



Research Article

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EVALUATION OF CLINICAL EFFICACY AND SAFETY OF BONTON ACTIVE GRANULES IN THE MANAGEMENT OF OSTEOPOROSIS (ASTHI-MAJJA KSHAYA)

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ABSTRACT

Asthi-majja kshaya (Osteoporosis) is decrease in the bone tissue and vitiation of vata. Osteoporosis is a growing public health problem worldwide. A large proportion of the population from middle age onwards is at risk of suffering a fracture during their remaining lifetime. Osteoporosis is often known as “the silent thief” because bone loss occurs without symptoms and it is usually diagnosed when fracture occurs in situations where healthy people would not normally have a fracture. The present study is designed for “Evaluation of clinical efficacy and safety of bonton Active granules in the management of Asthi-majja kshaya with special reference to osteoporosis.” Randomised open labelled clinical trial is designed. Total 60 patients of Asthi-majja kshaya (Osteoporosis) are registered; the clinical work is completed in 60 patients. The effect is analyzed on the basis of improvement in classical signs and symptoms of Asthi-majja kshaya and BMD (T-Score). Satisfactory significant improvement is found in Asthi shool (Pain in Bone) 68%, Sandhi-Saithilya 60% Bone mineral density is improved by 48.33%.The Medicine provides improvement on classical signs and symptoms of Asthi-majja kshaya as well as on BMD (T-Score). Study indicated that Bonton Active Granules play a significant role in the management of Asthi-majja kshaya (Osteoporosis).

Keywords: Asthi-majja kshaya, Osteoporosis, Bonton Active Granules

INTRODUCTION

Osteoporosis is characterised by abnormal reduction in bone mass per unit volume, due to poor formation of organic protein matrix. The total bone mass is dismissed but the bone present is qualitatively normal. Osteoporosis results because the rate of bone resorption is higher than that of bone formation. There occurs marked reduction in the mechanical strength of the bone and makes the bone vulnerable for fractures following a trivial trauma.¹The bone mass increases up-to the fourth decade of life and then it decreases progressively.²It is found that the fractures from osteoporosis are more common than heart attack, stroke and breast cancer combined. Due to its prevalence worldwide, osteoporosis is considered as a serious public health concern. Currently it is estimated that over 200 million people worldwide suffer from this disease³. Approximately 30% of all postmenopausal women have osteoporosis in the United States and in Europe. At least 40% of these women and 15-30% of men will sustain one or more fragility fractures in their remaining lifetime.

MATERIAL AND METHODS

Study design

Present study was an open label, Interventional and Single random method study. Patients attending OPD Kaya chikitsa (Medicine) department I.P.G.T. &R.A. Gujarat Ayurved University Jamnagar, Gujarat, India complaining regarding Asthi-Majja Kshaya (Osteoporosis) included in the study. A total No. of patients of age above 40 years and below 60 years of either sex, satisfy the inclusion criteria were enrolled for the study. During this study, 25 patients dropped out and 60 patients were followed till the end. Informed consent was taken from the

patients before including to trial. All the patients were administered with trial drug Bonton Active Granules 5 gram twice a day with warm milk. The patients were registered their data or demographic and clinical profile was maintained. The drug given with follow ups every 20 days follow up for duration of 120 days. The study was conduct in OPD of Kaya chikitsa department, Research project during the period Dec 2013 to Dec 2014 sponsored by Vasu Pharma ltd. Baroda. Ethically proved before study No. PGT/7/-A/Ethics/2013-14/2753. On dated 09/12/2013.

Diagnostic Criteria

The criteria of diagnosis were based on the sign & symptoms (Bone pain, continuous body-ache, extreme fatigue, joint Pain, peri-dental disease, hair loss, weakness, forward bending of spine, brittle and soft bones, difficulty in walking) of osteoporosis & osteo-penia (asthi-majja kshaya) and relevant physical examination (overall body-ache or pain in one joint) was carried out. In addition to this bone mineral density test was carried out in all the patients to confirm the diagnosis as well as to exclude the normal patients.

Inclusion Criteria

- Osteopenic/osteoporotic patients of either sex whose BMD (t score) is equal to or less than -1 will be selected for the present study.
- Patients between the age group of 40 and 70 years and willing to give consent to participate in the study.

Exclusion criteria

- Patients whose age is below 40 and above 70 years
- Patients whose BMD (t score) is above -1 will be excluded from the present study.
- Patients suffering from neoplasm of the bone will be excluded.
- Known cases of poorly controlled Hypertension or with uncontrolled Diabetes Mellitus or suffering from Thyrotoxicosis, Hyper Parathyroidism, Addison’s disease, Paget’s disease, Cushing’s Syndrome, Tuberculosis of the bone, Osteomalacia, chronic renal failure, hepatic and cardiac failure will also be excluded from present clinical trial.
- Rheumatoid arthritis, Gouty arthritis and any long standing systemic disease will be excluded.

