International Journal of Applied Ayurved Research ISSN: 2347- 6362

EFFICACY OF *GANDHA TAILA* ON OSTEOPOROSIS A CLINICAL STUDY

[1]Rao Veena G [2]Patil Deepa c [3]Prashanth Akila

[1]Professor Dept. of PG Studies in Panchakarma JSS Ayurveda Medical College &Hospital Lalithadripura road, Mysuru, Karnataka

[2]Reader Dept. of Kayachikitsa JSS Ayurveda Medical College &Hospital, Mysore, Karnataka

[3]Professor, Centre for Medical Genomics and counselling & Centre of Excellence in molecular Biology and Regenerative Medicine Department of Biochemistry, JSS Medical college JSS Academy of Higher Education and Research, Mysuru

ABSTRACT

Osteoporosis is defined as a disease in which there is "Low bone mass and micro architectural deterioration of bone tissue" which increases bone fragility and leads to a high risk of fracture. *Asthikshaya* can be paralleled with osteoporosis. According to the principle of *ashraya-ashrayee bhava*, *asthi dhatu* is the seat of *vata dosha*. *Asthi* and *vata* are inversely proportional to each other regarding *vriddhi* & *kshaya*. *Vriddha vata* leads to *kshaya* of *asthi*.

Though *virechana*, *tiktaghrita*, *ksheera basti*, *asthivardhaka dravyas* etc are the treatments for *asthikshaya*; *bahya* & *abhyantara sneha* have been considered as the choice of treatment for *asthimajjagata vata*. '*Gandha taila*' is one such *sneha* which can be administered orally and said to be good to bestow sturdiness to the bone. So, in this clinical study, a novel formulation "*Gandha taila*" was administered orally in 51 subjects of osteoporosis for a duration of 4 months to see the improvement in BMD and influence over biochemical markers of bone formation i.e. serum osteocalcin & Alkaline Phosphatase(ALP). In this study, *Gandha taila* has shown overall improvement as measured by increase in the BMD indicating its positive influence over the bone density. The reduction in the serum osteocalcin indicates that it acts as an inhibitor of bone resorption. The analysis of outcome has given very promising result in the management of osteoporosis and understanding the probable mode of action of *Gandha taila* over osteoporosis.

Keywords: Osteoporosis, *Asthikshaya*, *Gandha taila*, Serum Osteocalcin, Serum ALP

INTRODUCTION: *Ayurveda* is an ancient science of life deals with the preventive as well as curative aspect. It explains human body as a "congenial homeostasis" of *dosha*, *dhatu* and *mala*. Among the *dhatu*, *asthi dhatu* is responsible for maintenance of structural frame work of the body and protects the vital organs. The state of equilibrium of *dhatus* is health and their disequilibrium is disease[1].This disequilibrium may be either *vriddhi* or *kshaya*. *Asthidhatukshaya* (decrease in bone tissue mass) is a condition explained in *Ayuveda*, under the heading of *Ashtaadasha* i.e 18 *kshayas*.

WHO employs a functional definition of osteoporosis as a disease in which "low bone mass and micro architectural deterioration of bone tissue" increases bone fragility, and leads to a high risk of fracture.[2]Osteoporosis is the second most common metabolic bone disease in India[3]This is clinically silent but progressive, usually only noted when a fracture occurs. Under-recognition of low-trauma fractures as osteoporotic fractures

leads to lack of osteoporosis treatment, which further increases fracture risk. Prevention and early intervention can prevent osteoporosis in majority.

The actual prevalence of osteoporosis is unknown as it is asymptomatic. It is estimated to affect >10 million individuals in USA but only 10-20% are diagnosed. It is a global dilemma that is expected to increase in significance with the growing elderly population as bone tissue is progressively lost. It affects both sexes but women are more prone to have osteoporosis due to loss of ovarian function at menopause.

Asthikshaya can be paralleled with osteoporosis. According to the principle of *ashraya-ashrayee bhava*, *asthi dhatu* is the seat of *vata dosha*. *Asthi* and *vata* are inversely proportional to each other regarding *vriddhi&kshaya*. *Vriddha vata* leads to *kshaya* of *asthi*[4].The *asthi dhatu* constitutes of *prithvi* and *vayu mahabhuta* in dominance.[5]*Asthi dhatu* is considered as *ashraya* for *vata* because of its *kharatva*(hardness) due to *prithvi mahabhuta* and *sushira*(porous) because of its *akasha mahabhuta*. So, *vata vriddhi* leads to *sushirata* in *asthi dhatu* causing *asthikshaya* which describes 'porous bones' of "osteoporosis".

As modern synthetic molecules in the treatment of osteoporosis pose adverse effects, establishing an evidence based formulation which can arrest the pathology and improve the density and quality of bone, is the need of the hour in the treatment of osteoporosis.

Virechana, tikta ghrita ksheera basti, tarunasthi vikara (like *kukkutanda twak bhasma*), food & drugs having similar qualities of *asthi* (like milk) are the treatments for *asthikshaya*. *Bahya* & *abhyantara sneha* have been considered as the choice of treatment for *asthimajjagata vata*. *Gandha taila* is one such *sneha* which can be administered orally and said to be good to bestow sturdiness to the bone.[6] *Gandha taila* possess properties like *Vatahara, bhrimana, asthidhatu vardhaka*.

