EFFECT OF LAKSHA GUGGULU AND MUKTA SHUKTI PISHTI IN THE MANAGEMENT OF OSTEOPENIA/OSTEOPOROSIS W.S.R TO B.M.D AND S. CALCIUM

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ABSTRACT

Study design: A prospective study of 42 patients suffering from Osteopenia/ Osteoporosis (age ranging from 45-65 years) treated by Laksha Guggulu and Mukta Shukti Pishti. Place: S.D.M. College of Ayurveda and hospital Hassan – 573201 Duration: 84 days

Objectives: To assess the efficacy of Laksha Guggulu and Mukta Shukti Pishti in the management of Osteopenia/Osteoporosis. To assess the safety of Laksha Guggulu and Mukta Shukti Pishti in the management of Osteopenia/Osteoporosis.

Material and Methods: The 42 patients were selected randomly in the Out Patient Department.

Results: Duration of 84 days treatment has provide significant result with a value of 15.35 % in BMD, 3.39 % improvement in serum calcium after the treatment of Laksha Guggulu and Mukta Shukti Pishti. Conclusion: The Laksha Guggulu and Mukta Shukti Pishti significantly (p<0.001) improved the Bone Mineral Density significantly (p<0.001) in patients of Osteopenia/Osteoporosis (Asthi Kshaya).

KEYWORDS: Osteopenia, Osteoporosis, Laksha Guggulu, Mukta Shukti Pishti, Lukewarm water.
INTRODUCTION
Osteoporosis is a condition of major health importance because of its association with fractures. During the past decade, it has increasingly been perceived as a serious disabling disease needing substantial involvement of all medical sciences to develop and assess potential treatments. We, being the learners of great science of life-Ayurveda, it is our moral duty to apply this invaluable system of medicine to assist people in journey towards better health in the latter half of life and add quality to life.

In the contemporary science Osteopenia means decrease in the bone tissue. Osteoporosis is defined as “a progressive systemic skeletal disease characterized by low bone mass and loss of bone tissue that may lead to weak and fragile bones and increased risk for fracture of bones (broken bones), particularly in the hip, spine, and wrist”.[1]

Osteoporosis is a global dilemma that will increase in significance with the growing elderly population. The condition affects both the sexes and all races albeit to different degrees. Women are at high risk compared to men. The risk increases at menopause, which is a transition period of hormonal imbalance. Around the world, one in three women and one in five men over the age of 50 will experience an Osteoporotic fracture in their lifetime.[2, 3]

Osteopenia is a condition where bone mineral density is lower than normal (T score – 1.0 to -2.5). Osteoporosis has been operationally defined on the basis of bone mineral density (BMD) assessment. According to the WHO criteria, Osteoporosis is defined as a BMD that lies (T score of <-2.5 SD).[4]

In classics there is no direct reference regarding Osteopenia/Osteoporosis and its management. Acharya Sushruta in the context of Sushruta Sutra Sthana, 15th Chapter (Dosha Dhatu Mala Kshaya Vriddhineeyam Adhyayam).[5] had explained about Asthi Kshaya. Which causative factors, sign and symptoms are similar to the Osteopenia/Osteoporosis. Same is the opinion of different Acharya like Charaka, Vagbhata.[6, 7]

In Ayurvedic Pharmacopeia of India there is reference for management of Asthi Kshaya (Osteopenia/Osteoporosis) i.e. Laksha Guggulu, and in Siddha Yogasangraha i.e. Mukta Shukti Pishti. So this study has been included on both drugs.[8, 9]
Need for the study
The incidence of Osteoporosis is high in Indian people because of lack of awareness and inadequate calcium intake. Bone loss is only partly reversible. Currently, no treatment exists to reverse established Osteoporosis. Prevention and early intervention can prevent Osteoporosis in majority.

Patients were registered by organising free Osteoporosis diagnostic camps in the hospital of the S.D.M. College of Ayurveda and Hospital Hassan. Standard FDA approved Mc Cue CUBA clinical Ultrasonic Bone Sonometer was used for analysing the bone mineral density (BMD). A survey of 79 patients was carried out to study the incidence of Osteopenia/Osteoporosis in and around Hassan.

Aim and Objectives
1. To assess the efficacy of Laksha Guggulu and Mukta Shukti Pishti in the management of Osteopenia/Osteoporosis.
2. To assess the safety of Laksha Guggulu and Mukta Shukti Pishti in the management of Osteopenia/Osteoporosis.

NAME AND ADDRESS OF THE SPONSOR

Study design
A prospective observational clinical study was undertaken on 42 patients.

