Role of *Naimittika Rasayana* in Elderly Patients suffering from *Asthi Kshaya* vis-a-vis Osteopenia / Osteoporosis - A Randomized Controlled Clinical Trial

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Abstract:

Ayurveda emphasizes on the equilibrium of Dhatu (body tissues) to be healthy. Among the Dhatu, Asthi (bone) Dhatu does the dharana of the body. Disease occurs when there is a loss of equilibrium of Dhatu. Asthi kshaya is a condition in which there will be kshaya of Asthi Dhatu. It may be compared to Osteopenia/Osteoporosis where there is a decrease in the bone mass. People all over the world suffer from this condition. Its incidence is high with the ageing population. Females have the higher risk compared to males. Management of Osteopenia/Osteoporosis is a challenge to the medical fraternity. There is a high risk of fracture when falls occur. Ayurveda has mentioned the treatment of Asthi Kshaya many Centuries ago. The use of Naimittika Rasayana is mentioned by Acharya Sushruta to treat a disease with Rasayana. This present study was carried out to find the efficacy of Naimittika Rasayana in the management of Asthi Kshaya vis-à-vis Osteopenia/Osteoporosis. Abha Guggulu and Lakshadi Guggulu were used as test and control drugs respectively. The results showed significant results in reducing the symptoms of Asthi Kshaya. Both the medicines were almost equally effective in the management of pain, problems of hair and teeth, weakness etc. There was statistically significant improvement in the Bone Mineral Density in both the groups.

Key words: Asthi kshaya, Osteoporosis, Naimittika Rasayana, Bone Mineral Density

Introduction

Ayurveda defines health as homeostasis of the Doshas, Agni, Dhatu, Malakriya and the liveliness of the Indriyas and Mana1. Among all the Dhatu, Asthi Dhatu perfoms the function of Shareera Dharana. It is rightly said the "Vikaro Dhatu VaishamyamSamyam prakrutiruchyate" Any disorder in the equilibrium of this Asthi Dhatu leads to abnormalities in the body. Chakrapani says Dhatu vaishamya may be Vriddhi, Kshaya or Gamana2. As per the natural consequence of ageing, all the Dhatu of the body attain degeneration. Old age in Ayurveda, is said to be dominated by Vata dosha. Hence, the wear and tear process accelerates in old age. As a result of this, many degenerative

diseases manifest in old age. Asthi Kshaya is one of them which can be closely correlated to Osteopenia / Osteoporosis, where there will be decrease in the bone density. Osteoporosis is defined as "a disease in which the density and quality of the bone are reduced, leading to weakness of the skeleton and increased risk of fracture, particularly of the spine, wrist and hip"3. In 1994 World Health Organization defined Osteoporosis as "a systemic skeletal disease characterized by low bone mass and bone architectural derangements leading to increased fracture risk"4. In relation to BMD, Osteoporosis is operationally a femoral neck BMD value 2.5 standard deviation or more below the mean for normal young white women or a „t"-score of −2.5 or below. The global scenario of incidence of Osteoporosis is alarming. In United States, as many as 8 million women and 2 million men have Osteoporosis. In Asia, Osteoporosis has become one of the most prevalent and costly health problems. Unsurprisingly, Asia is the region expecting the most dramatic increase in hip fractures during coming decades. By 2050 one out of every two

hip fractures worldwide will occur in Asia5. Osteoporosis in India remained neglected for many years. Till recently it was considered as an inevitable consequence of aging with no treatment available. With increasing number of the elderly in India, Osteoporosis is emerging as an important public health problem7. The lifetime risk for an osteoporotic fracture is 30-50% in women and 15-30% in men8. Women are at high risk compared to men. The risk even increases at menopause, which is a physiological transition period of hormonal imbalance.

Materials & Methods:

Study Design: The study was a single blind randomized standard controlled clinical trial.

Source of data: Established cases of Asthi Kshaya vis-à-vis Osteopenia / Osteoporosis from the O.P.D and I.P.D of Kayachikitsa, BVVS Ayurved Medical College & Hospital were selected for this study. Such osteopenic/ osteoporotic patients selected were randomly assigned into two groups „A" & „B".

Randomization: Randomization was done by generating Random Numbers

from www.randomnumbergenerator.com

Inclusion criteria:

Osteopenic / Osteoporotic patients of either sex whose BMD (t-score) is equal to or less than -1 were taken for the study.