Most guidelines suggest that patients should be considered for treatment when BMD is less than 2.5 SD, below the main value for young adults (T. score<=-2.5) a level consistent with the diagnosis of osteoporosis. Biochemical markers of bone formation that is osteocalcin, alkaline phosphatase is of value to predict the rate of bone loss and the risk of osteoporotic fracture and to monitor treatment response in osteoporosis[7].

So, in this clinical study, a novel formulation "*Gandha taila*" was administered orally in subjects of osteoporosis, to see the improvement in BMD and influence over biochemical markers of bone formation i.e. osteocalcin & alkaline phosphatase[8.] This clinical Study is directly proposed in human subjects without prior pre-clinical and toxicological tests because of time tested usage of this traditional formulation over years.

REVIEW OF LITERATURE: The word *Asthi* is derived from the root 'as' + 'kthin' meaning 'to stay' or in the sense of 'stability'[9].The main functions of dhatus are *dharana* & *poshana*[10].*Asthi dhatu* is the fifth among seven *dhatus*. It is described as *katinatam* (hardest), *guru, khara, sthula,sthira*, and *murtimad* . Function of *asthi dhatu* is compared with the hard core of stem of a tree[11].As without stem the tree cannot stand, in the same way without *asthi dhatu*, the body cannot stand and is just like the mass of flesh[12].

Asthi dhatu formation starts in the intra-uterine life. It keeps growing and get nourished by the food just like any other *dhatu*. Precursor of *asthidhatu* (*poshak asthi*) is formed at the time of formation of *medo dhatu*. Nutrients of *asthi dhatu*(*poshak asthi*) reaches the *asthivaha srotas* where it is acted upon by *asthidhatwagni* and results in the formation of *poshya asthi dhatu*, *upadhatu*(*danta*), *mala*(*kasha, loma, shmashru*) and the formation of *poshaka majja dhatu*[13].

The word *asthi kshaya* is composed of two words *asthi* and *kshaya*. The definitions of *asthi* are "*Asyate kshipyate yat*" ; "*asyate iti asthi*"; "*mamsa abhyantarasthah sharirastha sapta dhatvantargata dhatu visheshaha*". That which is present in its own state for a long time is called *asthi*. *Sushruta* mentions that *twacha, mamsa* etc tissues gets destroyed soon (after death) but *asthi* persists in its own state for a long time. Hence it is called as the *sara* of *sharira*[14].

Asthi pancha-bhautikatva[15(a)]can be explained as *akasha* - porous cavity inside the bone, *vayu*- flow of blood nutrients etc, *agni* – conversion of cartilage into bone, *jala*- bonemarrow, *prithvi* - constituents of bone. *Purisha dhara kala* is also called as *asthidhara kala*[16(a)]

The definitions of *kshaya* are "*ksheeyate anena iti kshaya*"; "*kriyakshaya karatwat tu kshaya ityuchate budhaihi*" "*kshaya vyadhi visheshaha*"[17].That which decreases is called as *kshaya* and it is *vyadhi vishesha*. Hence the combined meaning of *asthi kshaya* is decrease in bone tissue.

During life, bone undergoes **modelling** and remodelling. Bone modelling is the process by which bones change shape or size in order to respond to physiologic stimuli or mechanical forces which skeleton is subjected to. This occurs during birth to adulthood and is responsible for gain in skeletal mass and changes in skeletal form. Skeletal **remodelling** is the replacement of old tissue by new bone tissue so that bone can maintain its strength and properties. Bone remodelling is a life-long process. The main cells involved in bone remodelling are osteoblasts and osteoclasts. These cells are tightly coupled, their co-operative functions lead to resorption of old damaged bone and formation of new bone sequentially. Other cells involved in bone remodelling are osteocytes, that act as mechanosensors, endocrine cells and the bone lining cells[18].

The osteoporosis which develops as a consequence to aging or natural menopause without any identifiable cause is called as the Primary osteoporosis. The risk or etiological factors of primary osteoporosis are increasing age, menopause/andropause, surgical menopause(radical hysterectomy or oophorectomy in early age), Caucasian race, female gender, low body mass index(BMI) <19, lack of exercise(sedentary life style), history of fracture as an adult, history of fracture in an immediate relative, low calcium diet, malnutrition, magnesium & vitamin D deficiency,smoking or tobacco in any form, alcoholism, astronauts (living in low gravity areas.)[19]

Secondary Osteoporosis is caused by number of diseases and drugs. Some of the causes of secondary osteoporosis[20]are Ehler Danlos Syndrome, premature menopause, osteogenesis imperfecta, anorexia nervosa/ bulimia, androgen insensitivity, Turner's and Klinefelter's syndrome, DM, hyperparathyroidism, Cushing's syndrome,gastrectomy & celiac

disease, malabsorption, Protein Calorie Malnutrition(PCM), Rheumatoid Arthritis, long term glucocorticoid therapy etc.