Source of Data
42 Patients were selected from outpatient and inpatient department of P.G.Studies in Shalya Tantra, S.D.M. college of Ayurveda and Hospital, Hassan.

Methods of Collection of Data
Patients were registered with the help of research proforma prepared for the study.
Diagnostic Criteria
Diagnosis were made on the basis of Lakshanas of Osteoporosis like back pain, fracture of axial skeleton, compression of thoracic vertebrae, loss of height, wrist fractures, rib fractures, loss of bony trabeculae and thinning of cortices.\(^{[10]}\)

Inclusion Criteria
- Patients of both sexes above 45 years and below 65 years.
- Patients with Osteopenia or spinal deformities in spine x-rays.
- Patients with history of Osteoporosis related fractures.
- Quantitative calcaneal ultrasound, ‘T’ score > -1.0.
- Assessed using the DEXA scan or calcaneal/wrist ultrasound
- Willing and able to participate for 16 weeks.

Exclusion Criteria
- Age below 45 and above 65 years.
- Hypoparathyroidism/Hyperparathyroidism, Hypothyroidism/Hyperthyroidism
- Malabsorption syndrome and Pregnant or lactating woman.
- Patient whose serum ca++ level < 2.2 or > 2.6 mmol/l (< 9 or > 10.5mg/dl).
- Any metabolic bone disease e.g. Paget’s disease, Psycho-Neuro-Endocrinal disorder, Rheumatoid arthritis, Osteomalacia, Dysosteogenisis imperfecta Marfan’s syndrome, Cushing’s syndrome or hyperprolactinemia.
- Patient with history of fragility fracture and Long bone fracture in last 6 months.
- Chronic liver disease, Chronic renal failure (GFR < 30ml/min/1.73m\(^2\)) and uncontrolled Pulmonary Dysfunction.
- Organ transplantation and evidence of malignancy.
- Prolonged immobilization (≥ 6 weeks).
- Alcoholics/drug abusers and hypersensitivity to any of the trial drugs.
- H/O Atrial fibrillation, Acute coronary syndrome, Myocardial Infarction, stroke or Severe Arrhythmia in last 6 months and clinical evidence of heart failure.
- Uncontrolled diabetes mellitus (HbA1c>10%).
- Patient under any drug which is known to affect bone metabolism (SERMs,) Bisphosphonates, Calcitonin, Vitamin-D and corticosteroids for more than 3month.
- Any other condition which the P.I thinks may jeopardize the study.
Drugs used for Osteopenia/Osteoporosis:

1. **Laksha Guggulu**[^11]
   - **Dose**: 1 gm (2 tablets of 500 mg) twice daily
   - **Dosage form**: Tablet of 500 mg
   - **Route of Administration**: Oral
   - **Time of Administration**: Twice a day after food
   - **Anupana**: Lukewarm water
   - **Packing form**: A bottle of 30 gm (containing 60 tablets of 500 mg each)
   - **Duration of therapy**: 12 weeks

2. **Mukta Shukti Pishti**[^12]
   - **Dose**: 250 mg twice daily
   - **Dosage form**: Capsule of 250 mg
   - **Route of Administration**: Oral
   - **Time of Administration**: Twice a day after food
   - **Anupana**: Lukewarm Water
   - **Packing form**: A plastic jar of 7.5 gm (Containing 30 capsules of 250 mg each)
   - **Duration of therapy**: 12 weeks

**Medicine Preparations**
Details as raw material were subjected to standard test as per the standard criteria mentioned in API and Siddhayagosangraha.

**Formulation composition of Laksha Guggulu**
1. Laksha (API) Laccifer lacca Res. Enc. 1 Part
2. Asthisamharaka (API) Cissus quadrangularis St. 1 Part
3. Kakubha (Arjuna API) Terminalia arjuna St. Bk. 1 Part
4. Ashvagndha (API) Withania somnifera Rt. 1 Part
5. Nagabala (API) Sida veronicaefolia Ar. Pt. 1 Part
6. Guggulu (API) Shuddha Commiphora wightii O.R. 5 Parts

**Formulation composition of Mukta Shukti Pishti**
Mukta Pishati, Shukti Pishti and Nimbu Rasa
Manufactured by: Dabur Research & Development centre 22, Site IV, Ghaziabad, U.P., India for central council for research in Ayurveda & Siddha (CCRAS).

