

Therapeutic potentials of Ayurvedic Rasayana in the management of Asthi Kshaya vis-à-vis osteopenia/osteoporosis

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Abstract

Ayurveda attributes prime importance to safeguard the health of healthy individuals and to mitigate diseases of the ailing. The equilibrium of Dhatu is health. Among the Dhatus, Asthi (bone) does sharira dharana. Any commotion in equilibrium of Dhatus leads to abnormalities in the body. Asthi kshaya is a condition in which there will be kshaya of Asthi dhatu. In contemporary science Asthi kshaya may be compared to osteopenia/osteoporosis where there is a decrease in the bone tissue. Osteoporosis is a global problem that will increase consequently with the ageing population. Females have the higher risk compared to males. Treatment available in the contemporary science is not devoid of adverse effects. Hence, the present study was carried out to find natural, safe and effective therapy for the management of osteopenia/osteoporosis. The patients were divided into two groups – A and B. In group A, Ayurvedic Rasayana compound consisting of Ashwagandha, Shatavari, Shukti bhasma and Lakshadi guggulu was given for 4 months with milk as vehicle and in group B, modern control drug, tablet Shelcal 500 mg was given with water for 4 months. The Ayurvedic Rasayana regimen provided significant results in subjective as well as objective parameters including bone mineral density (BMD) compared to control drug.

Introduction

Ayurveda defines human body as a hospitable homeostasis of Dosha, Dhatu and Mala [1]. The equilibrium of Dhatu is health [2]. Any commotion in their equilibrium leads to diseases. This commotion may either be increase, decrease or movement away from their natural abode [3]. Asthi kshaya is a condition in which there will be kshaya of Asthi dhatu. Asthi kshaya may be compared to osteopenia/osteoporosis where there is a decrease in the bone tissue. Osteopenia means decrease in the bone tissue. Osteoporosis is defined as “a progressive systemic skeletal disease characterised by

low bone mass and micro architectural deterioration of bone tissue with a consequent increase in bone fragility and susceptibility to fracture” [4].

Osteoporosis is a global problem. Females are at higher risk. This risk even increases at menopause, which is the period of hormonal imbalance. One in three women and one in five men over the age of 50 will experience an osteoporotic fracture in their lifetime [5,6].

Europe and the Americas accounted for just over half of all these fractures while most of the remainder occurred in the Western Pacific region and in Southeast Asia [7]. In India, approximately 26 million were suffering from osteoporosis in 2003 and the number may reach to 36 million by 2013 [8].

The adult skeleton undergoes a continuous process of remodeling (formation and resorption). When bone resorption exceeds formation, then osteopenia/osteoporosis occurs. Modern treatment is mainly intended at preventing further bone loss and fractures, maintaining bone mass, calcium and vitamin D supplementation, hormone replacement therapy (HRT), and use of certain drugs like bisphosphonates, selective estrogen receptor modulators (SERMs), anabolic steroids and strontium etc. HRT, bisphosphonates, SERMs and anabolic steroids may produce side/adverse effects. Hence, it is need of the hour to carry researches for finding efficient, economic, natural and safer formulations to manage osteopenia/osteoporosis. The Ayurvedic rejuvenation therapy (Rasayana) may be useful in treating osteopenia/osteoporosis. Keeping these principles in mind the present study was carried out to clinically evaluate the disease Asthi Kshaya vis-à-vis osteopenia/osteoporosis and to assess the efficacy of Ayurvedic Rasayana in its management.

Aims and Objectives

1. To evaluate the efficacy of Ashwagandha, Shatavari, Shukti Bhasma and Lakshadi Guggulu in the management of Asthi Kshaya vis-à-vis osteopenia / osteoporosis.

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2. To evaluate the Rasayana effect of these drugs on degenerative changes of aging related to bone.
3. To compare the efficacy of the Ayurvedic Rasayana drugs with the modern standard control drug Shelcal 500 mg (containing calcium with vitamin D3).

Materials and Methods

Study design: Present study was a randomized, open, standard controlled clinical research.

Source of data: The patients were selected by conducting free osteoporosis diagnosis camps in the Hospital of the Institute for Postgraduate Teaching and Research in Ayurveda (I.P.G.T & R.A), Gujarat Ayurved University, Jamnagar, India.

