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Clinical efficacy of *Withania somnifera* and *Glycin max* to Increase Bone Marrow Density

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ABSTRACT

Osteoporosis is a growing public health problem worldwide and second most common metabolic bone disease in India. It is reported that 1 in every 2 women and 1 in every 5 men having a fracture attaining the age of 50 is known to be suffering from osteoporosis. The disease osteoporosis doesn't have much description in *Ayurvedic* texts apart from brief discussion on *asthi* and *majja kshaya lakshnas*. However, in both the conditions the treatment is *brimhana*. This can be ideally achieved by both *aahara* as well as *aushadha dravyas*. The present work tries to evaluate the efficacy of *Ashwagandha* and *Soybean* on Osteoporosis. 30 patients coming under inclusion criteria were selected and registered for clinical trial and randomly divided them into three groups of 10 patients each. Study suggests that both groups A (*Ashwagandha* granules) and B (*Soybean* granules) showed effect on Osteoporosis but group C treated with Mix granules was found as the most beneficial group of all, with a relief of 21.60% ($t=5.3$) on t-score.

INTRODUCTION:

Osteoporosis is a condition that leads to fragile bones and increases the risk of wrist, hip, or spine fractures. Screening tests, which are non-invasive and painless, measure bone mineral density (BMD) of the hip, spine, wrist, or heel. Osteoporosis is a very common disease associated with women post 40, especially post-menopausal women. Men also suffer from osteoporosis while women are four times more prone to develop the disease.¹

NEED OF STUDY:

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. With a predicted dramatic increase of the older population in both developed and developing countries, the number of those with osteoporosis and suffering fractures is set to increase dramatically.

Osteoporosis is the second most common metabolic bone disease in India. It is reported that 1 in every 2 women and 1 in every 5 men having fracture attaining age of 50 is known to be suffering from osteoporosis. The term describes a group of bone disorders in which the absolute bone mass is less than normal. It is a silent underlying condition that often remains asymptomatic until a fracture occurs. In India, it has been presumed that 35% of post-menopausal women are at risk of developing osteoporosis. On an average a post-menopausal woman has 40-50 % chance of developing a fracture including 15% chance of hip fracture in her lifetime.²

To emphasize just how common the problem of osteoporosis is, a recent report from the Surgeon General's office stated that by the year 2020, half of all Americans older than age 50 will be at risk for fractures from osteoporosis. 40% of women of 50 and above age suffer a fracture of the hip, wrist, or spine. At some point early detection and preventive treatment before fractures occur is the vital key to treating osteoporosis.³

SELECTION OF TRIAL DRUG:

There is no exact clinical entity mentioned in classics like Osteoporosis but there are two conditions mentioned in Ayurveda may be discussed in this regard. One is *asthi kshaya* and the other is *asthi saushirya*. *Asthi saushirya* is not mentioned as a separate condition but as a symptom of *majja kshaya* whereas; *asthi kshaya* is mentioned as an independent condition.

Asthi kshaya is decrease in the bone tissue and *Asthi saushirya* means porous bones. Hemadri has commented on the word *Saushirya* as *Sarandhratvam* which means with pores. This condition is explained in the context of *majja kshaya*. Osteoporosis means the decrease in the bone tissue. Moreover there is another condition termed as osteopenia, which is a pre stage (prodromal symptom) of osteoporosis in which there is also decrease in the Bone Mineral Density. But the decrease is not so remarkable as compared to osteoporosis.

The disease osteoporosis doesn't have much description in *Ayurvedic* texts apart from brief discussion on *asthi* and *majja kshaya lakshnas*. However in both the conditions the treatment is *brimhana*. This can be ideally achieved by both *aahara* as well as *aushadha*.