Vata prakopaka nidana in the form of *aharaja, viharaja, manasika, jara* (in females *rajonivritti*), *abhighata, chikitsa vibhrama,* excessive *shodhana* along with the *sroto dushti nidana* of *meda, asthi, majja* and *purishavaha srotas* , *agni dushti*, i.e, *jatharagni, bhutagni, asthi dhatwagni* altogether form a complex mechanism of pathogenesis of *asthikshaya*.

Two conditions mentioned in *Ayurveda* may be discussed in this regard. One is *asthikshaya* and another is *asthisaushirya*. *Asthisaushirya* is not mentioned as a separate condition but as a symptom of *majja kshaya*, whereas *asthikshaya* is mentioned as an independent condition. *Asthikshaya* is 'decrease in the bone mass' and *asthisaushirya* means 'porous bones'. Hemadri had commented on the word '*saushirya*' as '*sarandrathvam*.' which means 'with pores'[21].

The three major pathognomonic reasons for low bone mass are failure to achieve optimal peak bone mass, increased bone resorption & inadequate bone formation

Among the clinical features of *Asthikshaya* mentioned by *acharyas*, the *asthishula, toda, sandhishaithilya* are the major ones. Generally, when *dhatu* is affected its *upadhatu* and *mala* are also affected. So, *kesha loma nakha danta vikara* are also seen in *asthi kshaya*. Other *vataja* features like *dourbalya, rukshata, shrama, shosha*, reduction in *meda, veerya* & *bala, ati manda cheshta, vikampana* are also seen[22].

The clinical features of osteoporosis include pain due to fractures, tenderness, general debility, muscular weakness, abdominal distension, insomnia, loss of appetite, osteo-arthritis, constipation, kyphosis, scoliosis, deformity in teeth and brittle nails.

The radiological techniques used to assess the bone quantity and qualities of bone in osteoporosis are x-ray, measurement of Bone mineral density (BMD), Quantitative computed tomography (QCT), MRI and Ultrasound. With the 'Singh's Index.' One can grade the osteoporosis on the basis of X-rays[23].

With BMD it is possible for clinician to diagnose osteoporosis using the WHO criteria for osteoporosis, to predict fracture risk, to monitor the natural progression of diseases that affect BMD or monitoring the therapeutic response to osteoporosis specific treatments.

As per the WHO Criteria, depending upon the't'-score, bone health can be graded as follows[24]

i) Normal: A value of BMD (t-score) within 1 standard deviation of young adult reference mean, i.e,'t'-score>-1.

ii)Osteopenia:. A value of BMD (t-score) more than 1 and less than 2.5 standard deviation below the young adult reference mean, i.e, -1>'t'-score >-2.5. It means the reading of t-Score ranges between -1.1 to -2.4.

iii) Osteoporosis: It is operationally defined as a bone density that falls 2.5 SD below the mean, or also referred to as a t-Score <-2.5.

iv) Severe osteoporosis: A value of BMD more than 2.5 standard deviation below the young adult reference mean i.e, 't'-score <-2.5 and presence of at least one or two fragility fractures.

Deterioration in the quantity & quality of bone mass is brought by an imbalance between bone resorption and

bone formation processes that are normally coupled and is called as bone turnover. Markers of this bone turnover (BTM) have a variety of potential clinical applications based on their rapid response to treatment, their value in monitoring compliance to medications.

Depending upon their origin, BTMs are classified as indices of either bone formation or resorption[25].

Bone Formation Markers: These are released into the circulation from osteoblasts during their activity of bone matrix synthesis.

Bone Resorption Markers: These are released into the circulation from osteoclasts during their activity of bone resorption.

Among the markers,serum ALP **(**Alkaline phophatase) &serum Osteocalcin are the biochemical markers of bone formation.

Alkaline phophatase (ALP) is a glycosyl –phosphatidyl-inositol anchored ectoenzyme present on the membrane of osteoblastic cells[26]**.** ALP is a commonly encountered laboratory value that is included in the panel of bone and liver function tests. BAP is considered to be a highly specific marker of the bone-forming activity of osteoblasts.

Osteocalcin is a bone matrix protein(bone gla protein) dependent on vitamin K and vitamin D, and is synthesised by mature osteoblasts[27].Osteocalcin is released from the bone matrix into blood during bone resorption, which suggests that osteocalcin is useful in the diagnosis and follow-up of high turnover osteoporosis, also an important marker of bone turnover. Either RIA, ELISA, or a chemiluminiscence immunoassay may be used to detect osteocalcin.

Significant reductions in BTMs are seen with antiresorption therapy and have been associated with fracture reduction, whereas significant increase indicates good response to anabolic therapy[28].

"*Gandha Taila*" is the traditional poly herbal oil formulation (*taila yoga*) described in *Ashtanga Hrudaya*. Though this preparation is explained in other classical textbooks like *sushruta Samhita*, *Vagbhata* has explained its only beneficiary effect as "to bestow the sturdiness of the bone". This is gingelly oil (*tila taila*) based preparation, wherein milk, *yashtimadhu, manjishta,sariva, ela, jivaka, tagara* etc 20 drugs are used in its preparation.