Inclusion and exclusion criteria

Osteopenic/osteoporotic patients of either sex who's BMD (t-score) is equal to or less than - 1, patients presenting with the classical signs and symptoms of Asthi Kshaya vis-à-vis osteopenia/osteoporosis and patients between the age group of 40-80 years were included in the present study.

The patients aged below 40 and above 80 years, BMD (t-score) above - 1, suffering from neoplasms and tuberculosis of the bone, and systemic disorders like uncontrolled hypertension, thyrotoxicosis, hyper parathyroidism, rheumatoid/gouty arthritis, Paget's disease, Cushing's syndrome were excluded.

Patients fulfilling above criteria were subjected to physical, radiological, haematological and urine examinations (as and when required). A special clinical proforma was prepared incorporating both Ayurvedic and modern parameters.

Group A (study group): patients in this group were given;

1. Ashwagandha
(*Withania somnifera*) powder - 3 gm b.i.d.
2. Shatavari
(*Asparagus resimosa*) powder -- 3 gm b.i.d.
3. Tablet Lakshadi guggulu - 500 mg b.i.d.
4. Capsule Shukti bhasma - 500 mg b.i.d.

All these drugs were given with cow's milk for 4 months.

Group B (control group): patients in this group were given Tab. Shelcal 500 mg (calcium 500 mg and vitamin D, 250 IU) one tablet b.i.d. with water for 4 months.

Parameters of assessment

Subjective parameters: Shula (Pain), Kesha pata (Hair fall), Danta vikara/pata (Dental deformity/fall), Nakha vikara (Nail deformity) and Daurbalya (General debility) [9].

Objective parameters: Serum calcium, serum alkaline phosphatase, X-ray Singh's index, BMD (t-score). To measure the BMD the FDA approved McCue CUBA

Clinical Ultrasound Bone Sonometry system was used which was sponsored by the Elder Pharmaceutical, Mumbai, India.

Follow up study: The patients were followed up for 2 months. All the subjective parameters of assessment were assessed during the follow up.

Assessment of total effect of therapy: Total effect of therapy was assessed as follows;

1. Marked improvement: more than 75% but less than 100% improvement.
2. Moderate improvement: more than 50% but less than 75% improvement.
3. Mild improvement: more than 25% but less than 50% improvement.
4. No improvement: less than 25% improvement.

Statistical analysis: The results were analyzed statistically by applying students' t-test (paired and unpaired) and Chi square test.

Observations

Total, 117 patients were registered; 64 in group A and 53 in group B. Among these 117 patients, 110 completed the treatment, 60 in group A and 50 in group B and 7 patients discontinued the treatment, 4 in group A & 3 in group B.

Maximum numbers of patients were between the age group of 40-50 years (37.61%), were females (64.1%). The main complaints observed were back pain and joint pain (100%) followed by skeletal pain (58.12%) and weakness in joints (53.85%), hair fall (100%), general debility (93.16%), dental deformity/fall (76.07%) and nail deformity (59.83%). Positive family history of fracture was found in 20.51% of patients. Out of 75 females, 4% were in their perimenopausal stage and 82.67% had attained menopause. Maximum number of patients, consumed Katu rasa (pungent taste) dominant food (71.79%), irregular diet (52.13%), were addicted to tobacco chewing (18.80%), smoking (9.40%) and alcohol (2.56%). Total, 65.81% performed less exercise, 70.08% were afflicted by chinta and 78.63% were of vata pitta predominant prakriti. Among the 117 patients, 72 patients (61.54%) were osteopenic and the remaining 45 (38.46%) were osteoporotic.

