IAMJ

INTERNATIONAL AYURVEDIC MEDICAL JOURNAL

Research Article ISSN: 2320-5091 Impact Factor: 6.719

A CLINICAL TRIAL ON THE EFFECT OF AN AYURVEDIC FORMULATION IN THE MANAGEMENT OF OSTEOPOROSIS

BeegumYasmina Hussain

Santhigiri Ayurveda Medical College, Institution where the study was conducted: Government Ayurveda Medical College, Thiruvananthapuram, Kerala, India

Corresponding Author:yasminahussain43@gmail.com

https://doi.org/10.46607/iamj1210082022

(Published Online: August 2022)

Open Access

Article Received:27/07/2022 - **Peer Reviewed:** 08/08/2022 - **Accepted for Publication:** 12/08/2022

Check for updates

ABSTRACT

The World Health Organization operationally defines osteoporosis as a bone density that falls 2.5 standard deviations (SD) below the mean for young healthy adults of the same sex- also referred to as a T-score of -2.5. It is prevalent in post-menopausal women but also occurs in men and women with underlying conditions or major risk factors associated with bone demineralisation. Osteoporotic fractures are a major cause of morbidity and disability in the elderly and case of hip fractures, they can lead to premature death also. In addition, they impose a considerable economic burden on health services. Through *Ayurveda*, it can be explained as '*AsthiSaushirya'* one of the symptoms of *Majjakshaya*. It can also be correlated as *Asthigatavata* with resultant *Asthikshaya* and finally ends in *Asthisaushirya*. Drugs having *Rasayana, Brimhana*, and *Sandhaneeya* properties can be well applicable for the management of this condition. The study drug *Lakshamadhuka churna*, one of the formulations mentioned in *Bhaishajya Ratnavali Bhagna Chikitsa* is given in the dose of 6g mixed with 12ml *Ghrita* followed by the intake of 24ml *Ksheera* morning on empty stomach for a period of 90 days. The evaluation was done on the 0^{th}, $91^{st,}$ and 130^{th} days. The results were statistically analysed by Wilcoxon signed rank test and paired 't-test. The trial drug was found to be significant with a p value less than 0.001 ($p<0.001$) in BMD and also significant in reducing the signs and symptoms of osteoporosis.

Keywords: Osteoporosis, *Lakshamadhukachurna*, *Asthisoushirya*

INTRODUCTION

Osteoporosis is a common metabolic bone disease characterised by reduced bone mass and micro architectural deterioration in bone tissue that results in increased susceptibility to fragility fractures. The World Health Organization operationally defines osteoporosis as a bone density that falls 2.5 standard deviations (SD) below the mean for young healthy adults of the same sex- also referred to as a T-score of -2.5[1]. Post-menopausal women are at increased risk of osteoporosis and the importance of osteoporosis can be gauged by the fact that a woman's lifetime risk of hip fracture equals the combined risk of breast, uterine, and ovarian cancer. The risk of dying from hip fracture equals mortality from breast cancer.[2] Men too are not spared, they account for nearly 20-30% of all hip fractures and one-third of them will not survive more than one year.[3] Genetic predisposition, menopause, and old age are the main cause of primary osteoporosis. The disease also occurs secondary to other diseases like Cushing's syndrome, type 1 diabetes, inflammatory bowel disorders, mal absorption syndrome etc. Among drugs steroids, mainly glucocorticoids, anticonvulsants, and anticlotting agents like heparin, diuretics etc. also result in osteoporosis.[4,5] The most common complaint of osteoporosis is back pain of acute onset and with great intensity which often reflects an underlying compression fracture of a vertebral body, mostly twelfth thoracic and first lumbar vertebrae. In some patients, it presented as a gradual onset of height loss and kyphosis with chronic vague muscular pain and aches. The term dowager's hump or widow's hump is used to denoting the dorsal kyphosis with exaggerated cervical lordosis brought about by vertebral compression.The investigative procedures of osteoporosis are X-ray; Quantitative computed tomography, Quantitative ultrasound, Single energy x-ray absorptiometry, Magnetic resonance imaging, Bone Scanning, and Dual-energy x-ray absorptiometry (DXA). Pharmacological therapy mainly includes hormone replacement therapy. Cyclical hormone replacement therapy with estrogen and progestogen prevents postmenopausal bone loss and reduces the risk of fractures. Administration of estrogen has long-term side effects like endometrial cancer, breast cancer, venous thrombo embolism, coronary heart disease, and Alzheimer's disease. Selective Estrogen Receptor Modulators (SERMs), bisphosphonates, calcitonin, parathyroid hormone, calcium & vitamin D, fluoride, alfacalcidol, and anabolic steroids are also applicable.[6]
In *Ayurveda* Osteoporosis, the disease causes increased porosity of bone (*Asthisoushirya*) is well explained as one of the symptoms in *Majjakshaya(depletion of majja dhatu)*. It can also be considered as a disease characterized by localisation of vitiated *Vata* in *Asthi dhatu* ie, '*Asthigatavata'* resulting in *Asthikshaya*(depletion of *Asthi dhathu*) and ultimately ends in *Asthisoushirya* in a long course. Many formulations mentioned in the classical texts of ayurveda are found to be effective in this clinical condition. This study aims to revalidate one of the formulations mentioned in *Bhaishajyaratnavali Bhagna Chikitsa*.[7, 8]