Preparation of *Gandha Taila: Krishna tila* well cleaned is tied into a bundle with a thick cloth and allowed to stay in flowing water for 7 days. Then it is soaked in milk and *Madhuka Kashaya* during night time and dried in sun at day time for 7 days each. Once again soaked in milk, removed of its husk and powdered.

Then it is mixed with fine powder of *Nalada, Valaka, Lohita, Yashtika, Nabra, Mishi, Plava, Kushta, Balatraya, Agaru, Kunkuma, Chandana, Sariva, Sarala, Sarjarasa, Amaradharu, Padhmakadi gana dravya* and cooked with *Eladi Gana Dravya siddha Ksheera.* It is then cooked with *Taila* and *Ksheera* prepared out of *Shaileya, Rasna, Amshumathi, Kasheru, Kalanusari, Nata, Patra, Rodra, Ksheerashukla, Erva*. This is called as *Gandha Taila*.

AIMS & OBJECTIVES: To validate the efficacy of "*Gandha taila*" on osteoporosis through biochemical markers of bone formation i.e, serum ALP & Osteocalcin

MATERIALS & METHODS:

Study design: An open label, Single arm, interventional clinical study with pre and post test design.

Source of data

The formulation "*Gandha taila*" was procured from a GMP certified Ayurveda Pharmacy, AVN (AryaVaidya Nilayam)

a) Sample size: 51 subjects diagnosed as suffering from osteoporosis was selected from the OPD and IPD, JSSAMH. Based on the success rate of other studies on osteoporosis & alpha value, the sample size was selected as minimum of 50, including expected dropouts. Informed consent was taken & patient's data were recorded in detail in the proforma of case study specially designed for this purpose.

b) Inclusion criteria –

- Subjects having BMD t-score </= -2.5
- Clinical features of osteoporosis i.e. skeletal pain, tenderness, fracture.
- Subjects of either sex with age above 35years
- Pre and Post menopausal women

c) Exclusion criteria -

- Subjects in whom *taila* is contraindicated.
- Subjects under corticosteroids and other interfering drug
- Pregnant and lactating women

d) Diagnostic criteria

Subject with BMD t score </= -2.5 with or without clinical features.

e) Investigations

- BMD test – was done using Bone Densitometer at the mid shaft of tibia. (DEXA i.e. Dual Energy X ray Absorptiometry which is accurate & consistent)
- Serum Osteocalcin – was done using ELISA Kit
- Serum Alkaline Phosphatase(ALP) – was done using fully automated clinical chemistry analyser.

All the three investigations were done before & after intervention.

f) Intervention

The formulation *Gandha taila* was given orally in the dosage of 1ml twice daily with luke warm water 30 minutes before food for a period of four months[29]for all the 51 subjects of osteoporosis, selected for this study.

1 ml is taken as dosage here in this study because of *anubhuta pramana*, (the dosage clinically practiced since long, as per the dosage of *avartita taila*), as there is no specific dosage form for *Gandha taila* in our classics.

g) **Assessment criteria**

- BMD
- Serum osteocalcin
- Serum alkaline phosphatase

All the three investigations were done before intervention(0day) & after intervention (120th day)

Statistical analysis: The data collected was entered in MS excel 2010 and analyzed using SPPSS version. 22 descriptive statistical measures like percentage, mean, and standard deviations are applied. Inferential statistical test like 'paired t test' was done to test the difference between mean level of quantitative parameters, before and after the intervention. The difference was interpreted statistically significant at a $p<0.05$.

OBSERVATIONS: In this research work no subjective criteria was taken for the assessment. The human subjects who were diagnosed as osteoporosis on the basis of

BMD values were administered '*Gandha taila'* in the above mentioned format to validate its influence on serum ALP & Osteocalcin, the biochemical markers of bone formation or BTM (Bone Turn over Markers).

Table No -1 Gender wise distribution of Subjects:

Gender	Frequency	Percent
Female	37	72.5
Male	14	27.5
Total	51	100.0

In this study, among 51 subjects 37 (72.5%) were females and 14 (27.5%) were males.

Table No -2 Diet wise distribution of Subjects:

Diet	frequency	Percentage
Vegetarian	18	35.29%
Non-vegetarian	33	64.71%

18 subjects (35.29%) were vegetarians & 33 subjects (64.71%) were non-vegetarians

Table No -3 Physical activity wise distributions of subjects

Physical activity	Frequency	Percentage
Regular exercise / Yoga/ walking	6	11.76%
Routine work	45	88.24%

6 subjects (11.76%) had history of regular exercise / yoga / walking and 45 subjects (88.24%) had history of only engaged with routine works.

Table No -4 Age wise distribution of Subjects

Age group	Frequency	Percent
< 40	3	5.9
41-50	6	11.8
51-60	20	39.2
61 and above	22	43.1
Total	51	100.0

Among 51 subjects, 3 subjects (5.9%) were at the age of <40yrs, 6 subjects(11.8%) were between 41-50yrs, 20 subjects (39.2%) were between 51-60yrs, 22 subjects (43.1%) were above 61yrs.