Results

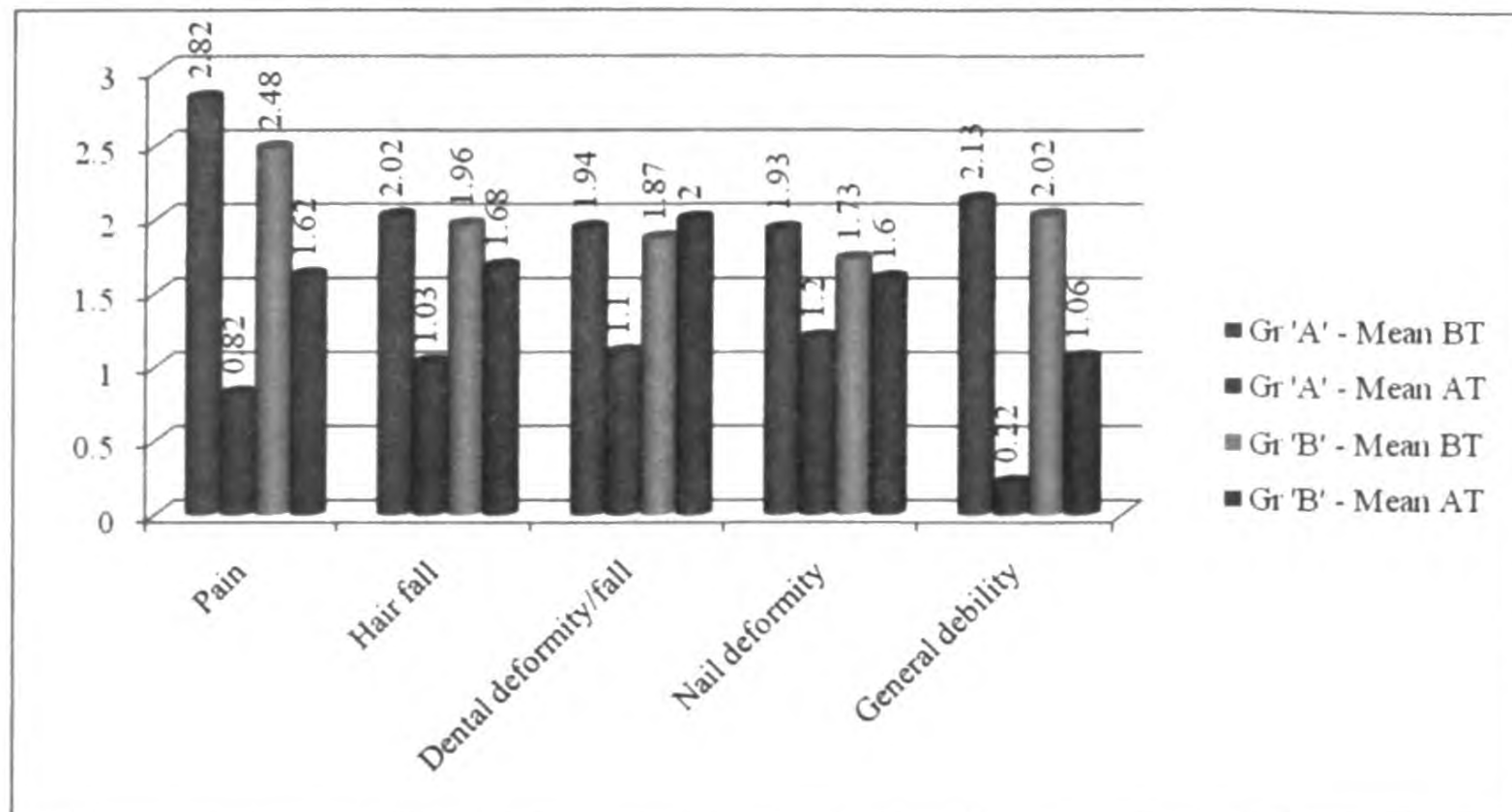
Effect of therapy on subjective parameters

The percentage relief from pain in group A and B was 70.92% and 34.68% respectively. Effect of therapy in group A was statistically highly significant than group B at $p < 0.001$ (unpaired 't' test and Chi square test). Relief from kesha pata was 48.51% in group A and 14.28% in group B. It was highly significant in group A than group B at

$p < 0.001$. Percentage relief from danta vikara/pata was 43.29% in group A whereas it worsened by 6.95% in group B. Statistically group A was highly significant at $p < 0.001$. Percentage relief from nakha vikara was in group A was 37.82% and 7.51% in group B. On comparison, group A was highly significant at $p < 0.001$. There was 90.14% relief

in daurbalya group A and 47.52% in group B. Group A showed highly significant results at $p < 0.001$. But, Chi square test was not significant ($p > 0.10$) indicating that the ratio between the number of patients significantly improved and non-significantly improved in both the groups was almost similar.