Ashwagandha is known for its *balya* and *brimhana* actions. It is a *rasayana dravya* and hence should be preferred for delaying the degeneration/ impairment that has resulted by natural aging process.⁴ Further it is best *vatahara* and *vrishya* drug and hence likely to have better efficacy on rectifying *dhatvagni mandhya*. However no work has been reported so far to evaluate its efficacy on Osteoporosis.⁵ Soybean is not described in *Ayurvedic* classical texts. In the medieval period so many exotic plant varieties were added to *Ayurvedic Nighantus*. However, the process has stopped at that and it is on the shoulder of new generation of *Ayurvedic* scholars to explore the qualities and efficacy of present generation foods and enrich *Ayurvedic* knowledge. Soybean is now a days becoming popular as a protein rich diet with low content of saturated fat and cholesterol. Recent reports have suggested presence of unique compounds known as Isoflavones that acts as phytoestrogens. Hormonal factors strongly determine the rate of bone resorption; lack of estrogen (e.g. as a result of menopause) increases bone resorption as well as decreases the deposition of new bone that normally takes place in weight-bearing bones.⁶ The amount of estrogen needed to suppress this process is lower than that normally needed to stimulate the uterus and mammary gland. The α -form of the oestrogen receptor appears to be the most important in regulating bone turnover. The conventional hormone replacement therapy though effective in arresting rate of bone resorption, it has potential side effects like inducing cervical cancer etc. Therefore food substances rich in phytoestrogens like soybean can be taken as an alternative to this therapy.⁷

The present work tries to evaluate the efficacy of *Ashwagandha* and Soybean on Osteoporosis.

AIMS AND OBJECTIVES:

- a) To collect, compile and analyse the literary materials regarding *Ashwagandha* and Soybean with regarding their effect on Osteoporosis.
- b) To collect, compile and analyse the literary materials regarding the disease Osteoporosis.
- c) To evaluate the comparative clinical efficacy of *Ashwagandha* & *Soybean* on Osteoporosis.

CLINICAL STUDY:

a) Material and Methods:

30 patients coming under inclusion criteria were selected and registered for clinical trial and randomly divided into three groups of 10 patients each.

- I. **Group A:** 10 Patients of this group were administered *Ashwagandha granules* 10 gm. b.d.
- II. **Group B:** 10 Patients of this group were administered *Soybean granules* 10 gm.b.d.
- III. **Group C:** 10 Patients of this group were administered Mix (*Ashwagandha* and *Soybean*) granules 10 gm b.d.

Drug- Ashwagandha and *Soybean granules* 2348-7203

Dose- 10 gm. twice a day

Vehicle- Milk

Drug duration- 45 days

b) Inclusion Criteria:

- Patients between the ages 30 and below 70 yrs.
- Bone mineral density -2.5 standard deviations below peak bone mass (20-year old healthy female average) as measured by Dual energy X-ray absorptiometry.

c) Exclusion Criteria:

- Pregnant women,

- Patients suffering from systemic diseases like hypertension, diabetes mellitus, heart diseases etc.

d) Laboratory Investigations:

- Bone mineral density measured by DEXA (Dual energy X-ray absorptiometry) or PDXA scan (Peripheral Dual Energy X-Ray Absorptiometry).

e) Assessment Criteria:

Subjective criteria:

As the present study was aimed to minimize bone loss; *asthikshayatmaka lakshana* were included as subjective parameters by devising a specific scoring pattern i.e. Bone pain, joints pain, stiffness, backache, hair loss and general debility.

Objective criteria:

t-Score (BMD-Bone Mineral Density)

Note: WHO Criteria for assessing osteoporosis: Normal –t score greater than -1, Osteopenia –t score between -1 to -2.5, Osteoporosis –t score less than or equal to -2.5 and severe osteoporosis –t score less than -2.5 with fracture. B.M.D. (t Score) was done by DEXA and PDXA scan (Peripheral Dual Energy X-Ray Absorptiometry). PDXA measures only peripheral sites, such as the wrist, and heel.

OBSERVATIONS AND RESULTS:

The results so generated are presented through tables and graphs. Total 30 patients were registered for the treatment of Osteoporosis. Observations and result of these 30 patients are shown in the following tables.

