

CLINICAL EVALUATION OF LAKSHA GUGGULU AND MUKTA SHUKTI PISHTI IN THE MANAGEMENT OF OSTEOPENIA/ OSTEOPOROSIS

Dr. Brijesh Singh^{*1}, Dr. Gopikrishna B.J², Dr. P.Hemantha Kumar³

¹Assistant Professor, Department of Shalya Tantra, Uttaranchal Ayurvedic College, Rajpur, Dehradun, Uttarakhand, India.

²H.O.D, Department of Shalya Tantra, S.D.M. College of Ayurveda and hospital Hassan Karnataka, India.

³H.O.D, Department of Shalya Tantra, N.I.A Jaipur, Rajsthan, India.

ABSTRACT

Article Received on
30 June 2015,

Revised on 24 July 2015,
Accepted on 19 Aug 2015

*Correspondence for Author

Dr. Brijesh Singh

Assistant Professor,
Department of Shalya
Tantra, Uttaranchal
Ayurvedic College,
Rajpur, Dehradun,
Uttarakhand, India.

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 44.22 % improvement in pain, 31.79 % in activity of daily living, 23.42 % in job around the house, 15.93 % in mobility, 11.99 % improvement seen in leisure social activity, 40.81 % in

general health, 16.37 % in mental function and 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 quality of life (QUALIFFO-41) and 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 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 compare 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 life time.,^[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

Central Council for Research in Ayurveda and Siddha (C.C.R.A.S.), Jawahar Lal Nehru Bhartiya Chikitsa Evam Homoeopathy Anusandhan Bhawan 61-65, Institutional Area, Opposite D-Block, Janakpuri, New Delhi-110058

Under Department of AYUSH, Ministry of Health & Family Welfare, Government of India, IRCS Building, 1, Red Cross Road, New Delhi – 110001

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.
- Improve in quality of life (QUALIFFO-41)
- 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 > 10.5 mg/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 ($\text{GFR} < 30 \text{ ml/min/1.73m}^2$) 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 ($\text{HbA1c} > 10\%$).
- 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

Age	Total No. Of Patient	Percentage
45-50	21	50%
50-55	8	19.05%
55-60	7	16.66%
60-65	6	14.29%

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

Sex	Total no.	Percentage
Male	17	40.48%
Female	25	59.52%

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

TABLE 19 PHYSICAL EXERCISE WISE DISTRIBUTIONS OF 42 PATIENTS

Work	Total no.	Percentage
Heavy labour	28	66.67%
Moderate labour	10	23.81%
Office job	4	9.52%

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.

Disease	Total No.	Percentage
Osteopenia	26	61.90%
Osteoporosis	16	38.10%

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.

TABLE 26 EFFECT OF THERAPY ON IMPROVEMENTS ON QUALIFFO-41 IN 42 PATIENTS OF OSTEOPOROSIS

Symptoms	Mean BT	Mean AT	Difference mean	% of relief	SD	SE	T value	P value
Pain	15.83	8.83	7.0	44.22%	2.36	0.36	19.24	<0.001
Activity of daily living	8.21	5.6	2.61	31.79%	2.09	0.32	8.10	<0.001
Jobs around the house	10.76	8.24	2.52	23.42%	2.34	0.36	6.33	<0.001
Mobility	17.76	14.93	2.83	15.93%	2.56	0.39	7.18	<0.001
Leisure, social activity	20.02	17.62	2.4	11.99%	1.88	0.29	7.06	<0.001
General health perception	9.90	5.86	4.04	40.81%	1.01	0.16	25.95	<0.001
Mental function	28.90	24.17	4.73	16.37%	3.34	0.52	9.37	<0.001
Total score	110.97	85.22	25.75	23.25%	9.49	1.47	17.59	<0.001

Duration of 84 days treatment has provide significant result with a value of 44.22 % improvement in pain, 31.79 % in activity of daily living, 23.42 % in job around the house, 15.93 % in mobility, 11.99 % improvement seen in leisure social activity, 40.81 % in general health, 16.37 % in mental function and 3.39 % improvement in serum calcium after the treatment of Laksha Guggulu and Mukta Shukti Pishti 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).

Effect of the Treatment

Duration of 84 days treatment has provide significant result with a value of 44.22 % improvement in pain, 31.79 % in activity of daily living, 23.42 % in job around the house, 15.93 % in mobility, 11.99 % improvement seen in leisure social activity, 40.81 % in general health, 16.37 % in mental function improvement after the completion of treatment of Laksha Guggulu and Mukta Shukti Pishti in the management of Osteopenia/Osteoporosis (Asthi Kshaya).

ACKNOWLEDGEMENT

It is an inexplicable to offer my sincere & respectful regards to the persons whom I admire the most, my beloved father **Sri. Rajendra Bahadur Singh**, mother **Smt. Asha Singh** who's Blessings, affection and inspiration reflected in me in the present position. It gives me immense pleasure to offer profound gratitude to my beloved Principal Prof. **Dr. Prasanna Narasimha Rao** for all his guidance & co-operation in this work as well as throughout.

I am thankful to all my teachers, peer research scholars, non-teaching staff and hospital staff for their affection, timely help and co-operation throughout my research. The co-operation shown by my patients, the foundation bricks of this work is not at all forgettable as they followed up throughout the work.

REFERENCES

1. <http://www.emedicinehealth.com/script/main/art>.
2. Melton LJ 3rd, Artinson EJ, O'Connor MK, et al. Bone density and fracture risk in men. J Bone Miner Res., 1998; 13: 1915.
3. Melton LJ 3rd, Chrischilles EA, Cooper C, et al. Prospective. How many women have osteoporosis? J Bone Miner Res., 1992; 7: 1005.
4. Assessment of fracture risk & its application to screening for postmenopausal osteoporosis – Report of W.H.O Study Group Geneva, 1994 (WHO Technical Report Series, No.843).
5. Sushruta Samhita, with the Nibandhasangraha commentary of Sri Dalhanacharya, edited by Vaidya Yadavji Trikamji Acharya, Chaukhambha Sanskrit Sansthan, Varanasi, 4th edition, 1980. Sutra Sthana 15/13.
6. Agnivesha - Charaka Samhita revised by Charaka & Dridhbala, with Ayurveda Dipika commentary by Chakrapanidatta, edited by Vaidya Yadavaji Trikamji Acharya, Chaukhambha Sanskrit Sansthan, Varanasi, 5th edition, 2001. Sharira Sthana 3/7

7. Vagbhata – Astanga Hridayam with commentaries Sarvangasundara of Arunadatta and Ayurvedarasayana of Hemadri, edited by Pt. Bhisagachara Harishastri Paradkar Vaidya, Krishnadas Academy, Varanasi, 2000, Sutra Sthana 11/29
8. The Ayurvedic Pharmacopoeia of India Part II–Vol. - II Pg.117-118.
9. Siddhayogasamgra 3rd chapter Page no. 298-299.
10. Watson-Jones Fractures and Joint Injuries-Edited By J.N.Wilson. Volume 1st Edition: 6th, 14th Chapter Page No.297
11. The Ayurvedic Pharmacopoeia of India Part II–Vol. - II Pg.117-118.
12. Siddhayogasamgra 3rd chapter Page no. 298-299.