Patients presenting with the classical symptoms of Asthi Kshaya vis-à-vis Osteopenia / Osteoporosis were included.

Patients between the age group of 50-80 years were selected irrespective of race, caste, religion etc.

Exclusion criteria:

BMD „t"- score above -1 were excluded.

Patients suffering from neoplasms of the bone

Known cases of Diabetes Mellitus, uncontrolled hypertension, thyrotoxicosis, hyper parathyroidism, Addison"s disease, Paget"s disease, Cushing"s syndrome, tuberculosis of the bone, osteomalacia, and chronic renal, hepatic and cardiac failure etc.

Rheumatoid arthritis, Gouty arthritis and any long standing systemic disorder were excluded.

History and relevant data along with Prakriti were recorded in a detailed research/clinical proforma, which was prepared for the study by incorporating all the aspects of the present disease on Ayurvedic and modern parlance.

Intervention: -

Drug, Dosage and Duration

Group A (Study Group, N=30): Abha Guggulu, 1 tab of 500 mg twice daily with milk as anupana for 6 months

Group B (Control group, N=30): Lakshadi Guggulu, 1 tab of 500 mg twice daily with milk as anupana for 6 months

Criteria of assessment of effect of therapy: -

The following were the assessment parameters used to the study the effect of therapies;

Assessment Parameters:

Asthi Sandhi Shoola,

Kesha Vikara and Pata

Nakha Vikara

Danta Vikara and Pata

Daurbalya

Serum calcium

Serum alkaline phosphatese

BMD t-score

FOLLOW UP STUDY:

Patients were followed up once in every 15 days and the assessment of subjective and objective parameters were recorded before and after treatment.

Observations: Total, 60 patients were registered; 30 in group A and 30 in group B.

Maximum numbers of patients were between the age group of 50-60 years (63.33% in Group A and 60% in Group B), were females (70%% in both Group A and B). The main complaints observed were back pain and joint pain (100%) followed by hair fall (100%), general debility (93.16%), dental deformity/fall (76.07%) and nail deformity (59.83%). Out of 42 females, 36 (85.7%) had attained menopause. Maximum number of patients, consumed katu rasa dominant food (76.67%), maximum patients had Vata pitta predominant prakriti (76.7%). In Group A, out of 30 patients 11 (36.67%) were ostepenic and 19 (63.33%) were osteoporotic and in Group B, out of 30 patients 8 (26.67%) were ostepenic and 22 (73.33%) were osteoporotic.

Results: In Group A, the mean score of pain before treatment was 4.2 and the mean score of after treatment was 1.7. The mean difference was 2.5 with a standard deviation of ±0.18. There was almost 60% reduction in pain and the result was statistically higly significant at P<0.001.

Regarding kesha vikara, the mean score before treatment was 2.5 and the mean score after treatment was 1.0. The mean difference was 1.5 with a standard deviation of ±0.11. Percentage wise the reduction in kasha vikara and pata was 60% and the result was statistically higly significant at P<0.001.

The mean score of Danta vikara before and afer treatment was 1.3 and 0.47 respectively. The mean difference was 0.83 with a standard deviation of ±0.13. Percentage wise the reduction in danta vikara was 63.85% and the result was statistically higly significant at P<0.001. The mean score of Nakha vikara before and afer treatment was 1.06 and 0.23 respectively. The mean difference was 0.83 with a standard deviation of ±0.14. Percentage wise the reduction in danta vikara was 78.30% and the result was statistically higly significant at P<0.001. The mean score of Daurbalya before and afer treatment was 2.57 and 0.8 respectively. The mean difference was 1.77 with a standard deviation of ±0.12. Percentage wise the reduction in danta

vikara was 68.87% and the result was statistically higly significant at P<0.001.