OBSERVATION AND RESULTS

TABLE 10 AGE WISE DISTRIBUTIONS OF 42 PATIENTS

<table>
<thead>
<tr>
<th>Age</th>
<th>Total No. Of Patient</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>45-50</td>
<td>21</td>
<td>50%</td>
</tr>
<tr>
<td>50-55</td>
<td>8</td>
<td>19.05%</td>
</tr>
<tr>
<td>55-60</td>
<td>7</td>
<td>16.66%</td>
</tr>
<tr>
<td>60-65</td>
<td>6</td>
<td>14.29%</td>
</tr>
</tbody>
</table>

Majority of the patients i.e. 50 % belonged to the age group of 45-50 years, where as 19.05 % of patients were between the age group of 50-55 16.66 % were from 55-60 years and 14.29% were from 60-65 years of age group.

TABLE 11 SEX WISE DISTRIBUTIONS OF 42 PATIENTS

<table>
<thead>
<tr>
<th>Sex</th>
<th>Total no.</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>17</td>
<td>40.48%</td>
</tr>
<tr>
<td>Female</td>
<td>25</td>
<td>59.52%</td>
</tr>
</tbody>
</table>

From the total number of patients, 40.48 % were male and 59.52 % are female.

TABLE 19 PHYSICAL EXERCISE WISE DISTRIBUTIONS OF 42 PATIENTS

<table>
<thead>
<tr>
<th>Work</th>
<th>Total no.</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heavy labour</td>
<td>28</td>
<td>66.67%</td>
</tr>
<tr>
<td>Moderate labour</td>
<td>10</td>
<td>23.81%</td>
</tr>
<tr>
<td>Office job</td>
<td>4</td>
<td>9.52%</td>
</tr>
</tbody>
</table>

Observation on the habit of physical exercise shows that maximum number of patients is doing heavy labour work i.e. 66.67 %, 23.81 % of patients were doing moderate labour work and were 9.52 % of patients are doing office job.

TABLE 23 DISEASE WISE DISTRIBUTIONS OF 42 PATIENTS

<table>
<thead>
<tr>
<th>Disease</th>
<th>Total No.</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteopenia</td>
<td>26</td>
<td>61.90%</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>16</td>
<td>38.10%</td>
</tr>
</tbody>
</table>

Disease of all the registered patients indicated that maximum number of patients were of Osteopenia i.e. 61.90 %, 38.10 % patients were of Osteoporosis.
EFFECT OF THERAPY ON MARKERS OF BONE FORMATION IN
42 PATIENTS OF OSTEOPOROSIS

<table>
<thead>
<tr>
<th>Markers</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>% of Change</th>
<th>SD</th>
<th>SE</th>
<th>T value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. calcium</td>
<td>8.55</td>
<td>8.26</td>
<td>3.39%</td>
<td>0.85</td>
<td>0.13</td>
<td>2.22</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>S. Alk. phosphate</td>
<td>66.6</td>
<td>70.16</td>
<td>-5.35%</td>
<td>20.16</td>
<td>3.11</td>
<td>-1.15</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

There was no result in serum calcium statistically (p<0.05) found in the patients after therapy was statistically insignificant but result was found in levels of serum alkaline phosphatase. (p<0.001).

TABLE 25 EFFECT OF THERAPY ON MARKERS OF BONE FORMATION IN
42 PATIENTS OF OSTEOPOROSIS

<table>
<thead>
<tr>
<th>B.M.D</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Difference mean</th>
<th>% of relief</th>
<th>SD</th>
<th>SE</th>
<th>T value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>t score</td>
<td>-2.21</td>
<td>-1.87</td>
<td>0.34</td>
<td>15.35%</td>
<td>1.37</td>
<td>0.21</td>
<td>-3.01</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Increased levels of BMD (15.35 %) found in the patients after therapy was statistically significant at p<0.001.

CONCLUSION
1. The effect of Laksha Guggulu and Mukta Shukti Pishti on these Lakshana like pain, activity of daily living, jobs around the house, mobility, leisure, social activity, general health perception, mental function was better i.e. statistically highly significant(p<0.001) in the management of Osteopenia/Osteoporosis (Asthi Kshaya).
2. The Laksha Guggulu and Mukta Shukti Pishti significantly (p<0.001) improved the quality of life (QUALIFFO-41) in patients of Osteopenia/Osteoporosis (Asthi Kshaya).
3. The therapies improved the Bone Mineral Density significantly (p<0.001) and(p<0.05) improvement in serum calcium which indicates beneficial effect in the management of Osteopenia/Osteoporosis (Asthi Kshaya).

Effect of the Treatment
Duration of 84 days treatment has provide significant result with a value of 15.35 % in BMD improvement after the completion of treatment of Laksha Guggulu and Mukta Shukti Pishti in the management of Osteopenia/Osteoporosis (Asthi Kshaya).
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12. Siddhayogasamgra 3rd chapter Page no. 298-299.