Table 1: Bone Loss Signs and Symptoms wise distribution of 30 patients

S. No.	Signs and Symptoms	No. of Patients			Total	%
		Group A	Group B	Group C		
1.	<i>Asthitoda</i>	05	09	08	22	73.33
2.	<i>Cramps in leg</i>	04	03	05	12	40.00
3.	<i>Sandhi Shool</i>	09	08	10	27	90.00
4.	<i>Bhrama</i>	04	05	06	15	50.00
5.	<i>Timira Darshanam</i>	05	03	07	15	50.00
6.	<i>Keshaprapatanama</i>	09	09	10	28	93.33
7.	<i>Dantaprapatanama</i>	05	06	07	18	60.00
8.	<i>Extreme Fatigue</i>	02	05	04	11	36.67
9.	<i>Pratata Vata Rogi</i>	05	06	04	15	50.00
10.	<i>Low Back-ache</i>	06	05	07	18	60.00
11.	<i>Fractures (Hip/Spine/Others)</i>	02	03	02	07	23.33
12.	<i>Dowagers Hump</i>	01	02	01	04	13.33
13.	<i>Periodontal disease</i>	03	05	04	12	40.00
14.	<i>Brittle Nails</i>	04	05	07	16	53.33
15.	<i>Premature Greying Hairs</i>	02	04	05	11	36.67

- Out of 30 patients a very high number of 28 (93.33%) were found with *Keshprapatanama*. And 27 patients (90%) were found with *Sandhi school*. 22 (73.33%) were noticed with *Asthitoda*. 27 (67.50) were found with *dantaprapatana*, followed by 16

(53.33%) from brittle nails. 15(50%) cases suffering from Vataroga, *Bhrama*, and *Timardarshana* each. 12(40%) patients were identified with periodontal disease and cramps in leg. Followed by 11(36.67%) cases suffering from premature greying of hairs & extreme fatigue. 7(23.33%) with the history of fracture and 4(13.33%) patients having Dowagers hump.

Table no. 2: Effect of Trial on Objective Bio-chemical & Subjective Parameters of Group A

SYMPTOMS	N	Mean		Dif.	% of Change	SD	SE	t	p	RESULT
		BT	AT							
<i>Asthi Vedana</i>	10	1.4	0.7	0.7	50.00	0.8233	0.2603	2.69	p< 0.05	s
<i>Sandhi Shool</i>	10	1.8	0.9	0.9	50.00	0.7379	0.2333	3.86	p<0.01	ms
<i>Sandhi Shaithilya</i>	10	2.2	1.2	1	45.45	0.4714	0.1491	6.71	p<0.001	hs
<i>Kati Shoola</i>	10	2.0	1.1	0.9	45.00	0.7379	0.2333	3.86	p<0.01	ms
<i>Daurbalya</i>	10	1.6	0.5	1.1	68.75	0.5676	0.1795	6.13	p<0.001	hs
<i>Kesha Patana</i>	10	1.9	0.7	1.2	63.16	0.9189	0.2906	4.13	p<0.01	ms
BMD (t-Score)	10	-3.36	-2.99	-0.365	10.86	0.2450	0.0774	4.71	p<0.01	ms

Table no. 3: Effect of Trial on Objective Bio-chemical & Subjective Parameters of Group B

SYMPTOMS	N	Mean		Dif.	% of Change	SD	SE	T	P	RESULT
		BT	AT							
<i>Asthi Vedana</i>	10	1.1	0.6	0.5	45.45	0.5270	0.1667	3	p< 0.05	s
<i>Sandhi Shool</i>	10	1.6	1.2	0.4	25.00	0.5164	0.1633	2.45	p< 0.05	s
<i>Sandhi Shaithilya</i>	10	2.4	1.7	0.7	29.17	0.4830	0.1528	4.58	p<0.01	ms
<i>Kati Shoola</i>	10	1.6	1.1	0.5	31.25	0.5270	0.1667	3	p< 0.05	s
<i>Daurbalya</i>	10	2.3	1.1	1.2	52.17	0.4216	0.1333	9	p<0.001	hs
<i>Kesha Patana</i>	10	2.0	.9	1.1	55	0.5676	0.1795	6.13	p<0.001	hs
BMD (t-Score)	10	-3.43	-2.88	-0.55	16.03	0.4807	0.1520	3.62	p<0.01	ms