Figure 1: Effect of therapy on subjective parameters in groups A and B

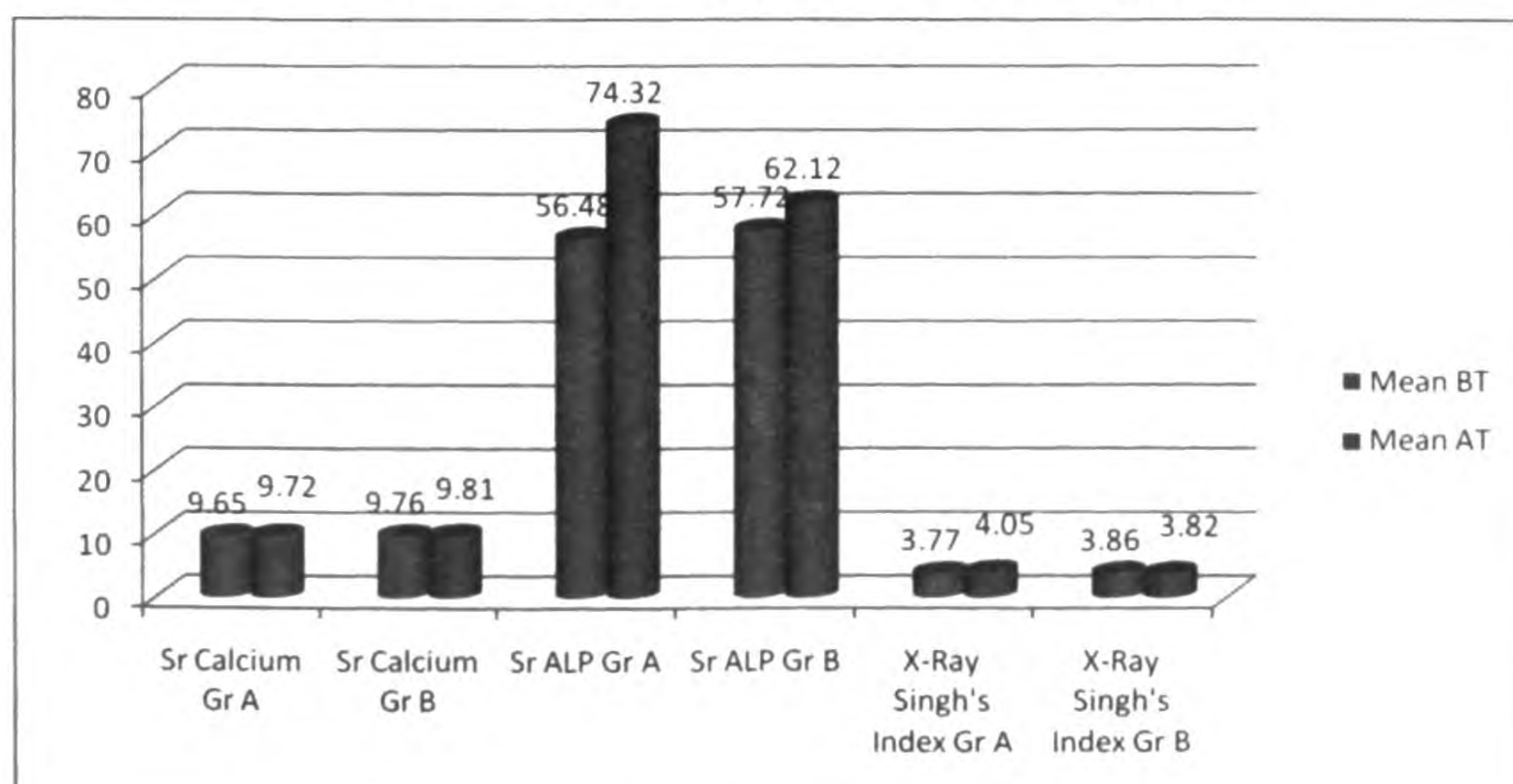


Effect of therapies on objective parameters

The effect of therapy on serum calcium was statistically not significant in both groups at $p > 0.10$. But, serum alkaline phosphatase increased significantly in group A at $p < 0.001$ and the increase was not significant in group B at $p > 0.10$.