Figure 1: Effect of therapy on assessment parameters in Group A
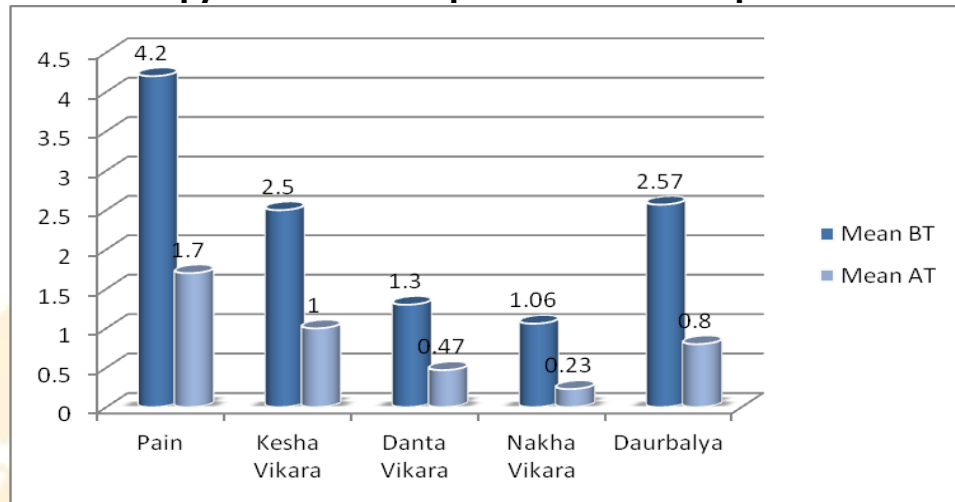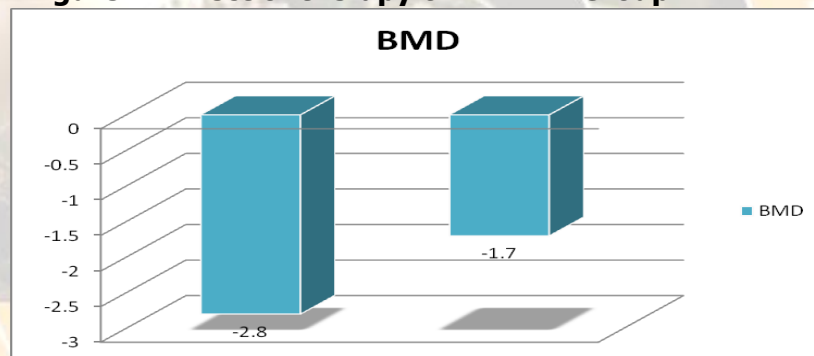

Figure 2: Effect of therapy on BMD in Group A

The mean Bone Mineral Density (BMD) before treatment was -2.8 and mean BMD after treatment was -1.7. The result was statistically highly significant at P<0.001 with a SD of ±0.23

In Group B, the mean score of pain before treatment was 5.03 and the mean score of after treatment was 1.93. The mean difference was 3.1 with a standard deviation of ±0.19. There was almost 62% reduction in pain and the result was statistically higly significant at P<0.001. Regarding kesha vikara, the mean score before treatment was 2.83 and the mean score after treatment was 1.13. The mean difference was 1.7 with a standard deviation of ±0.11. Percentage wise the reduction in kasha vikara and pata was 60% and the result was statistically higly significant at P<0.001.

The mean score of Danta vikara before and afer treatment was 2.17 and 0.83 respectively. The mean difference was

1.34 with a standard deviation of ±0.14. Percentage wise the reduction in danta vikara was 61.75% and the result was statistically higly significant at P<0.001. The mean score of Nakha vikara before and afer treatment was 1.77 and 0.70 respectively. The mean difference was 1.07 with a standard deviation of ±0.15. Percentage wise the reduction in danta vikara was 60.45%

and the result was statistically higly significant at P<0.001. The mean score of Daurbalya before and afer treatment was 2.5 and 0.83 respectively. The mean difference was 1.67 with a standard deviation of ±0.12. Percentage wise the reduction in danta vikara was 66.80% and the result was statistically higly significant at P<0.001.

