



Management Of Asthikshaya (Osteopenia /Osteoporosis) By Laksha Guggulu And Mukta Shukti Pishti

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Abstract:

Osteoporosis is 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. Osteopenia is considered to be a precursor to osteoporosis. In India, osteoporosis is emerging as an important public health problem with increasing numbers of elderly. In Ayurveda under the heading “Asthi kshaya” many signs and symptoms described can closely be correlated with this clinical entity. Laksha guggulu & Mukta shukti pishti are in practice for the disorder of the Asthivaha Srotasa. So clinical trial was undertaken in 45 patients of Osteopenia/Osteoporosis to evaluate the efficacy and safety of Laksha guggulu and Mukta shukti pishti in the management of Osteopenia/Osteoporosis. Result of the study were encouraging. All the points will be discussed in full paper.

Key words- Osteopenia, Osteoporosis, Laksha guggulu, MuktaShukti Pishti, Asthikshaya, Asthivah Srotasa

Introduction :

Osteopenia is a condition where bone mineral density is lower than normal. It is considered by many doctors to be a precursor to osteoporosis. More specifically, Osteopenia is defined as a Bone Mineral Density T score - 1.0 to - 2.5.¹ 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 -2.5 standard deviation or more below the average value for young healthy women (T score of <-2.5 SD).² In other words Osteoporosis is defined as “a systemic skeletal disease characterized by low bone mass and micro-architectural deterioration of bone tissue leading to enhanced bone fragility and a consequent increase in fracture risk”.³

In Ayurveda under the heading “Asthi kshaya” many signs and symptoms described can closely be correlated with this clinical entity⁴. Osteoporosis is a global health problem which may become more serious as people live longer. The condition even though affects both the sexes; women especially post-menopausal are at greater risk. One in three women and one in five men over the age of 50 will experience osteoporotic fracture in their lifetime⁵. Even Osteopenia/osteoporosis is global problem; by 2050 more than 50% of all osteoporotic fractures will occur in Asia. In India, osteoporosis is emerging as an important public health problem with increasing numbers of elderly⁶. About 26 million Indians suffer from osteoporosis and this number is expected to reach 36 million by 2013.

Aims And Objectives Of The Study

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.
3. To assess the impact of the disease on the quality of life of the ailing population.

Materials And Methods

Study design- A prospective observational clinical study was undertaken on

50 patients. Source of Data:

50 Patients were selected from outpatient and inpatient P.G.department of ShalyaTantra,

National institute of Ayurveda Jaipur.5 patients were drop out due to discontinuation of follow up.

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.

Inclusion Criteria:

- Patients of both genders 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, Dysosteogenesis 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/1.73m²) 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.

Drugs used for Osteopenia/Osteoporosis:

1. Laksha Guggulu⁷

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 Pishti⁸

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

Laboratory

Examinations:

BMD-T score,

X-ray-Lumbo sacral Spine-Antero

posterior/lateral view, Haematology:

Haemoglobin (%), T.L.C. D.L.C,E.S.R., Blood Sugar: Fasting,

Bio-chemistry:

Blood Urea, Serum Uric Acid, Serum Creatinine, S.G.O.T. (A.S.T.), S.G.P.T. (A.L.T.), Total protein, S. Albumin, S. Globulin, A/G ratio, Conjugated bilirubin, Unconjugated bilirubin, Serum Alkaline Phosphatase, Total Cholesterol, Low Density Lipoprotein (LDLc), High Density lipoprotein (HDLc), Very Low Density Lipoprotein (VLDL), Serum Triglycerides, Serum Calcium, Electrocardiography (ECG).

Outcomes

Primary Outcome Measure:

Change in Quality of Life index (QUALEFFO-41) ref

Secondary Outcome Measures:

Change in Bone Mineral Density (T-score)

RESULTS

Table No2.EFFECT OF THERAPY ON QUALEFFO-41 SCORE AFTER TREATMENT

Symptoms	Mean BT	Mean AT	Difference mean	% of relief	SD	SE	T value	P value
Pain	51	42.11	8.889	17.43	6.733	1.004	8.857	<0.001
Activity of daily living	17.5	15	2.5	14.29	3.096	0.462	5.416	<0.001
Jobs around the house	26.67	21.67	5	18.75	6.124	0.913	5.477	<0.001
Mobility	27.78	24.23	3.544	12.76	2.546	0.38	9.338	<0.001
Leisure, social activity	78.68	68.65	10.03	12.74	7.096	1.058	9.479	<0.001
General health perception	62.03	42.59	19.44	31.34	11.78	1.757	11.07	<0.001
Mental function	56.65	51.27	5.381	9.498	4.615	0.688	7.821	<0.001
Total score	46.97	40.03	6.942	14.78	3.25	0.484	14.33	<0.001

Table No. 3 EFFECT OF THERAPY ON BMD T SCORE

BMD	Mean BT	Mean AT	Difference mean	% of relief	SD	SE	T value	P value
T Score	-2.674	-1.708	-0.966	36.13	0.768	0.115	8.436	<0.001

Increased levels of BMD (36.13 %) found in the patients after therapy was

Discussion

The statistical data of present research work have shown that 55.55% patients belongs to age groups 45 to 50 yrs & 26.66% belong to age group 50- 55 yrs. The probable reason for it may be that after the age of 45 during the process of bone remodelling bone resorption over shadows the speed of bone formation . The rate of bone resorption increases after the age of 50 years in both genders and it is more in females due to postmenopausal effects⁹. In the persons of old age the dhatuagnimandta particularly for the formation of Asthi dhatu may be held responsible for this¹⁰. This very fact is accepted in modern as well as Ayurvedic science.