The effect of therapy on X-ray - Singh's index was statistically highly significant in group A at $p < 0.001$ and not significant in group B at $p > 0.10$. On comparison, unpaired t-test showed that effect of therapy in group A was highly significant than group B at $p < 0.001$.

Figure 2: Effect of therapies on objective parameters in groups A and B



Effects of therapies on BMD

Since the Ultrasound Bone Sonometer was not available at Jamnagar, the after treatment analysis of the BMD was not possible after exactly 4 months. Depending upon the duration analysis of BMD before and after treatment (BT and AT) the patients of both the groups were divided into 3 sub groups viz A1, A2, A3 and B1, B2, B3 respectively. BMD was assessed after 3½ months in A1 and B1, 4 months in A2 and B2 and 5½ months in A3 and B3.

Statistical analysis was also done separately in each sub group. The effect of therapy was statistically highly significant in groups A1 at $p < 0.001$ and not significant in group B1 at $p > 0.10$. The effect of therapy was statistically not significant in both the sub groups A2 & B2 at $p > 0.10$. The effect of therapy was statistically not significant in group A3 at $p > 0.10$ whereas it was highly significant in group B3 at $p < 0.01$.

Discussion

Pathogenesis of Asthi kshaya is a complex mechanism and hence no single drug can be used to reverse the pathogenesis. It requires a 'Holistic approach' to manage Asthi kshaya effectively. Rasayana helps in the formation of quality body tissues. It increases the life span, memory, promotes intellect, youthfulness, luster, color. It gives pleasant voice, strong body and senses [10]. Hence, in this study Ashwagandha, Shatavari were used as systemic Rasayanas whereas, Lakshadi guggulu and Shukti bhasma were used as Asthi Dhatu specific Rasayanas in group A. In group B, tablet Shelcal-500mg was used as standard control.

Recent researches have suggested that Ashwagandha is anti-inflammatory, anti-rheumatic and anti-arthritic and hence useful in painful conditions [11]. It is also an analgesic which helps to relieve pain associated with osteodystrophic disorders and osteoarthritis [12,13]. Asthi shrinkhala (*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 [14]). The anti-inflammatory features suggest that it acts by preventing the conversion of arachidonic acid to inflammatory prostaglandins [15]. Hence, Ayurvedic drugs were potent enough to overcome the pain compared to the control drug.

Ashwagandha and Shatavari are systemic Rasayanas 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 and 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.

Scientific studies have proved that Ashwagandha, Shatavari and Nagabala are having anabolic and tonic actions on the human body. Shatavari is adaptogenic and immune-stimulator [16] and is indicated in general debility [17].

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 Ashwagandha and Asthisrinkhala. A study conducted by Nagareddy *et al.* in 2006 showed potent anti-osteoporotic activity of Ashwagandha in ovariectomized rats [18].

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.

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.

There were no significant changes in the serum calcium levels after treatment. But, in serum alkaline phosphatase levels there was a significant increase in group A. ALP is biomarker of bone resorption. Its levels are high during increased bone resorption. But, after treatment even when there was increase in BMD, the reason for its increase is unknown.

In group A, 2 patients complained of nausea and vomiting by taking Ashwagandha may be because of its bitter taste and typical odour. The other unwanted effect was weight gain in previously over weight/obese patients. This may be because of continuous use of Ashwagandha and Shatavari for 4 months. But, it was a positive effect for those patients who had low Body Mass Index (BMI < 19 kg/m²). In group B, 43.67% of the patients complained of flatulence and epigastric distress. Majority of the patients felt gastritis, if the Shelcal tablets were taken on empty stomach. Constipation was another adverse effect noted in 36.68% patients of group B.

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. By the effect of therapy obtained in the control group B, it is clear that only calcium and vitamin D₃ 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 and 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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