Table No -5 BMI wise distribution of Subjects:

BMI	Frequency	Percentage
25-30	5	9.8%
31-35	20	39.2%
36-40	23	45%
>40	3	6%

Among 51subjects, BMI of 5 subjects (9.8%) was between 25-30, 20 subjects (39.22%) was between 31-35, 23 subjects was between 36-40, and 3subjects (5.88%) was >40.

- During the intervention, no subject developed any adverse effects.

RESULTS: The data collected was entered in MS excel 2010 and analyzed using SPPSS version as follows

Table 6- Before and after treatment values of BMD, ALP& Osteocalcin

Sl No	BMD BT	BMD_AT	ALP BT	ALP_AT	Osteocalcin_ BT	Osteocalcin_AT
1	-2.6	-2	151	182	8.0876	5.0976
2	-2.5	-1.8	242	226	3.7378	1.1341
3	-2.5	-1.7	183	105	13.0427	6.75
4	-2.5	-1.7	263	196	5.2134	0.0488
5	-2.6	-1.9	149	126	21.1159	2.878
6	-2.5	-1.8	177	172	20.1585	5.3659
7	-2.5	-1.8	175	174	16.2988	2.2134
8	-2.6	-1.6	242	200	9.3537	5.5183
9	-2.5	-1.6	163	128	18.6036	1.4939
10	-2.79	-1.9	204	194	4.6098	3.9086
11	-2.5	-1.7	126	226	10.3049	5.3659
12	-2.57	-1.83	380	349	25.3964	17.4024
13	-2.5	-1.64	224	136	14.3353	1.3232
14	-2.7	-1.84	237	212	9.6158	3.9329
15	-2.61	-1.53	261	184	7.0854	2.3964
16	-2.5	-1.94	192	210	4.9207	6.6463
17	-2.62	-1.94	217	248	3.689	4.2195
18	-2.5	-1.74	211	180	6.8476	2.7988
19	-2.5	-1.92	343	310	8.8293	5.0305
20	-2.79	-1.92	221	141	7.8841	5.6524
21	-2.6	-1.7	237	290	11.122	5.1341
22	-2.5	-1.9	239	240	5.2012	3.9268
23	-2.5	-1.7	206	237	9.8476	8.2073
24	-2.6	-1.82	174	257	14.2744	9.0549
25	-2.54	-1.8	175	224	4.75	2.8232
26	-2.6	-1.7	200	272	5.1098	3.6037
27	-2.5	-1.9	139	380	10.4451	9.2073
28	-2.5	-1.8	92	206	8.128	5.9756
29	-2.6	-1.9	217	254	3.2195	2.5488
30	-2.6	-1.7	208	167	7.3117	8.9939
31	-2.5	-1.62	129	140	2.5122	5.3659
32	-2.5	-1.75	275	270	8.7805	6.5305
33	-2.5	-1.82	155	190	4.9573	3.0793
34	-2.6	-1.63	210	157	16.0488	9.6402
35	-2.5	-1.81	136	163	2.5549	0.811
36	-2.5	-1.9	121	186	16.0488	9.6829

37	-2.5	-1.74	180	229	4.628	3.1524
38	-3.06	-2.24	240	277	1.1524	4.3476
39	-2.67	-1.94	144	266	2.7195	8.3293
40	-2.58	-1.32	180	121	5.4268	3.4207
41	-2.59	-1.74	143	173	8.2744	5.9695
42	-2.79	-1.53	190	225	3.4024	7.872
43	-2.55	-1.64	230	273	3.0549	0.6159
44	-2.55	-1.32	105	125	2.3354	2.8415
45	-2.52	-1.54	138	131	2.811	3.5732
46	-3.18	-1.63	135	159	2.1585	3.0122
47	-2.7	-1.52	129	177	4.9573	2.7356
48	-2.61	-1.53	106	172	4.628	2.7927
49	-3.52	-1.64	144	161	6.628	4.3719
50	-2.6	-2	151	182	8.0876	5.0976
51	-2.91	-1.74	188	261	3.5854	3.4024

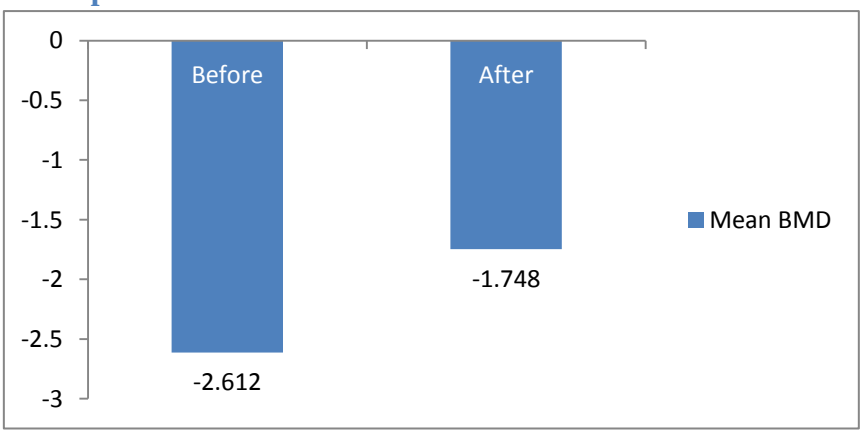
The following are the results obtained after statistical analysis of the data of the subjects taken before & after intervention.