Laboratory Investigations

- BMD test.
- Hematological investigations
- Urine Analysis for Routine and Microscopic test.
- X-Ray of joints.
- Serum Vitamin D3,
- Serum phosphate

Dose

5 g twice Bonton Active Granules twice a day after breakfast and after dinner
Anupana: Warm milk

Route of administration: Oral

Duration: 120 days

The Patients were given medicine for 120 days and were assessed after every 20 days. i.e. 6 times during the course of treatment to observe the extent of relief and side effects, if any.

Diet: Patients were kept under normal diet with Special restriction of excessive lentels and pistana (Fast foods) copy of diet chart was given to each patient.

OBSERVATIONS AND RESULTS

In the present study, all patients were selected in the age group of 40-70 years. Out of total enrolled subjects, 60 completed the study of which 40 (66.67%) patients were Female and 20 (33.33%) patients were Male (Table 3: Gender wise Distribution). The mean age of patients was 53.581 years with 45% patients in the age group of 50-60 yes of age. (Table 4: Age wise Distribution). On First visit pain, Sandhi Saithilyam (looseness of joints) Sadana (weakness without doing any work) and Sandhi Sfutanam (crepitus) were 2,550,1,600,1,133 and 1,972. Respectively clinical significant improvement in symptoms was seen after completion of treatment 120 days. And mean of symptoms were 0.750, 0.283, 0.200 and 0.444. Vitamin D3 was also increased (Table 11). The range of change in symptoms before and after treatment is showing table 7-10.

Statistical analysis: Before and after treatment was analyzed by paired t-test and the result was found to be statistically significant.

Table 1: Pain

0	No Pain
1	Mild Pain (pain exaggerated by movement but subsided by rest)
2	Discomforting pain
3	Distressing pain
4	Horrible

Table 2: Tenderness

0	No Tenderness
1	Mild Tenderness (Patient feels pain on pressure but does not withdraw joint)
2	Wincing of face on pressure
3	Wincing of face and withdrawal of the affected part on pressure
4	Resist touch due to tenderness

Table 3: General debility

0	No daurbalya
1	Not able to perform strainous activity
2	Not able to perform moderate activity
3	Cannot perform moderate activity but can perform mild activity without any difficulty
4	Even mild activities cannot be performed.

Table 4: Overall effect of therapy

Improvement in percentage	Justification
80% to 100%	Cured
60% to 79%	Marked Improvement
40% to 59%	Moderate Improvement
20% to 39%	Mild Improvement
0% to 19%	Unchanged

Table 5: Bone Mineral Density (T-Score)-WHO Criteria for assessing osteoporosis

(T-Score)	Condition
greater than -1	Normal
between -1 to -2.5	Osteopenia
less than or equal to -2.5	Osteoporosis

Table 6: Ingredients of the Bonton Active Granules

No.	Name	Part Used	Form
1.	<i>Cissus quadrangularis</i> (Hajod)	Stem	Extract
2.	<i>Asparagus racemosus</i> (Shatavari)	Root tuber	Extract
3.	<i>Withania somnifera</i> (Ashwagandha)	Root	Extract
4.	<i>Vitex nigundo</i> (Nirgundi)	Leaves	Extract
5.	<i>Terminalia arjuna</i> (Arjun)	Bark	Extract
6.	<i>Macuna pruriens</i> (Kauncha)	Seed	Extract
7.	<i>Commiphora mukul</i> (Guggulu)	Gum Resin	Extract

Table 7: Gender Wise Distribution of 60 patients of Osteoporosis

Sex	No. Of Patients	%
Male	20	33.33%
Female	40	66.67%

Table 8: Age Wise Distribution of 60 patients of Osteoporosis

Age	No. Of Patients	%
40-50	17	28.33%
51-60	27	45%
61-70	16	26.67%

Table 9: On the basis of t-score data of 60 patients which have completed the treatment Sign of Pure Asthi Majja Kshaya & Partial Asthi Majja Kshaya

