CLINICAL EVALUATION OF GUGGULU TIKTAKA GRITHA MATRAVASTI AND PRAVALAPISTI IN THE MANAGEMENT OF ASTHI KSHAYA W.S.R TO OSTEOPOROSIS

Vasu ray¹*, S. Ramalingeswara rao², J Srinivasulu²

¹PG Scholar, ²Reader, Dept. of Kayachikitsa, Dr.BRKR.Govt. Ayurvedic College & Hospital, Hyderabad, Telangana, India.

ABSTRACT

Ayurveda explains health as an equilibrium of the Dhatus “Dhatu Samyamorogata”. Among the Dhatus, Asthī is blessed with the function of Shareera Dhāranā. Any derangement in Asthī results in disease. Being the principle seat of Vata doshā, Asthī related Rogas generally show a Vata dominance in pathology. In Ayurveda both Vridhi and kshaya are mentioned as the pathological states of Dhāta. Osteoporosis can be placed under the spectrum of Asthikshaya. Classics mention the use of Vasti prepared with Tikta Dravya, Ksheera and Ghrita for the treatment of Asthī Kshaya. The present study was undertaken to assess the efficacy of Guggulu Tiktakagritha matravasti and Pravalapisti in the management of Osteoporosis. A total number of 10 patients were selected and treated with Matra vasti for a period of 1 days along with Pravalapisti 250mg (oral) B.D. The combined therapy of Vasti and Pravalapisti showed encouraging results in the subjective and objective parameters of Osteoporosis.

KEYWORDS: Asthī Kshaya, Osteoporosis, Matravasti, Pravalapisti.

INTRODUCTION

Ayurveda explains Human body as a congenial homeostasis of Dosha, Dhatus and Mala.[1] It highlights the importance of Dhatus and their related Srotases in the maintenance of positive health. Asthī dhatu which has the function of Dhāranā[2] carrying the weight of the body is directly related with the principal Dosa Vata. Being the principal seat of Vata dominance in pathology any derangement in Asthidhatu leads to different kinds of diseases.

In Ayurveda both Vridhi and Kshaya are mentioned as the pathological states of Dhāta.[3] Osteoporosis can be placed under the spectrum of Asthikshaya. Asthī Kshaya is a condition in which there will be Kshaya (diminution) of Asthī Dhatu (bone tissue). Asthī Kshaya may be compared to Osteoporosis, in which there is a decrease in bone mass leading to increased bone fragility and susceptibility to fractures. Osteoporosis is commonest condition affecting the older population. According to the principle of Ashraya Ashrayee Bhava[4] when Vata increases Asthī decreases because, Vata and Asthī are inversely proportional to each other. Hence the etiological factors of Vata Vriddhī are the etiological factors for Asthī Kshaya. In osteoporosis, the primary stage in the Sampratī is Vatakopa nidanas of the individual. While analysing the cause of vitiation of Asthīvāha srotas and Majja vahu srothas, it can be seen that Vatala aharas and Viruddha ahara play pivotal role in Asthī dhatu related diseases. Here the Vatala aharas represented the low nutrient diet which aggravated the bone reabsorption rate. The Viruddha ahāras impaire metabolic processes, hampering the Dhatwagnis. By the result of above mentioned pathogenetic factors the provoked Vata either by Dhatukshaya or by Margavarana enters the Rikta Asthīvāha Srotas and leads to Asthī Kshaya. The clinical features of Asthī Kshaya are Asthishula, Toda, and Sandhi Sthaithilya, Kesha, Loma, Nakha, Danta Vikara and Paata, Dourbalya, Rukshata etc.[5]

Ayurvedic treatments for osteoporosis mainly aim the improvement of Asthisara and Vataasama. Vataasama can be brought about by the proper administration of Snehana and Swedaṇa followed by the mild Shodana. Acharya Charaka suggests very special treatment for Asthikshaya.[6] According to this, the medicated Ksheera or Ghrita preferably by Tikta rasa dominant drugs are the first choice. The Vasti chikitsa by the above Ksheera-ghritas has unique role here. Tiktaras when combined with Ksheera or Ghrita will improve the Dritatatha of Asthidhatu.[7] For Asthivardhana, there should be the combination of Snigdhātha, Shosana and Kharathwa as explained by Arunadatta in Astangahrdaya,[8] Since there exists no drugs with all these properties, Acharya selected this combination of Ksheera or Ghrita with Tiktaras drugs. Vasti kalpana is the best treatment for the vitiated Vata doshā.[9] When Vata gets vitiated in its own related Dushya-Asthī the strength of the Samprapthī will be more severe. Hence medicated Vastikalpanas play a key role in the Samprapthivighatana of osteoporosis.