Table no. 4: Effect of Trial on Objective Bio-chemical & Subjective Parameters of Group C

SYMPTOMS	N	Mean		Dif.	% of Change	SD	SE	t	P	RESULT
		BT	AT							
<i>Asthi Vedana</i>	10	1.1	0.3	0.8	72.72	0.4216	0.1333	6	p<0.001	hs
<i>Sandhi Shool</i>	10	2.3	1.3	1	43.48	0.4714	0.1491	6.71	p<0.001	hs
<i>Sandhi Shaithilya</i>	10	2.6	1.2	1.4	53.85	0.5164	0.1633	8.57	p<0.001	hs
<i>Kati Shoola</i>	10	2.3	1.2	1.1	47.83	0.5676	0.1795	6.13	p<0.001	hs
<i>Daurbalya</i>	10	2.4	0.7	1.7	70.83	0.4830	0.1528	11.13	p<0.001	hs
<i>Kesha Patana</i>	10	2.3	0.6	1.7	73.91	0.8232	0.2603	6.53	p<0.001	hs
BMD (t-Score)	10	-3.20	-2.51	-0.69	21.60	0.4115	0.1301	5.30	p<0.001	hs

Comparison of Different Groups on Various Signs and Symptoms by Using Kruskal-Wallis Test (Nonparametric ANOVA)*

(*Calculations by Graph Pad In-Stat)

T-Score

One-way Analysis of Variance (ANOVA)

The P value is 0.1961, considered not significant.

Variation among column means is not significantly greater than expected by chance.

Table 5. Tukey-Kramer Multiple Comparisons Test

If the value of q is greater than 3.509 then the P value is less than 0.05.

Comparison	Mean Difference	S.D.	S.E.M.	Q	P value	Result
Group A vs. Group B	0.1850	0.2450	0.07748	1.493	P>0.05	ns
Group A vs. Group C	0.3250	0.4807	0.1520	2.623	P>0.05	ns
Group B vs. Group C	0.1400	0.4115	0.1301	1.130	P>0.05	ns

$$F = 1.731 = (\text{MS treatment} / \text{MS residual})$$

ANOVA assumes that the data are sampled from populations with identical SDs. This assumption is tested using the method of Bartlett.

ANOVA assumes that the data are sampled from populations that follow Gaussian distributions. This assumption is tested using the method Kolmogorov and Smirnov.

In the present study, total 30 patients of Osteoporosis were registered. The observations regarding their etio-pathological aspects obtained were as follows:

1. Age: Atrial study based on 30 patients shows that the age group 51-60 is mostly affected by Osteoporosis and 33.33% of the patients belong to this particular age group. It indicates that Osteoporosis increases with age, as described in *Ashtang Samgraha* that in old age *vata* is the predominating *dosha*. The rate of resorption of bone speeds up after the age of 50 years in both sexes and it is more in females. (*A.Hr.Su.11/27*)*

*(Ashtang Hruday sutrasthan chapter number/ shlok number)

2. Sex: Among these 30 cases 21 (70%) are related with females and 9(30%) with males and out of these 21 females 12 (57.14%) belong to menopausal age. It shows that women are more prone to osteoporosis and mainly after menopause.

3. Religion: Out of 30 patients 93.33% are *Hindu* and 6.67% are *Muslim*. Since the patients were collected from the Hindu dominated area.

4. Marital status: 93.33% of married and 6.67% of unmarried patients were found to be suffering from Osteoporosis.

5. Occupation: 10 Housewives were found with a maximum of 33.33% followed by 26.67% of service personnel.

6. Educational Status: 13 (43.33%) of the patients were postgraduate and illiterate stood with 16.67%.

7. Socio-economic status: Maximum patients i.e. 20(66.67%) belong to middle class, followed by 20% from poor class. This data reflects that it could be because of improper nutrition, over exercise & stressful lifestyle of the people of these two segments of society. These two classes generally remain under stress, middle class tries to compete with upper class and lower with middle class. And there are so many other reasons generated by modern way of life style.