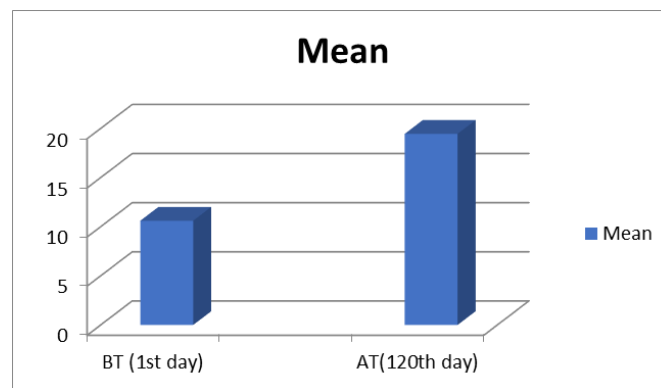
Asthi-Majja Kshaya	No. Of Patients	%
Osteoporosis	36	60%
Osteopenia	24	40%

Table 10: Menopausal wise distribution of 40 Female out of 60 Patients of Osteoporosis (Asthi Majja kshaya)

Menopausal	No. of patients	%
Present	36	90%
Absent	04	10%

Table 11: Statistical analysis of symptom Pain before and after treatment Osteoporosis (Asthi Majja kshaya)

Duration	Mean	Mean Diff.	% of change	SD	SE	T-Value	P Value
BT (1 st day)	2.550	1.800	70.757	0.632	0.0816	22.045	<0.001
AT (120 th day)	0.750						



Graph 1: Statistical analysis of symptom Vit. D3 before and after treatment Osteoporosis (Asthi Majja kshaya)

Table 12: Statistical analysis of symptom Sandhi Saithilyam before and after treatment Osteoporosis (Asthi Majja kshaya)

Duration	Mean	Mean Diff.	% of change	SD	SE	T-Value	P Value
BT (1 st day)	1.600	1.317	82.41	0.930	0.120	10.971	<0.0001
AT(120 th day)	0.283						

Table 13: Statistical analysis of symptom Sadana before and after treatment Osteoporosis (Asthi Majja kshaya)

Duration	Mean	Mean Diff.	% of change	SD	SE	T-Value	P Value
BT (1 st day)	1.133	0.933	87.72	0.861	0.111	8.397	<0.0001
AT(120 th day)	0.200						

Table 14: Statistical analysis of symptom Sandhi futanam before and after treatment Osteoporosis (Asthi Majja kshaya)

Duration	Mean	Mean Diff.	% of change	SD	SE	T-Value	P Value
BT (1 st day)	1.972	1.528	80.48	0.506	0.0844	18.105	<0.001
AT(120 th day)	0.444						

Table 15: Total effect of therapy on (Subjective Criteria) asthi majja kshayatmak lakshan in 60 patients

Criteria	No. of Patients	%
Cured (80%-100% relief)	37	62%
Marked Improvement (60%-79% relief)	18	30%
Moderate Improvement (40%-59%relief)	04	6.7%
Mild Improvement (20%-39%relief)	01	1.7%
No Change (0% -19 relief)	00	00%

DISCUSSION

Osteoporosis has emerged as new challenge for medical science. Osteoporosis term describes a group of bone disorders in which the absolute bone mass is less than normal within the third decade of life the skeletal mass begins to diminish at a rate of about 0.5% per year in both sexes. In males, bone loss proceeds continuously into senescence at the same low rate, and generally reaches the “fracture threshold” at a more advanced age than in women. When female entering the menopause, due to cessation of ovarian function bone loss is accelerated to about 3% per year (particularly in cancellous bone, e.g., in the spine; Vertebral fracture risk in the second half of life is 5% for males and 16% for females of the same age. Concepts of Ayurveda have been helpful in treating new diseases arising due to changing lifestyles and environment. This study was an attempt to understand the disease in Ayurvedic concept and find an effective therapy in preventing the disease. General properties of asthi dhatu, its location, relation with other body tissues and its functions; sthayi asthi dhatu can be considered as bones. The nutrients essential for formation and metabolism of asthi such as calcium, magnesium and other minerals can be taken as asthayi (poshaka) asthi dhatu. Bone is continuously being remodelled – old bone is replaced by new bone. In our classics also, the dhatu nirmana is a continuous process going on in body. Vitamin D, which is derived from sterols, is essential for absorption of calcium in the body⁵. Hence the moola (root) of asthi vaha srotas is rightly considered as meda.⁶ Imbalance in asthi dhatvagni leads to improper formation of sthayi (permanent) asthi dhatu from posaka asthi dhatu. Parathyroid hormone, calcitonin, estrogen etc. play significant role in metabolism of bone. The asra-asrayi (dependant-dependency relationship) of vata dosha and asthi dhatu forms a fundamental base to understand any pathological condition related to asthi-bone dhatu⁷. Also the management of asthi related diseases is unique because of this relationship. Majja is apya (water) pradhan (dominant) dhatu vitiated vata also decreases majja means kshaya of majja dhatu. Atparpan (lack of nutrition) janya vata prakop is due to taking ahara and vihar which vitiate vata or due to jara (old age) janya and samtarpan janya is due to creating margarodha (blockage) causing vitiation of vata. reviewing all the available literatures related to asthi (bone) dhatu & majja (bone marrow) dhatu the fina diagnosis of the disease was given as ‘Asthi Saushirya’⁸Vata dosha contributes largely for occurrence of asthi related diseases because of unique relationship of vata and asthi (bone). Management of established asthi saushirya difficult. Hence prevention of the condition becomes all important. This disease can become yapy (a condition whenever patient take treatment gets relief) by intervention at proper level, followed with pathyapathaya (do & don’t). Prevention of asthi saushirya (Osteoporosis) should be commenced at the level of asthi majja kshaya, which is