Table No -7 Result on BMD, Serum ALP & Osteocalcin before & after intervention

Parameter	**Before**	**After**	**Mean Difference**	**95% CI**		**P**
				Lower bound	Upper bound	
BMD	-2.612 ± 0.192	-1.748 ± 0.167	-.86510 ±0.250	-0.93557	-.079463	0.001
ALP	189.29 ± 57.74	206.04 ± 59.66	-16.745 ±61.09	-33.929	0.439	0.056
Osteocalcin	8.023 ± 4.71	5.558 ± 3.100	3.303 ±4.94	1.911	4.695	0.001

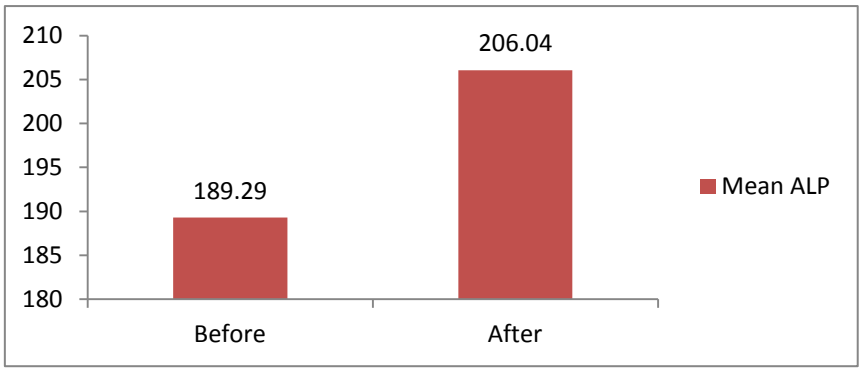
The mean levels of **BMD** before intervention was -2.612 +/- 0.19 and the levels of BMD have risen to -1.748 +/- 0.167 after intervention with the mean difference of –o.865 +/- 0.250. This mean difference was found to be statistically significant at P value 0.001

Graph No -1 Results on BMD before and after treatment



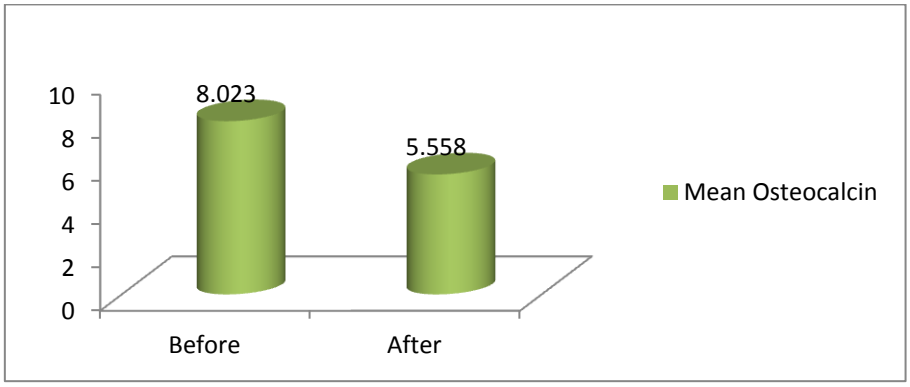
The mean levels of ALP before intervention was 189.29 +/- 57.74 and the levels of ALP have raised to 206.04 +/- 59.66 after intervention with the mean difference of 16.745 +/- 61.09. This difference was found to be statistically non- significant at P value 0.056.

Graph No -2 Results on Serum Alkaline Phosphatase(ALP) before and after treatment



The mean levels of **Serum Osteocalcin** before intervention was 8. 023 +/- 4.71 and the level of osteocalcin reduced to 5.558 +/- 3.100 after intervention with the mean difference of 3.303 +/- 4.94. This difference was found to be statistically significant at P value 0.001.

Graph No -3 Results of Serum Osteocalcin before and after treatment



In total, *Gandha taila* has shown overall improvement as measured by increase in the BMD indicating its positive influence of over the bone density. The reduction in the serum osteocalcin indicates that it acts as an inhibitor of bone resorption. We can't draw any conclusion regarding the non significant change in the serum ALP level.

DISCUSSION: Osteoporosis is a major public health problem especially for women, in India. It is also one of the major risk factor for fractures, especially among elderly women. So, herbal formulation which can treat the disease effectively is the need of the hour. As the herbal formulation '*Gandha taila'* is considered to be the best in making or keeping the bones sturdy, it is taken up in this study to validate its efficacy on osteoporosis.