8. Deha Prakriti: A major number of 15 (50%) out 30 cases were discovered with *vata kaphaj prakriti* along with 10 (33.33%) having *vata paitik* and 5 (16.67%) with *pittakaphaja*. This study suggests that Vata plays an important role in the manifestation of the disease independently and along with *kapha* it causes *srotorodh*, improper formation of *asthi*. As *asthi dhatu poshakansh* do not reaches to *asthivaha srotas*, hence proper bone formation disturb. Along with *pitta* it increases *asthyagni* and results in excessive degeneration of bones. (C.Vi. 8/96-98)*

*(Charak samhita vimansthan chapter number/ shlok number)

9. Manasa Prakriti: Maximum number of 21 (70%) patients found with *rajasika prakriti*. 7(23.33%) with *tamasika* and two (6.67%) were having the *satvika prakriti*. People of *rajsika prakriti* are over active and more prone to stress in day to day life. In these peoples *vata* and *pitta* dominates and these are responsible for increasing catabolic activities in *dhatus*, especially of bones i.e. *asthidhatu*.

10. Sara: Highest 15 (50%) cases were found with *madhyama sara*, 11 (36.67%) with *avara sara*, and 4(13.33) cases were being found with *pravara sara*. (C.Vi.8/107)

11. Samhanana: Maximum 14 (46.67%) cases were noticed with *madhyama samhanana* and 12(40%) with *avara samhanana*, and 4(13.33%) cases were found with *pravara samhanana*. (C.vi.8/116)

12. Satmya: Highest Number of patients 15 (50%) were noticed with *madhyama satmya*, 10 (33.33%) with *avara* and 5 (16.67%) cases found with *pravara satmya*. (C.Vi.8/118)

13. Satva: 14 (46.67%) Patients were identified with *madhyama Satva*, 12 (40%) with *avara satva*, and only 4 (13.33%) cases were found with *pravara satva*. *Madhyama satva* people are more prone to osteoporosis; it could be because of laxity in their food habits and life style.

14. Agni: Highest numbers of 16 patients with a percent of 53.33 were found with *sama Agni* followed by 8 (26.67%) cases *manda*. And only a little number of 3(10%) were noticed with *tikshana* and *vishama* each. *Agni* plays an important role in *dhatu poshna* thus indicating that osteoporotic patients are having *mandagni* and *vishamagni* than the normal persons. (C.Chi.16)*

*Charak samhita chikitsa sthan

15. Desha: 22(73.33%) patients belongs to *jangala-sadharana desha* and 8 (26.67%) from *jangala*. This incidence is due to geographical status of this area particularly but *jangala desha* is vata vitiating factor also. (C.Vi.8) N 2349-7203

16. Koshtha: 16 (53.33%) cases identified with *madhyam kostha* along with 7 (23.33%) *krura* and *mridu kostha* each. This reflects that *madhyam kostha* peoples are more prone to Osteoporosis however we can't say it firmly because these are small data for making any concrete statement.

17. Dietary Habit: On the basis of dietary habit observations it is being found that 24 (80%) cases were of the vegetarians and 6 (20%) patients had mixed dietary habits. This can be the reason for osteoporosis as vegetarian diet is lacking in certain minerals like calcium which are essential for bone formation and secondly non vegetarian edibles are better absorbed by the body in comparison to vegetarian diets.⁸

18. Rasa Satmya: 10 (33.33%) cases were identified with *lavana rasa satmya* followed by 9 (30%) with *sarvarasa*, 8 (27.50%) of *madhura* and only 3 (10%) were discovered with *amla rasa satmya*. High salt intake increases risk for osteoporosis.⁹

19. Emotions: Maximum 27(90%) patients were of anxious nature, 13 of angry nature, 9(30%) irritative, 8(26.67%) depressed and 7(23.33%) of scary nature. This data reflects the role of Anxiety, anger, irritation and depression in the production of the disease. Normally taken food is not digested properly under the influence of above-mentioned factors thus proper nutrition to bone formation is hampered which leads to osteoporosis in long run (C.Chi.19/12).