Osteoporosis is defined as “a progressive systemic skeletal disease characterized by low bone mass and micro architectural deterioration of bone tissue with a consequent increase in bone fragility and susceptibility to fracture”[10]

Epidemiology

Osteoporosis is a global dilemma that is expected to increase in significance with the growing elderly population. It affects both sexes and all races albeit to different degrees. Women are at high risk compare to men and the risk even increases at menopause, which is physiological transition period of hormonal imbalance.
The life time risk of osteoporotic fracture is 30- 40% in women and 13 -15% in men.[11]

The etiological factors of Osteoporosis are increasing age, sex hormone deficiency, Caucasian race, low body mass index (BMI), malnutrition (low Calcium diet), smoking, alcohol, prolonged corticosteroid therapy etc.[12] The treatment is mainly aimed at preventing further.

Bone loss, maintaining the bone mass, prevention of fractures, calcium and vitamin-D supplementation, hormone replacement therapy (HRT), and the use of certain drugs like Bisphosphonates, Selective Oestrogen Receptor Modulators (SERMs) and anabolic steroids etc. Use of HRT, Bisphosphonates, SERMS and anabolic steroids are not devoid of adverse effects.[13] Hence, it is need of the hour to carry researches for finding efficient, economic, natural and safer formulations to manage Osteoporosis. Ayurveda has got many time tested formulations for this condition.

Present formulation of Guggulu tiktaka gritha[14] has the ingredients of Tikta rasa pradhana dravyas which when made Samskara with Gritha helps in nourishing the Asthi dhatu and thereby gives strength to Asthi.

Pravala pisti[15] is the Samana dravya of Asthi dhatu. The chemical composition of Pravala pisti has rich source of Calcium, Phosphorous, Iron, Silicon, Magnesium, Sodium and potassium which gives strength and stability to the bones. Calcium and Phosphate may combine to form Calcium phosphate which is the major component of Bone mineral complex called as Hydroxyapatite.[16]

**Aims & Objectives**

1. To study Asthikshaya w.r.t Osteoporosis in the light of Ayurveda and Modern sciences.
2. To study the efficacy of Guggulu tiktaka gritha matra vasti and Pravala pisti in Asthikshaya.
3. To find out natural, safest and cost effective treatment measurement in the Osteoporosis.

**Materials & Methods**

**Source of data:** Patients attending the OPD and IPD of Kayachikitsa Department of Dr.BRKR Govt Ayurvedic Hospital, Hyderabad were selected for study.

**Criteria for Selection of Patients**

**Inclusion criteria**

- Patients presenting with the classical features of Asthi Kshaya vis-à-vis Osteoporosis
- Post-Menopausal women and Osteoporotic men were taken for the study
- Patients were selected between the age group of 40-60 years
- Patients of Osteoporosis diagnosed by B.M.D test (t-score < -2.5)

**Exclusion criteria**

- Patients below the age of 40 years and above the age of 60 years
- Patients suffering from pathological Osteoporosis and neoplasm of the bone
- Patients suffering from Diabetes Mellitus, Hyperparathyroidism, Paget’s disease, Thyrotoxicosis, Cushing’s syndrome, Endocrinal disorders and other serious systemic diseases were excluded

**Plan of study**

10 patients were selected for the study after properly diagnosed as Osteoporosis. Each patient was given (60-75 ml) of Guggulu tiktaka gritha matra vasti for 11 days continuously along with Pravalapisti 250mg (oral) twice in a day with Godhugdha as Anupana. The course of the study continued for 3 consecutive months. Results were assessed based on subjective and objective parameters before and after the treatment i.e. 90days.