Diagnosis of osteoporosis was done on the basis of BMD, as among the several available modalities for diagnosing osteoporosis and its severity, BMD of the spine and proximal femur measured by dual- energy X-ray absorptiometry (DEXA) is considered the current standard [30]

At present, BTMs are not routinely used in the clinical setting. However

BTMs have a variety of potential clinical applications based on their rapid response to treatment, their value in monitoring compliance to medications, and in guiding therapeutic decisions in certain cases. So, the serum ALP and Osteocalcin, the biochemical markers of bone formation were considered as objective assessment criteria.

There is a reference regarding the significant negative correlation between BMD and Osteocalcin. It was found to be elevated in osteoporosis in post-menopausal women and its level reduced after treatment with risedronate.[31]Significant reductions in BTMs are seen with anti- resorption therapy and have been associated with fracture reduction; significant increases indicate good response to anabolic therapy[32].

According to the above reference, it can be understood in this study that, increased BMD signifies improvement in the bone density and decrease in the Serum Osteocalcin signifies the anti-resorption activity of *Gandha taila* in subjects of osteoporosis. As such there is no significant change in the value of serum ALP in this study.

CONCLUSION: Health and healing are the biggest challenges that the mankind is encountering all the time. Understanding, defining and achieving health has been the focus of research. Understanding the mode of action of drug/ formulation by scientific and pharmacological approach is ongoing phenomenon in the field of research. Scientific validation of the formulations and development of evidence based support for efficacy claims is highly essential in medicine.

In this study, '*Gandha taila'* has shown overall improvement as measured by increase in the BMD indicating its positive influence over the bone density. The reduction in the 'Serum Osteocalcin' indicates that it acts as an inhibitor of bone resorption. The analysis of outcome has given very promising result in the management of osteoporosis.

The present study has also thrown light on understanding the probable action of the interventional drug '*Gandha taila'* over pathophysiology of osteoporosis. Since the formulation contains herbal constituents, which are known to have minimum toxic effects, on long term use outcome would be better and safer than current mode of modern treatment.

REFERENCES:

1.Agnivesha, Charaka Samhita, edited by Vaidya Yadavji Treikamji Acharya, Chaukambha Sanskrit Sansthan, 5th edition, 2001, Sutrasthana, chapter 9,verse 4 Page no -62.

2.WHO(1994) Assessment of fracture risk and its application to screening for postmenopausal osteoporosis. Report of WHO study group. World Health Organ Tech Rep ser 843: 1-129.

3.Munjal Y P,API Text book of medicine, Jaypee brothers medical publishers Ltd, New Delhi, 9th edition,2012, vol 1,pp 309.

4. Ashtanga Sangraha, , edited by Kaviraj Atridev Gupta, ed 2002, Chaukambha Publications, Varanasi, UP,Vol 1, Sutrashana, Chapter 20, Verse 1.

5. Sushruta Samhita Sutra Sthana, edited by Dr. Ambikadutt Shastri, Chukambha Surbharati publication, Varanasi, chapter 15, Verse 6-8,Page No 74-75.

6.Ashtanga Hridaya,edited by Pt. Hari Sadashiva Shastri, Chaukambha Surabharati Prakashan,Varanasi,UP 2010, Uttarasthana 27th chapter, Verse36-41 Page no -876.