20. Addiction: Out of 40 patients 27 (90%) were found with the habit of taking tea 5 (16.67%) were found with a habit of taking alcohol. 7 (15%) patients were found indulging in the habit of smoking. 6(20%) Were found in the habit of chewing tobacco. All these are *kashaya rasa pradhana* so vitiating *vata* and lead to osteoporosis. (Ch.Su. 26)

21. Menstrual History: Out of 21 female patients 12 (66.66%) were in the menopausal phase and 9 (33.33%) with regular menstrual cycles. Indicating that hormones plays a key role in the development of osteoporosis.¹⁰

22. Family History of Osteoporosis: 6 (20%) were found with Positive family history and 19 (63.33%) with Negative family history and family history of 5 (16.67%) patients were found "Not Known".

23. Chronically: Highest number of 12 Patients (40%) were found with duration of Osteoporosis with 5-10 years, along with 10 patients (33.33%) with more than 10 yrs & disease starts accelerating in the 5th decade of life of either sex.¹¹

24. Weight: Maximum 16(53.33%) cases within 51-70 kg. range, 8(26.67%) from 71-90 kg. and only 6 (20%) were within 31-50 kg. range.

25. Drug History: Only 5(16.67%) patients were found to be taking anti-Osteoporotic drugs whereas 25(83.33%) patients on going without taking any medicine. The disease is nonsymptomatic so patients are not aware of that much to take medicine.

26. Dhatu Kshayatmaka Lakshana: All 30(100%) patients were suffering from *asthi dhatu kshaya lakshana* and other *dhatu kshaya lakshana* also present in association with it. This is due to the disease nature, because osteoporosis is mainly associated with *asthi dhatu*. (Ch.Vi.5)

27. Dosha: Maximum patients 16(53.33%) suffering from *Vataprakopa -kaphakshaya* and 7(23.33%) cases belongs to *Vatavriddhikaphakshaya* & *Vatapittavridhikaphakshaya* each. Vata is the *pradhana dosha* in the aetiology of osteoporosis. (*Ch.Chi.28/3*)

28. Aaharaj Nidan: Most of the patients 24(80%) are habitual of *rukshashana*, 12(40%) with the habit of *alpashana* and 5 (16.67%) patients of *adhyashana*. *Rukshashana* and *alpashana* are considered to cause vitiation of *vata dosha* therefore will cause *dhatukshaya* especially *asthikshaya* because of *aashrayaaashrayee bhav*. *Adhyashana* will cause *agni mandhya* and will lead finally to *dhatu vaishamya*.

29. Viharaj nidana: Most of the patients 15(50%) are habitual of *vegasamdhara*, 13(43.33%) of *divaswapana* habit, 12(40%) *ratrijagara* and *ati-adhvagaman* each, 11years. More chronic patients were found because maximum of them were of the age group between 51 – 70 patients doing *ativyayam*. All these factors are *vataprakopak*, *dhatukhayakar*.

30. Signs and Symptoms: Out of 30 patients a very high number of 28 (93.33%) were found with *Keshprapatanama*. And 27 patients (90%) were found with *Sandhi shool*. 22 (73.33%) were noticed with *Asthitoda*. Most of the patients were suffering from hair loss, *sandhi shool*, *asthitod*, nails and dental problems. (*Su.Su.15/13*)*

*(Sushrut samhita sutrasthan chapter number/ shlok number)

Effect of therapy on cardinal sign and symptoms of osteoporosis:

These sign and symptoms were given scoring pattern before and after treatment and were assessed statistically to see the significance. The effect of trial in all the groups on each sign and symptoms is given below.

1. Asthi Vedna: In group A, the mean score of *Asthi vedna* was 1.4 before treatment which reduced up to 0.7 after treatment with 50% relief, which is statistically significant ($P < 0.05$). In group B, The mean score of *Asthivedna* was 1.1 before treatment which reduced up to 0.6 after treatment with 45.45% relief, which is also statistically significant ($P < 0.05$). In group C, The mean score of *Asthi vedna* was 1.1 before treatment which reduced up to 0.3 after treatment with 72.72% relief, which is highly significant at the level of 1% ($P < 0.001$).