Figure 3: Effect of therapy on assessment parameters in Group B
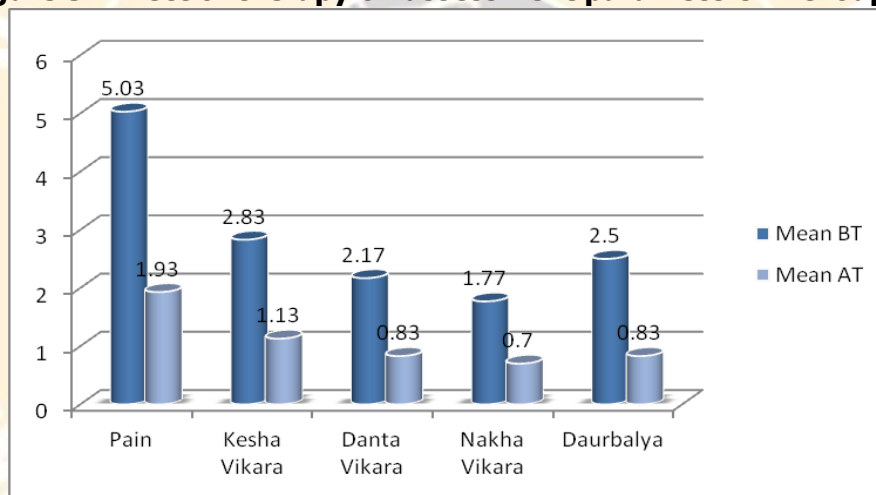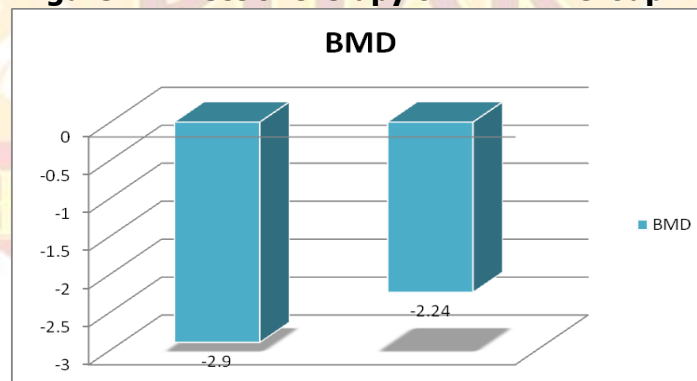

Figure 4: Effect of therapy on BMD in Group B

The mean Bone Mineral Density (BMD) before treatment was -2.9 and mean BMD after treatment was -2.24. The

result was statistically highly significant at P<0.001 with a SD of ±0.12
Even though the effect of therapy on serum calcium and alkaline phosphatise

in both the groups were statistically significant, both factors may not seem to have much clinical significance. in osteoporosis. Recent studies have shown that, the serum calcium is always maintained to normal levels in osteoporosis.

Discussion: *Asthi kshaya* is a natural consequence of ageing and is predominantly affects women than in men. The incidence increases rapidly after menopause which is the period of hormonal imbalance. The use of *Rasayana* has been mentioned in *Ayurveda* to treat *dhatu kshaya.* Naimittika Rasayana is used to treat a specific disease. *Abha Guggulu* and *Lakshadi Guggulu* were used as *Asthi Dhatu* specific *Rasayana*s in group A & B respectively.

Effect of therapy on pain: In both the groups there was a significant reduction in pain. Comparatively the result was slightly better in group B in which *Lakshadi Guggulu* was used. Both *Abha* and *Lakshadi Guggulu*s are anti-inflammatory and analgesic. *Asthishrinkhala* (*Cissus quadrangularis*) which is one of the ingredients of *Lakshadi Guggulu* has a proven analgesic effect comparable to aspirin or anti-inflammatory drugs like ibuprofen.[1] The antiinflammatory features suggest that it acts by preventing the conversion of arachidonic acid to inflammatory prostaglandins.[2] Hence, both the drugs were potent enough to control pain.

Effect of therapy on *Keshapata*, *Nakha vikara* and *Danta Vikara*: Ashwagandha & Shatavari are systemic *Rasayana*s and *Lakshadi Guggulu* and Shukti bhasma may be considered as *Asthi Dhatu* specific *Rasayana* (*Naimittika Rasayana*). Hence, they nourish the *Dhatu*. When *Asthi Dhatu* is nourished and is brought back to normalcy, simultaneously its mala i.e. kesha & nakha are nourished and hence the hair roots may become strong. This may reduce hair fall and brittleness of hair. Similarly the brittleness of the nails is reduced and they become strong and elastic.