precursor of asthi saushirya. For minimizing asthi majja kshaya (Osteoporosis) and preventing asthi saushirya, ideal period intervention can be the beginning of age of hani-loss (40 years)⁹ i.e. last phase of madhyamawastha (young age) when kshaya-decrease of all dhatu begins. As the nourishment to all dhatus through ahara (food) rasa is minimal in old age and it just supports life¹⁰.

DRUGS AND DOSES

Drug **Bonton Active Granules** was selected for the present study as the all contain of the drug is a well-known drug for having Asthi-Bhagna (fracture), rasayana (rejuvenation therapy), healing property and this drug having ascorbic acid, carotene, and anabolic steroid like substance.

Asthishrinkhala (*Cissus quadrangularis*) & **Kauncha** (*Mucuna pruriens*): Calcium is chief consisted of these drugs, calcium lacks create osteoporosis so we have to maintain calcium level. As these drugs contains its main chemical constituent as calcium by which we can maintain the calcium haemostasis (which regulates calcium how to and from the bones. When advised compounds which contains calcium, the release from which is regulated by parathyroid hormone. Vit. D is converted to calcitol in the liver which is then converted to calcitriol, the biologically active form of vit. D in the kidneys. Calcitriol regulates the levels of calcium and phosphorus in blood and helps maintain healthy skeletal system. Bone resorption by osteoclasts releases calcium into blood stream which helps regulates calcium homeostasis, the process of bone resorption by the osteoclasts releases stored calcium into systemic circulation & is on important process in regulating calcium balance. As bone formation actively fixes circulating calcium into mineral form removing it from blood stream, resorption actively an fixes it there by increasing circulating calcium levels. So, supplement of calcium, Vit. D slightly improves bone mineral density as well increasing the risk of skeletal disorders in old age. This will be more increased level of beneficiary in secondary osteoporosis which is caused due to decreased levels of Ca, Vit. D and parathyroidhormone.

Shatavari (*Asparagus racemosus*): This contains “Saponin”, Bone remodelling occurs through life via synthesis of bone materials through the action of 2 major bone cells- Osteoblasts & osteoclasts. The proper functioning of these cells is necessary for maintenance of bone mass as well as bone Mineral density. During old age especially, postmenopausal period there will be excessive bone resorption relative to bone formation due to hormone deficiencies which reduce bone mass & ultimately causes bone diseases& osteoporosis. Usually while going through pathophysiology of osteoporosis the main molecular factors involved in this are kappareceptor & osteoprotegerin,

saponin can reduce the op changes by inhibiting production of NF-Kb, Stimulates ALP and by increasing blood circulation.

Nirgundi (*Vitex nigundo*) & Guggulu (*Commiphora mukul*): As volatile oil is one of the chief comical constituent of these two plants, it helps relieving pain in muscles and joints by stimulates circulation and producing warmth. These oils will be accepted by the body due to some common like compatibility with human proteins, ability to regenerate tissue which will be destroyed in osteoporosis. These are so tiny, they are able to perpetrate human cells, so when therapeutic grade oil is applied to skin it reaches every cell in body within minutes, also stimulates production of white blood cells.

Ashvagandha (*Withania somnifera*) & Arjuna (*Terminalia arjuna*): These contain amino acids. These amino acids help the body to calcium & plays an important role in the formation of callogen, A substance important for bones & connective tissue including skin, tendon& cartilage Male idiopathic osteoporosis: this condition there will be change in free amino-acid profiles which will be constituted by *Withenia somnifera*.

CONCLUSION

The medicine provides improvement on classical signs and symptoms of asthi-majja kshaya (osteoporosis) as well as on BMD (T-Score) and Vit. D3. Study indicated that Bonton Active Granules play a significant role in the management of Asthi-Majja kshaya (Osteoporosis).

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