7. Lango,Fauci, Kasper,Harrison's, Principal of internal medicine,VoII,Mc Graw-Hill companies,2004,pp3173
8. Ayman F Darwish, Hosney S Ghany, Yasser M El Sherbinie, Current Opinion in Rheumatology, Egyptian Society for joint disease, 2011, Vol 1, Issue 9,pp 110-117.
9. Raja Radhakant Deva, Shabda Kalpa Dhruma, Chaukambha Sanskrit Series Office, Varanasi, 1961, Part 1, pp 155-156.
10.Ashtanga Hridaya, edited by Pt. Hari Sadashiva Shastri, Chaukambha Surabharati Prakashan,Varanasi,UP 2010, Sharira Sthana, chapter 11,Verse 4.
11. Sushruta Samhita nibandha sangraha teeka of dalhana, ed by Vaidya Yadavji Trikamji Acharya, Chaukambha Sanskrit Sansthana,Varanasi, UP 2010, Sutrasthana Chapter 5, Verse 21, page no -25.
12. Sushruta Samhita, nibandha sangraha teeka of dalhana, ed by Vaidya Yadavji Trikamji Acharya, Chaukambha Sanskrit Sansthana,Varanasi, UP 2010, Sharira Sthana , Chapter 5, Verse 23 &45, Page No- 60, 63.
13. Sushruta Samhita,nibandha sangraha teeka of dalhana, Dr.Ambikadatta Shastri Chaukambha Surbharati Publications,Varanasi, Sutrasthana Chaptar 14, Verse10, Page no- 65.
14. Sushruta Samhita, with the Nibandhasangraha commentary of Dalhanacharya, edited by Vaidya Yadavji Trikamji Acharya, Chaukambha Orientalia, Varanasi, 4th edition, 1980, Sutrasthana, Chapter 5, Verse 24, Page no -70.
15.(a) Sushruta Samhita, Bhanumati teeka Dr.Ambikadutta shastri, Chaukambha Surabharati Publication, Varanasi, Sutrasthana chapter 15, Verse 8, Page No -75.
(b) Charaka Samhita, Shukla V, Tripati RD, Chaukambha Pratishtana, Delhi, 2003 Chikitsa Sthana, chapter 15, Verse 30.
16 (a) Sushruta Samhita,Dalhana commentary by Dr. Ambikadutta Shastri, Chaukambha Surbharati Publication, Varanasi, Kalpa Sthana, Chapter 4, Verse 40, Page No -56.
(b) Ashtanga Hridaya, Hemadri,edited by Pt Sadashiva Shastri, published by Chaukambha Surbharati Prakashan, Varanasi 2010, Sutrasthana, Chapter11, Verse 26-28,Page no- 186.
17. Raja Radhakant Deva,Shabda Kalpa Dhruma, Chaukambha Sanskrit Series Office, Varanasi, Part 2, 1961, pp 229-230
18. Chen H, Senda T, Kubo K Y: The osteocyte plays multiple roles in bone remodelling and mineral homeostasis, Med, Mol, Morphol 2015; 48:61-8.
19. Harrison's Principles of internal medicine, Vol II, Mc Graw- Hill companies, 2001, page 2249, and www.nof.org<http//www.nof. Org>/April 25th 2005.
20. John P Bilezikian et al Endocrinology and metabolism clinics of North America Osteoporosis, Saunder 2004, Philedelphia, Pp 323, page no.116-117.)
21. Ashtanga Hridaya with commentaries Sarvanga Sundara of Arunadatta and Ayurveda Rasayana of Hemadri, edited by Pt. Bhisagacarya Harishastri Paradkar vaidya, Krishnadas Academy, Varanasi, 2000, Sutrasthana, Chapter 11, Verse 19,Page no- 185.
22.a) Sushruta Samhita, with the Nibandhasangraha commentary of Dalhanacharya, edited by Vaidya Yadavji Trikamji Acharya, Chaukambha Orientalia, Varanasi, 4th edition, 1980, Sutrasthana, Chapter 15, Verse 9,Page no-75.

b) Agnivesha, Charaka Samhita, revised by Charaka and Dhridabala with the Ayurveda Dipika, commentary of Chakrapanidatta edited by Vaidya Yadavji Treikamji Acharya, Chaukambha Sanskrit Sansthan, 5th edition, 2001, Sutrasthana, chapter 17,verse 67, Page no- 103.

c) Ashtanga Hridaya with commentaries Sarvanga Sundara of Arunadatta and Ayurveda Rasayana of Hemadri, edited by Pt. Bhisagacarya Harishastri Paradkar vaidya, Krishnadas Academy, Varanasi, 2000, Sutrasthana, Chapter 11, Verse 19, Page no -185.

23.Singh's M; Nagrath A.R and Maini P.S "Changes in the trabecular pattern of the upper end of the femur as an index to osteoporosis." Journal of Bone and joint surgery, 457- 467, 1970

24. John P. Bilezikian et al. Endocrinology and metabolism clinics of North America Osteoporosis, Saunder 2004 Philadelphia, Page no 159.

25.(cremers S, Garnero Ps and pitfalls. drugs (2006) Biochemical markers of bone turnover in the clinical development of drugs for osteoporosis and metastatic bone disease: potential use and pitfalls.Drugs 66:2031-2058

26. Low MG (1987)Biochemistry of the glycosyl –phosphatidylinositol membrane protein anchors. Biochem J 244:1-13**.**

27. Price PA (1987)vitamin k dependent proteins In:CohnDV(ed) calcium regulation & bone metabolism basic & clinical aspects. Amsterdam, Elsever Science. The Netherlands.pp419-425.

28. Pauline M. Camacho, et al, Clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2016, AACE/ACE postmenopausal osteoporosis CPG, Endocr pract,2016;22(suppl 4)

29.Lango,Fauci Kasper,Harrison's Principal of internal medicine,VoII,Mc Graw-Hill companies,2004

30.Practice bulletin(2004) Clinical management guidelines for obstetrician-gynaecologists. obstet gynecol 103 :203-216(number 50,January 2003)) ACOG

31. M Beg, N Akhtar et al, Vitamin D status and serum osteocalcin levels in post-menopausal osteoporosis: Effect of biphosphonate therapy, JIACM 2014;15(3-4):172-6.

32.Pauline M. Camacho, et al, Clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2016, AACE/ACE postmenopausal osteoporosis CPG, Endocr pract,2016;22(suppl 4).

Corresponding Author:

Dr Veena G Rao, Professor Dept. of P G Studies in Panchakarma JSS Ayurveda Medical College &Hospital Lalithadripura road, Mysuru , Karnataka

Email: drveenagrao@yahoo.in

Source of support: Nil Conflict of interest: None Declared

Cite this Article as :[Rao Veena G et al : Efficacy of Gandha Taila on Osteoporosisa Clinical Study] www.ijaar.in : IJAAR VOLUME IV ISSUE VI JAN –FEB 2020 Page No: 543-555