**Investigations**

- Regular haematological tests like Hb%, TC, DC, E.S.R, RBS were performed to rule out systemic disorders.
- Serum phosphorus and serum calcium.
- BMD: to measure bone mineral density before and after the treatment, standard ultrasound bone densitometer was used.

**Follow up**

Patients were followed up for 3 months after the completion of treatment.

**Parameters of the study**

**Subjective parameters**

**Shula (Pain)**

- Grade 0 - No pain
- Grade 1 - Mild pain
- Grade 2 - Discomforting pain
- Grade 3 - Distressing pain
- Grade 4 - Horrible

**Sandhishtaithiyam**

- Grade 0 - No pain on walking
- Grade 1 - Mild pain but no difficulty in walking
- Grade 2 - Walking with moderate pain and difficulty
- Grade 3 - Walking with severe pain and difficulty
- Grade 4 - Unable to walk

**Sparshasahyata (Tenderness)**

- Grade 0 - No Tenderness
- Grade 1 - Mild tenderness without any sudden response on pressure
- Grade 2 - Wincing of face on pressure
- Grade 3 - Wincing of face and withdrawal of the affected part on pressure
- Grade 4 - Resist touch due to tenderness

**Effect on Regular Activities**

- Grade 0 - No difference/ Able to perform normal duties
- Grade 1 - Strain on performing normal activities
- Grade 2 - Not able to perform normal activities
- Grade 3 - Cannot perform even moderate activities
- Grade 4 - Unable to do mild activities

**Objective parameters**

- Bone Mineral Density (T-Score): WHO Criteria for assessing osteoporosis

Normal - 't' score greater than -1; Osteopenia -'t' score between -1 to -2.5; Osteoporosis - 't' score less than or
equal to -2.5 and severe osteoporosis - ‘t’ score less than -2.5 with fracture.

**Overall effect of therapy**
- Marked improvement: >75% to 100% improvement
- Good improvement: >50% to <75% improvement
- Moderate improvement: >25% to <50% improvement
- Poor improvement: <25% improvement

**Observations**
The following are the observations of the study.
Since it is a pilot study, a total number of 10 patients were selected. Out of 10 patients, 7 patients were in the age group of 50 to 60 years – 70%.
6 patients were female and all had attained menopause – 60%.
5 patients were house wife 83.3%.
8 patients (both men & women) have the chronicity of 2-4 yrs – 80%.
After Guggulu tiktaka gritha in the form of Matra vasti there is relief of symptoms like Asti Sula, Sparshasahayata, Dourbalya, Sandhisaisithilyam.

**Results**
The results were calculated on the basis of scoring pattern given for subjective and objective parameters before and after the treatment.

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>No. of patients</th>
<th>Mean</th>
<th>% of Relief</th>
<th>'p' Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>BT</td>
<td>AT</td>
<td></td>
</tr>
<tr>
<td>Shula</td>
<td>10</td>
<td>3.2</td>
<td>0.8</td>
<td>75.6</td>
</tr>
<tr>
<td>Sandhisaitihilyam</td>
<td>10</td>
<td>1.9</td>
<td>0.5</td>
<td>73.6</td>
</tr>
<tr>
<td>Sparhashayata</td>
<td>10</td>
<td>2.1</td>
<td>0.5</td>
<td>76.1</td>
</tr>
<tr>
<td>Effect on regular activities</td>
<td>10</td>
<td>2.2</td>
<td>0.5</td>
<td>77.2</td>
</tr>
</tbody>
</table>

Table 2: Effect of treatment on BMD (t-score)

<table>
<thead>
<tr>
<th>No. of Patients</th>
<th>Mean</th>
<th>% of Relief</th>
<th>'p' Value</th>
<th>t' Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT</td>
<td>AT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>-2.04</td>
<td>-0.74</td>
<td>63.7</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 3: Total effect of treatment

<table>
<thead>
<tr>
<th>Results</th>
<th>No. of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marked Relief</td>
<td>7</td>
<td>70%</td>
</tr>
<tr>
<td>Moderate Relief</td>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td>Good Relief</td>
<td>1</td>
<td>10%</td>
</tr>
<tr>
<td>Poor Relief</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