In present study, maximum number of patients were male i.e. 51.11% followed by female (48.89%) though as per the previous studies Osteopenia/Osteoporosis is more common in females. Higher incidence was observed in males because most of them were above the age of 55 and had addictions like alcohol,tobacco-chewing & smoking, which are common factors responsible for increased incidence of Osteopenia/Osteoporosis in them in this study. Another factor like Females being less conscious about their periodic health check up like BMD, scanning in this case. Females were 48.89%, most of them belongs to age group 45-55yrs.this was observed in female because of low peak bone mass and postmenopausal effects.

In the present series of 45 registered cases the affliction of the disease was found more who were engaged in desk work i.e. 48.89%, followed by house wives 40%, & field work with physical labour 11.11%. The reason may be the less physical activities associated with desk job & housekeeping.

The majority of cases registered for the current trial, belonged to graduate section 28.88% followed by 22.22 uneducated, 20% higher secondary 15% high school,8.88% of primary level & 4.44% middle level. This may be attributed to less physical activities in graduates who are mostly engaged in desk work. Lack of education in the illiterates can be related with the inappropriate knowledge of proper eating habits and lifestyle which is beneficial for bone health.

Maximum numbers of patients i.e. 77.77% were vegetarians while remaining 22.23% patients were taking mixed diet. This may be due to the fact that high protein contains (Non-veg) tending to increase absorption of calcium from the diet and are associated with higher bone

density.

Addiction wise distribution shows that 2.22 % of patients had addiction of alcohol, 8.88 % of patients had addiction of tobacco chewing and 4.44 % patients had addiction of smoking and rest 84.44% patients having no addictions. It seems that the Alcohol, smoking & tobaccos are responsible for decreased bone density as well as earlier progression of disease.

Vatapitta Prakruti was observed in 82.22% of patients and Vatakapha Prakruti 17.78 % of patients. Vata & Asthi both are having the Ashraya -Ashrayi bhava. Vata prakriti person when took the Vatala Ahara-vihara then it easily provoked the Vata which in the further stage may degenerate the Asthi Dhatu due its qualities. Vata along with pitta increases asthyagni and hence excessive degeneration of bones. This study suggests that Vata plays a major role in the manifestation of the disease independently and along with kapha it causes srotorodh and improper formation of Asthi as Asthi dhatu poshakansh does reaches to asthivaha srotas¹⁰ and hence proper bone remodeling does not occur.

Out of all the registered patients maximum number of patients (55.56%,) were having Osteoporosis followed by 44.44% patients having Osteopenia. It may be due to the reason that previously diagnosed cases are comparatively more conscious about the particular screening camp (BMD).

Discussion On Results:

1. Effect on BMD T-Score:(Table No.-2)

Duration of 84 days treatment has provided significant improvement in BMD with a value of 36.13% .This may be attributed to combined therapy with Mukta shukti pishti & Laksha Guggulu. Mukta shukti pishti is the proven source of calcium (90-92% calcium carbonate). The ingredients of Laksha guggulu, Arjuna, laksha and Ashtishrinkhala, are also again the good source of calcium & other minerals. It reveals that combined therapy is having some definite role in Ashtisandhana as well as bone remodeling¹¹.

2. Effect on QUALEFFO-41 Score: (Table No.-3)

After the completion of treatment (84 days) 17.43% improvement is found in pain,14.29% in activity of daily living,18.75% in jobs around the house,12.76% in mobility,12.74% improvement seen in leisure social activities,34.34% in general health,9.498% in mental functions,14.78% in total score of QUALEFFO-41.This may be due to collective, cardio-protective, anti-inflammatory,analgesic, anti-bacterial, anti-aging, anti-stress, fibrinolytic, anti-osteoporotic ,fracture healing,anti tumour, hypo-lipidemic,adaptogenic, immune stimulatory, psycotropic, hepatoprotective and cytoprotective properties of ingredients of combined therapy with mukta sukti pristi¹² and Laksha guggulu¹³.

Discussion Regarding Probable Mode Of Action Of Study Drugs:

Discussion on the Laksha Guggulu:

Laksha Guggulu Vati is a preparation having Guggulu as the basic ingredient along with Laksha, Asthisamhari, Nagabala, Aswagandha and Arjuna¹³. The predominant rasa of the drugs were Madhura and Tikta. Madhura rasa having the quality of Brimhana, Asthi avivardhana, Kshata Sandhanakara¹⁴ and Pinana (Roborant nutritive effect on the particular tissue) & it also mitigate the Vata Dosha and on the other hand Tikta rasa having the effect of srota shodhaka which may able to destroy avarana janya srotarodha. Apart from this they may act as Rasayana, Balya, Dhatu Poshaka and Asthi Sandhankara for their Prabhava. Pharmacologically, the component are also proved for their anti-inflammatory, analgesic, fracture healing, adaptogenic, immune-modulatory, phyto-estrogenic and anti-osteoporotic activities. Mukta Shukti pristi also having the quality like madhura rasa , sheeta guna & Virya having some role in the roborant nutritive effect on particular tissue in the form of effective & proven calcium supplement¹⁵.

CONCLUSION

The effect of Laksha Guggulu and Mukta Shukti Pishti on pain, activities of daily living, jobs around the house, mobility, leisure, social activities, general health perception, mental functions (QUALIFFO-41) were encouraging i.e. statistically highly significant($p < 0.001$) in the management of Osteopenia/Osteoporosis (Asthi Kshaya).

The therapy improved the Bone Mineral Density significantly ($p < 0.001$) which indicates its effectiveness in the management of Osteopenia/Osteoporosis (Asthi Kshaya).

Hence, Laksha Guggulu and Mukta Shukti Pishti is found to be effective & Safe in the management of Osteoporosis/Osteopenia (Asthikshaya) .

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