Effect of therapy on Daurbalya: The *Rasayana* drugs used here are balya, *Dhatu* poshaka. Moreover, Godugdha was used for *Guggulu* sodhana during the preparation of *Lakshadi Guggulu* and also as anupana in group A which is jivaniya, balya, *Rasayana*, ajanma satmya and *Dhatu*

poshaka. Hence the combined effect might have provided bala to the patients. Even scientific studies have proved that Ashwagandha, Shatavari and Nagabala are having anabolic and tonic actions on the human body. Shatavari is adaptogenic and immunestimulator[3] and is indicated in general debility.[4]

Effect of therapy on BMD: *Lakshadi Guggulu* is indicated in *Asthi* bhagna and is said to make the body as strong as vajra (diamond). Shukti is the samana guna bhuyishtha dravya of *Asthi*. Recent researches have shown the anti-osteoporotic effect of Aswagandha and *Asthi*srinkhala. A study conducted by Nagareddy et al. in 2006 showed potent antiosteoporotic activity of Ashwagandha in ovariectomized rats. Treatment with Ashwagandha root extract which is known to contain estrogen like withanolides, particularly withaferin-A significantly prevented net bone loss. It is possible that the presence of a large number of withanolides, particularly withaferin A, an estrogen-like compound, may have contributed to anti-resorptive activity (Mishra et al 2000). Treatment with Ashwagandha appeared to maintain normal integrity, structure and compactness of the bone.[5]

Ethanol extract of *Cissus quadrangularis* was also evaluated for its anti-osteoporotic activity in ovariectomized rat model of osteoporosis. The findings assessed on the basis of biomechanical, biochemical and histopathological parameters showed that the ethanol extract of the plant had a definite antiosteoporotic effect.[6]

The analysis of Shukti bhasma in our Pharmaceutical chemistry laboratory revealed that it contains 36.73% of elemental calcium. *Terminalia arjuna* is also the richest source of natural calcium, the bio-availability of which may be more. Since the purification of *Guggulu* was done with cow"s milk, *Lakshadi Guggulu* also contained 6.18% of elemental calcium. Hence by all these facts the drugs of group A by their holistic approach might have increased the BMD in the patients of *Asthi Kshaya*. However, the effect of therapy on BMD was not statistically significant in subgroups B1, A2, B2 and A3.

Conclusions: The latest signs and symptoms of osteopenia/osteoporosis are almost similar to those of *Asthi kshaya*. Hence, in the present study osteopenia / osteoporosis was vis-à-vis correlated with *Asthi kshaya*. Sedentary lifestyle of the ultra modernized society, faulty dietary habits and premature ageing are the main causes of higher incidence of osteopenia/osteoporosis. In the quest for tasty foods, majority of the people are consuming fast foods and junk foods which lack proper nutrients leading to conditions like osteoporosis. India is emerging as the highest fracture risk prone area of the world by 2050. The prevalence of osteopenia/osteoporosis is more in people aged above 40 years. The incidence is more in females. The samprapti of *Asthi kshaya* is a complex mechanism involving the nidanas of *Vata*vriddhi, samanya nidanas of *Dhatu kshaya*, sroto pradushaka nidanas of Medovaha, *Asthi*vaha, Majjavaha and Purishavaha srotas. The involvement of psyche and the role of the dhatwagnis cannot be denied in the pathogenesis of *Asthi kshaya*.

The use of *Rasayana* in *Dhatu kshaya* is advocated in Ayurvedic classics. Here,

Ashwagandha and Shatavari were used as systemic *Rasayana* drugs. Shukti bhasma was used as a samana dravya for *Asthi* and as a natural calcium supplement and *Lakshadi Guggulu* as the *Naimittika Rasayana* or *Asthi Dhatu* specific *Rasayana*. By the effect of therapy obtained in the control group B, it is clear that only calcium and vitamin D_3 supplementation is not the complete treatment for osteopenia/osteoporosis. Management of *Asthi kshaya* requires a holistic approach, taking into account the nutritional, metabolic and hormonal aspects, which is fulfilled by Ayurvedic *Rasayana* therapy. The Ayurvedic herbo-mineral *Rasayana* drugs used in the present study provided significant relief from signs and symptoms like Kati, *Asthi* & Sandhi shula, Kesha pata, Danta vikara /pata, Nakha vikara and Daurbalya. The results on X-ray (Singh"s index) and BMD eventhough were encouraging but were not significant statistically. The antique therapeutic potentials of Ayurvedic *Rasayana* holds good even today in the management degenerative disorders related to ageing.

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