rasayana properties, so improvement may be due to the antioxidant and rasayana effects of drugs to the brain.
## Hamilton Anxiety Rating Scale:

<table>
<thead>
<tr>
<th>Signs and symptoms</th>
<th>% of improvement</th>
<th>Signs and symptoms</th>
<th>% of improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fear</td>
<td>42.22%</td>
<td>Depressed mood</td>
<td>46.75%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>51.21%</td>
<td>Gastro intestinal symptoms</td>
<td>45%</td>
</tr>
<tr>
<td>Somatic sensory</td>
<td>47.05%</td>
<td>Tension</td>
<td>44.73%</td>
</tr>
<tr>
<td>Anxious mood</td>
<td>47.50%</td>
<td>Behavioral change at interview</td>
<td>48.07%</td>
</tr>
</tbody>
</table>

In all the signs and symptoms, statistically highly significant improvement ($p<0.001$) was achieved.
Hamilton Depression Rating Scale:

<table>
<thead>
<tr>
<th>Signs and symptoms</th>
<th>% of improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depressed mood</td>
<td>44.44 %</td>
</tr>
<tr>
<td>Insomnia late</td>
<td>71.42 %</td>
</tr>
<tr>
<td>Anxiety somatic</td>
<td>63.63%</td>
</tr>
<tr>
<td>Hypochondriasis</td>
<td>41.79 %</td>
</tr>
</tbody>
</table>

Depressed mood, hypochondriasis and insomnia late improved in statistically highly significant manner (p<0.001 each) and anxiety (somatic) improved in statistically significant manner (p<0.05).

**Effect of therapy on Biomarker** On Biomarker - Serum Cholinesterase, 3.05% decrease was found which is statistically insignificant. Serum Cholinesterase level is generally decreased than normal in Senile Dementia
Conclusion

The present study concludes that depressed mood, negative thoughts and abstinence from sadvritta, swasthavritta disturb one’s psychological health and play an important role in dementia in old age by vitiating rajas and tamas manasika doshas, Prana, Udana, Vyanavayu, Rasavahasrotas, Majjavaha Srotas, Manovaha srotas and Ojas.

Patients who reported manovighatakarabhava like bhaya, chinta, shoka, dvesha, krodha and moha and taking vata kapha prokopa ahara vihara are at a high risk for developing smritibhramsha.

Dementia is a progressive degenerative disease of brain. There is no definitive treatment for this disease till now. Under such circumstances, Amalakyadi ghrita with Vachadi ghrita nasya (Pratimarsha) may definitely be efficacious in the management of senile dementia and can enable the senior citizens to lead a healthy and happy life.
References

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Cont.


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