The objective of the study: To evaluate the effect of *Lakshamadhuka Churna* in Osteoporosis.

The study drug consists of two drugs: *Laksha (Laciferlacca*), *Madhuka (Glycrrhiza glabra)*

Study design: Interventional study - One group pre-test post-test design- Quasi-experiment.

Study setting: OPD and IPD of Department of *Kayachikitsa*, Govt. Ayurveda College Hospital, Thiruvananthapuram.

Study population: Male and female patients attending the OPD and IPD of the department of *Kayachikitsa*, Government Ayurveda College, Thiruvananthapuram in the age group 40 to 60 years diagnosed with osteoporosis as clinically and as per BMD.

Inclusion criteria: Male and female patients in the age group 40 to 60years diagnosed with Osteoporosis clinically and as per BMD.

Exclusion criteria

- Diagnosed case of osteogenesis imperfecta, hyperthyroidism, hyperparathyroidism, and rheumatoid arthritis.

- Patients with a known history of chronic liver disease, malignancies, tuberculosis, and cardiac disorders.
- Patients on prolonged treatment with corticosteroids.
- Patients with a known history of major psychiatric diseases.
- Pregnancy and lactation.

Sample size: Twenty-two patients satisfying the selection criteria were entered into the study.

Sampling technique: Sequential sampling satisfies inclusion and exclusion criteria till attaining sample size.

Study tools

- Detailed clinical research proforma.
- BMD.

Ethical consideration: While conducting this study, a copy of the informed consent from the patient and clearance from IEC were obtained. The patient who had difficulties in being part of the study was taken as drop out and was directed to conventional treatment.

Intervention

The study drug *Lakshamadhuka Churnam* was given to the study subjects for 90 days. The minimum safety dose of the *Laksha* and *Madhuka* is considered and the dose is fixed as 6g.[9]. The drug was dispensed to the patients in airtight packets each containing 6g powder with the date of administration labelled on the packets and advised to take 6g powder by mixing with 12ml ghee followed by 24ml lukewarm milk, morning in empty stomach, for a period of 90days. The evaluation was done on the 0^{th}, $91^{st,}$ and 130^{th} days. Changes in subjective and objective parameters were recorded. The results obtained were statistically analysed and tables and graphs were drawn using the data.

Outcome variables

1. Clinical variables

Pain assessed by Changes in Visual analogue scale.
Tenderness is assessed by grading.

2. Changes in BMD.

ASSESSMENT CRITERIA

The assessment was done at two levels-

1. Clinical level - Based on clinical parameters.
2. Investigative level - Based on BMD test.

Clinical level

a) Pain during movements of joints was assessed by a visual analogue scale and graded as follows.