2. Sandhishool: In group A, the mean score of *Sandhishool* was 1.8 before treatment which reduced up to 0.9 after treatment with 50% relief, which is statistically moderate significant (P0.01). In group B, mean score of *Sandhishool* was 1.6 before treatment which reduced up to 1.2 after treatment with 25% relief, which was statistically significant (P 0.05). In group C, The mean score of *Sandhishool* was 2.3 before treatment which reduced up to 1.3 after treatment with 43.48% relief, which is highly significant at the level of 1% (P0.001).

3. Sandhi Shaithilya: In group A, the mean score of *Sandhi shaithilya* was 2.2 before treatment which reduced up to 1.2 after treatment with 45.45% relief, which is statistically highly significant (P0.001). In group B, mean score of *Sandhi shaithilya* was 2.4 before treatment which reduced up to 1.7 after treatment with 29.17% relief, which is statistically moderately significant (P0.01). In group C, The mean score of *Sandhi shaithilya* was 2.6 before treatment which reduced up to 1.2 after treatment with 53.85% relief, which is highly significant at the level of 1% (P0.001).

4. Katishool: In group A, the mean score of *Katishool* was 2.0 before treatment which reduced up to 1.1 after treatment with 45% relief, which is statistically moderately significant (p0.01). In group B, mean score of *Katishool* was 1.6 before treatment which reduced up to 1.1 after treatment with 31.25% relief, which is statistically significant (P0.05). In group C, The mean score of *Katishool* was 2.3 before treatment which reduced up to 1.2 after treatment with 47.83% relief, which is highly significant at the level of 1% (P0.001).

5. Kesha Prapatnam: In group A, the mean score of *Keshapatan* was 1.9 before treatment which reduced up to 0.7 after treatment with 63.16% relief, which is statistically moderate significant (P0.01). In group B, mean score of *Keshapatan* was 2.0 before treatment which reduced up to 0.9 after treatment with 55% relief, which is statistically highly significant (P0.001). In group C, The mean score of *Keshapatan* was 2.3 before treatment which reduced up to 0.6 after treatment with 73.91% relief, which is highly significant at the level of 1% (P0.001).

6. Dourbalya: In group A, the mean score of *Dourbalya* was 1.6 before treatment which reduced up to 0.5 after treatment with 68.75% relief, which is statistically highly significant (P0.001). In group B, mean score of *Dourbalya* was 2.3 before treatment which reduced up to 1.1 after treatment with 52.17% relief, which is statistically highly significant (P0.001). In

group C, The mean score of Dourbalya was 2.4 before treatment which reduced up to 0.7 after treatment with 70.83% relief, which is highly significant at the level of 1% (P0.001).

7. T-Score: In group A, the mean of T-score was - 3.36 before treatment which reduced up to - 2.99 after treatment with 10.86% relief, which is statistically moderately significant (P0.01). In group B, mean of T-score was -3.43 before treatment which reduced up to -2.88 after treatment with 16.03% relief, which is statistically moderately significant (P0.01). In group C, the mean of T-score was -3.20 before treatment which reduced up to -2.51 after treatment with 21.60% relief, which is highly significant at the level of 1% (P0.001).

CONCLUSION:

- Study suggests that both groups A and B showed effect on Osteoporosis but the group treated with Mix granules (Group C) provide better result in comparison to group A and B.
- In this clinical study maximum symptomatic relief was observed in group C (Treated with Mix granules).
- All the investigations made based on measurement of Osteoporosis (T-score) and reduction in its sign & symptoms group C proved as most affected in all three groups, so we can see the clear effect of *Ashwagandha* granules along with Soya bean granules.

❖ **In-group A symptomatic relief was 47.60%.**

❖ **In-group B symptomatic relief was 36.30%.**

❖ **In-group C symptomatic relief was 54.89%.**

In investigations of all three groups, **group C was found as the most beneficial group** of all, with a relief of **21.60% (t=5.3)** on T-score.

After long investigations and drug applications, it was being **found that combined therapy proved most effective to reduce Osteoporosis by increasing bone marrow density.**

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