**DISCUSSIONS**

- *Asthi Kshaya* is explained in almost all texts of *Ayurveda* along with 18 types of *Kshayas*. [17]
- As explained in the *Nidana* aspect, both *Ayurveda* and Modern science consider old age as one of the causative factor of Osteoporosis. This age is said to be dominated by *Vata*, where *Dhatus* becomes *Kshina* along with *Indriya, bala* and *Virya* etc. [18]
- Higher incidence of Osteoporosis was noted in females, the reason being the total body bone mass in men is 2065gms which is greater than in women i.e., 2368gms and BMD is also 13 % higher in males compared to females.
- All the women in the study had attained menopause. Menopause is one of the risk factors of osteoporosis, because of sex hormone (estrogen) deficiency.
- Among *Panchakarma*, *Vasti* is the choice for *Vata* disorders. *Vasti* has direct effect on *Pakwashaya* (large intestine) and is also considered as *Purishadhara kala*. *Dalhana* opined that there is a definite relationship between *Purishadhara kala* and *Asthidhara kala*. [19]

Hence *Vasti* will be definitely helpful in reducing the symptoms of osteoporosis.

- *Giggulu tiktaka ghritam* contains *Tikta rasa pradhana* *dravyas*. *Tiktha rasa* is *Agnidipana* and it alleviates *Ama* (toxic substances) the increased digestive fire helps in maintaining the normal stage of *Dhatwagni*, so that the body tissues will be in equilibrium state. In this way *Tiktha rasa* helps in formation of *Samyak Asthi dathu*. *As Tiktka rasa* is predominately contains *Akasa* and *Vayu mahabhuta* [20]

- It can reach the subtle parts of the body, especially those parts having the similar *Mahabhuta* dominances like *Asthi dhatu* and can act at the level of bony tissue.

- *Guggulu* is Anti-inflammatory and analgesic drug which relieves pain and tenderness. [21]

- *Pravala Pisti* is given as a *Shamana dravya* in different *Asthivikaras*. It is a red colour fossil having many pores with irregular shape.

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**Table 4: The chemical composition of Pravalapisti**

<table>
<thead>
<tr>
<th>Components</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ca</td>
<td>44.60%</td>
</tr>
<tr>
<td>Mg</td>
<td>3.39%</td>
</tr>
<tr>
<td>Fe</td>
<td>688.6mg/kg</td>
</tr>
<tr>
<td>P</td>
<td>174.3mg/kg</td>
</tr>
<tr>
<td>Si</td>
<td>1584.8mg/kg</td>
</tr>
<tr>
<td>Na</td>
<td>3516.7</td>
</tr>
<tr>
<td>K</td>
<td>253.8</td>
</tr>
<tr>
<td>Mn</td>
<td>11.3</td>
</tr>
</tbody>
</table>

**CONCLUSIONS**

1. The common causative factors described for 18 types of *Kshayas* here been considered as the causative factors for *Asthihsaya* also.
2. As we know *Asthi* and *Vata* both are having *Ashraya-ashrayee bhava* relationship and both are reciprocal to each other, therefore anything which causes *Vata* aggravation will bring degenerative changes in *Asthi*.
3. The *Chikitsa* should be planned to bring normalization of aggravated *Doshas*. To remove *Avarana* by *Srothoshodana* and to normalize as well as increase the *Poshan* of *Asthi dhatu*.
4. *Guggulu tiktaka gritha matra vasti* along with *Pravala pisti* was found to be effective in obtaining very good results on all the parameters.
5. No untoward incidence was reported during treatment course.
6. It can be safely concluded that *Matravasti* with *Guggulu tiktaka gritha* and *Pravala pisti* is a natural safe and cost effective therapeutic measure in Osteoporosis.
7. However, further evaluation is necessary by conducting clinical trials on a large sample to come to a final conclusion.

**REFERENCES**

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*Address for correspondence
Dr. Vasu Ray
PG scholar
Pg dept of Kayachikitsa
Dr BRKR Govt. Ayurvedic College
Hyderabad – 500038
Email: drraivasu@gmail.com
Mob: 08019724103