Grade 0 - No pain
Grade 1 - Mild pain
Grade 2 - Moderate pain
Grade 3 - Severe pain
Grade 4 - Impossible

b) Tenderness: Joint/ bone tenderness was assessed by palpation and graded as follows.

Grade 0 - No tenderness
Grade 1 - Patient says joint is tender
Grade 2 - Patient winces
Grade 3 - Patient winces and withdraws the affected part
Grade 4 - Patient won't allow touching the affected part

Investigative level

BMD.

Interpretation of Bone Density Values

T- Score is the number of standard deviations (SD) of the patient's BMD from the average bone density of a healthy 25-year-old person (young adult base line).
WHO has established diagnostic guidelines of T-score as follows:

Normal Bone: T- Score at or above -1 SD
Osteopenia: T-Score between -1.0 and -2.5 SD
Osteoporosis: T-Score at or below -2.5 SD

Statistical analysis

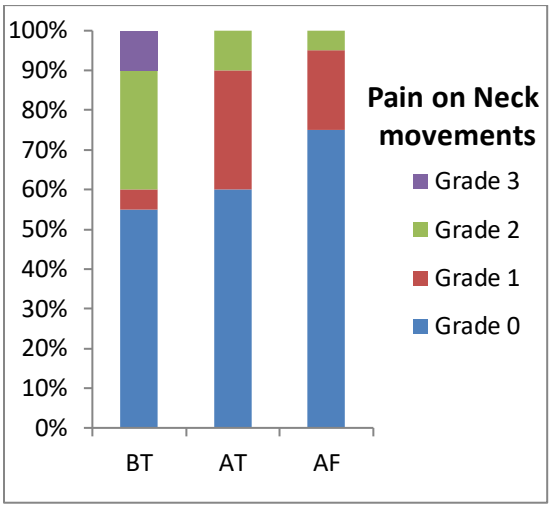
The efficacy of treatment in each group was analyzed by Wilcoxon signed rank test for qualitative data before & after treatment as well as after follow up. Quantitative data was analyzed by calculating the mean, standard deviation of the parameters; t and p values were found using paired t-tests.

Result

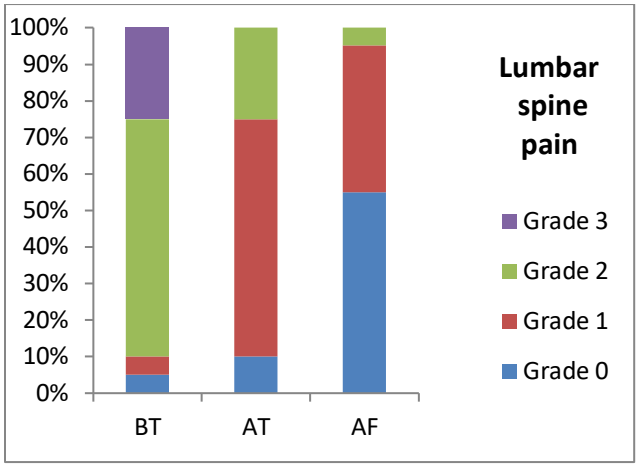
In this study, the age included was 40-60 years. 80% of patients were in between 50-60 years and 20% were in between 40-50 years. This can be due to an increased rate of bone resorption after the age of 50 years in both genders. The sex-wise distribution

shows dominancy of females (85%) compared to males (15%). This may be due to low peak bone mass or hormonal imbalance which occurs during the pre-menopausal or post-menopausal period. Early menopause (before 45years) or a history of hysterectomy was noted in 35% of female patients. During menopause, an abrupt sinking of female sex hormones especially estrogen may occur which accelerates the rate of bone resorption. 85% of patients accustomed to *Katu Rasa* (pungent taste), which is the main cause of *Vatavyadhi* (disorders of *Vata dosha*). A major part of the study population (70%) belongs to *Vatapitta Prakriti* (body constitution) and are susceptible to early degeneration. As the disease itself is of *Vata Pitta* predominance prognosis will be bad. Considering tenderness of the cervical spine before treatment Grade 2 tenderness was present on 20% of cases which was reduced to grade1 tenderness after treatment and after following up. Significant results were noted as BT-AT, BT-AF & AT-AF since $p<0.05$. Considering tenderness of the lumbar spine before treatment Grade 1 tenderness was present on 60% of cases and was reduced to 40% after treatment and 25% after following up. A significant reduction was found in BT-AT and BT-AF with $p<0.001$. Considering pain during movements of the neck before treatment there were 10% cases with severe pain and after treatment none was there with severe pain 30% had moderate pain before treatment and this was reduced to 10% after treatment. There was a significant reduction in pain in BT-AT, AT-AF, and BT-AF, $p<0.05$. Considering pain during movements of the lumbar spine before treatment 65% of cases had moderate pain which was reduced to 25% and 25% of cases had severe pain and no patients had severe pain after treatment. Significant results were noted on BT-AT, AT-AF &BT-AF as $p<0.001$.The mean value of BMD before treatment was -2.71± 0.26 and it remained the same after treatment and reduced to -2.33± 0.46 after following up. Since the p-value is <0.001, the result was found to be significant after following up.

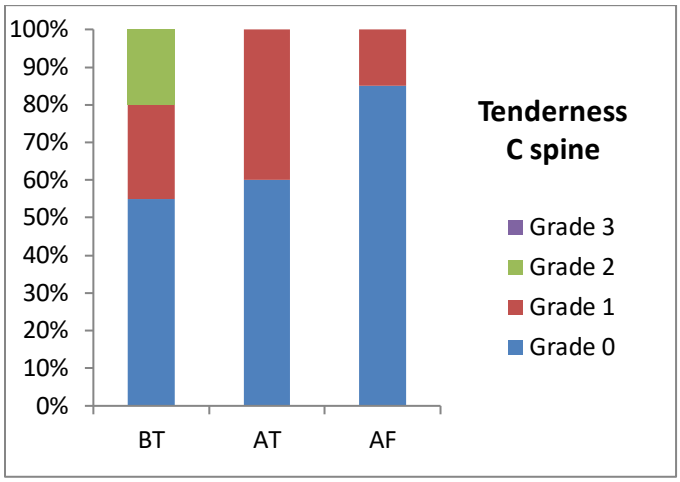
Graph 01:



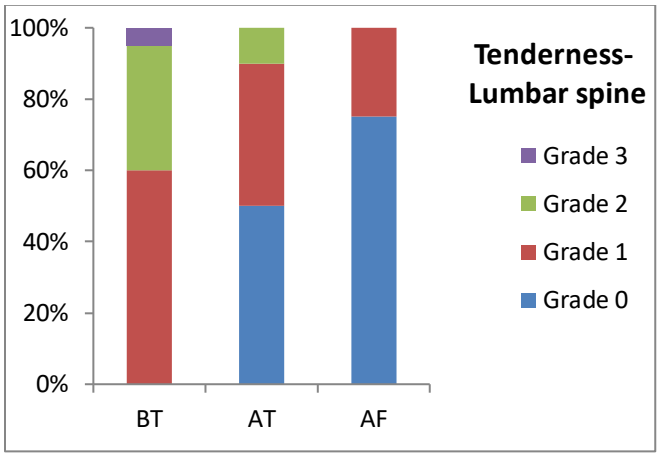
Graph 02:



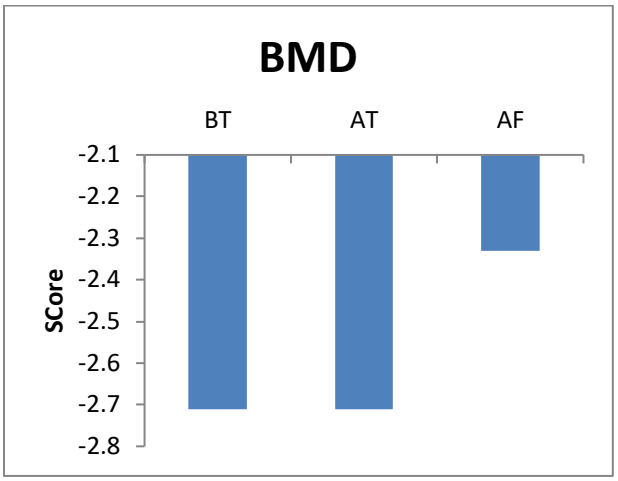
Graph 03:



Graph 04:



Graph 05:



DISCUSSION

Considering pain and tenderness more significant improvement was obtained for thoracic and lumbar spine movement which was got as the main presenting complaint of a major part of the study population. Significant improvement was observed in BMD ($p<0.001$). Better results were obtained in persons having early stages of disease and others remain static. It shows the importance of screening and early intervention of the disease. So, it can also be used as a simple formulation for persons having the risk of osteoporosis. *Lakshamadhuka Churna* is preparing with *Laksha* and *Madhuka* having *Goksheera* (cow's milk) and *Ghrita*(ghee) as *Anupana*. The combination is having *Tikta*(bitter), *Kashaya* (astringent) and *Madhura*(sweet*) Rasa*. *Tiktarasa* is having dominance over *Akasa* and *Vayumahabhutha* and has got affinity towards the body elements like *Asthi*. Due to its *Sookshmaguna*(penetrating capacity), it possesses a high penetrating capacity to reach the deep-seated *Asthidhatu*. It removes fluid and slimy material (*Soshana)* due to *Rooksha* (drying), *Visada* (clearness) *gunas*, and *Kharaguna* (rough). This *Soshana Karma* provides stability to the *Dhatus* by reducing pathological greasiness and aiding in the formation of *Asthi Dhatu*. *Tiktarasa* is having *Deepana*(kindling digestive fire), *Pachana(*enhances digestion), and *Lekhana* (scraping) properties and is *Srotoshodhaka*(cleansing body channels), which may be able to destroy *Avaranajanyasrotorodha*(blockage of body channels). All the classical texts describe *Tiktadravyas* in the treatment of *Asthidhathukshaya*. *Madhura Rasa* as being composed of *Prithwi* and *Jalamahabhuta* will cause nourishment of all *Dhathus* and cause alleviation of *Vata* mainly by the *Brimhana* (nourishing) property. It provides strength to the formed bone as having the properties *Sthairya* (firmness) and *Sandhan(*bone healing). *Kashaya Rasa* has *Vayu* and *Prithwimahabhuta* in dominance. *Asthi* is formed from *Prithwimahabhuta*, so drugs dominant in *Kashaya Rasa* helps in *Dhatu Poshana* by helping in the formation of bulk of *Asthi* and *Sandhanakara* also. *Laksha* and *Madhuka* are *Sandhaneeya* drugs that in turn promote osteoblastic activity and bone remodelling. *Laksha* is having *Tikta* and *Kashaya rasa,*[9] it will enhance bone growth by promoting callus formation. Also due to its *Balya*(strengthening*) Karma*, provides strength to the formed bone tissue. It is described as the best medicine for *Asthi Sandhana*[10] and is the main ingredient of all the formulations in *Asthibhagna (*fracture of bone). The experimental and histological study also showed that *Laksha* enhances bone healing. *Madhuka* is having *Madhura Rasa* and *Guru (*heaviness) *Snigdha (*unctuousness) *Gunas*[11]. These properties possess *Sandhaneeya* and *Rasayana* (rejuvenative) properties. Experimental studies have proven that it has anti-osteoporotic and oestrogen-like activities. The anti-inflammatory, anti-thrombotic, and anti-dyslipidemia

effects are also scientifically proven[12, 13, 14.] *Ksheera* and *Ghrita* are advised as *anupana*. By *Snigdhaguna, Ghrita* alleviates *Vata* and *Sookshmaguna* helps it to penetrate and reach the deepest *Dhathus* like *Asthi.* As it is being a *Deepanadravya* it corrects *Agnimandhya* (reduced digestive fire) also. Assimilation of the properties of other substances added to it without giving up its own properties is one of the remarkable properties of *Ghrita*. *Tiktarasa* drugs when processed with *Ghrita* improve the *Kharatwa* of *Asthi Dhatu*. *Ksheera* is having *Madhura rasa* and *Snigdhaguna*, it is *Balya*, *Sandhanakara* and *Rasayana*. Calcium and vitamin-K are the major constituents present in cow's milk. Vitamin-K activates the major non-collagenous protein osteocalcin which anchors calcium molecules in the bone. It also contains iron-binding protein lactoferrin which boosts the growth and activity of the bone. Similar properties are shared by ghee also. So, the *anupana* here mentioned is more suitable for the desired action of the formulation. The formulation as a whole possesses *Tikta, Kashaya* and *Madhura Rasas, Snigdhaguna, Balya, Sandhanakara*, and *Rasayana* properties. Thus, the combination of *Lakshamadhuka Churna* in ghee and milk as *Anupana* will definitely nourish *Asthidhathu*, imparts *Asthibala*, and at the same time, the presence of ghee acts as *Vatasamana*. The combination also acts as a *Naimitikarasayana (*disease specific rejuvenative therapy) for the management of osteoporosis. Moreover, the *Sandhaneeya* property improves the compactness of bone and there by prevents fragility fractures also.

CONCLUSION

Lakshamadhuka Churna is very effective in reducing the signs and symptoms of osteoporosis and increasing Bone Mineral Density. The trial drug was found to be significant with a p-value less than 0.001 ($p<0.001$) in BMD. From this study, it is clear that early intervention is more effective in increasing BMD. So, screening of individuals especially women above 40 years at regular intervals and the correction of the predisposed can reduce the social and economic burden.

REFERENCES

1. Fauci, Draunwald, Kasper, Longo, Jameson, Loscalzo; Harrison's principles of internal medicine,17thedition: McGraw – Hill companies;2008;354:3120.
2. JA Kanis, WHO Technical Report, University of Sheffield.UK:26.
3. LJ Melton, 3rd, EJ Atkinson, MK O'Connor, et al. Bone density and fracture risk in men. J Bone Miner Res 13:1915.
4. Riggs BL, Melton LJ., III Evidence for two distinct syndromes of involutional osteoporosis. *Am J Med.* 1983; **75:899**–901.
5. FaryalMirza, ErnestoCanalis, et al. Secondary osteoporosis: pathophysiology and management.
6. Kristie N. Tu, Janette D. Lie, Chew King Victoria Wan, et al. Osteoporosis: A Review of Treatment Options.
7. . Kaviraj Vinod Lal Sen; BhaisajyaRatnavali with Sanskrit commentary Vinodini. Krishnadas Academy Varanasi,2001;570.
8. Ambika Dutta Sastry, Govindadas Sen, BhaisajyaRatnavali, 19thedition, ChaukambhaKrishnadas Academy Varanasi, 2008;49:859.
9. Ayurvedic pharmacopoeia of India; Government of India, Ministry of Family Welfare. Department of Indian system of medicine and Homeopathy, New Delhi 1stedition 2001; Part1, Volume1,79:127-128.
10. PriyavrataSarma; DravyaGunaVijnana.4thedition, ChoukhambhaViswabharathi,1995,3rd Volume,4:65. laksha
11. GV Oblotenseva, VILivinenko, AS Ammosov, T P Popova, AM Sampiev. Pharmacological and therapeutic properties of licorice preparations (A review). Pharm Chem J. 1999; 33(8):24-31.
12. J Vaya, PA Belinky, M Aviram. Antioxidant constituents from licorice roots: isolation, structure elucidation, and anti-oxidative capacity towards LDL oxidation. Free Radic Biol Med.1997;23(2):302-313.
13. S Tamir, MEizenberg, D Somjen, S Israel, J Vaya, Eastrogen-like activity of glabrene and other constituents isolated from licorice root. J steroid Biochem Mol Biol.2001;78(3):291-298.

Source of Support: Nil
Conflict of Interest: None Declared

How to cite this URL: Sumit Kumar et al: Management of Irritable Bowel Syndrome W.S.R. to Grahani: A Case Study. International Ayurvedic Medical Journal {online} 2022 {cited August 2022} Available from: http://www.iamj.in/posts/images/upload/2107_2113.pdf