

Effect of *Panchatikta Ksheera Basti* and *Praval Panchamrut Vati* in *Asthikshaya w.s.r.* to Osteopenia/ Osteoporosis – A Randomized Controlled Pilot Study

Research Article

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Abstract

Background: Osteopenia and Osteoporosis are common prevailing ailments exhibiting reduced bone density and occur especially aging population. Various factors lead to Osteopenia/Osteoporosis including sedentary lifestyle and hormonal changes that affect the bone metabolism. Conventional management of Osteopenia/Osteoporosis focuses primarily on Calcium and Vitamin D supplementation. Asthi kshaya, a similar condition to Osteoporosis, has been mentioned in Ayurveda wherein vitiated Vata causes reduction in bone mass and is associated with same symptoms as Osteoporosis. Panchatikta Ksheera Basti is a formulation made from tikta dravya siddha Ksheera (milk decoction made from five bitter herbs), Panchatikta Ghrita and honey. Objective: To evaluate the efficacy of Panchatikta Ksheera basti and Praval Panchamruta Vati in Asthikshaya (Osteopenia/Osteoporosis) and compare the same with the conventional treatment. Trial Design: A Randomized Controlled Pilot Study. Method: Patients with signs and symptoms of Asthi kshaya and BMD (T-score) =<-1 were randomized, Group A (Trial group) patients received Panchatikta Ksheera Basti and Praval Panchamrut Vati while Group B (Control group) patients received oral organic Calcium and Vitamin D for 30 days. Primary Outcome: To improve the functional and physical activities of the patients. Secondary Outcome: To improve Serum Calcium, Serum Phosphorus and Vitamin D levels and BMD score. Results: Statistically significant results were observed in both the groups, however pain relief was better in Study group A, while Serum Calcium levels were significantly improved in both the groups. Conclusion: Panchatikta Ksheera Basti and Praval Panchamruta Vati have equal potential for addressing Asthi Kshaya (Osteopenia Osteoporosis) in comparison to conventional management.

Keywords: Bone Mineral density, Osteopenia, Osteoporosis, *Asthikshaya, Basti, Panchatikta ksheera, Praval Panchamruta.*

Introduction

Osteoporosis is a common prevailing issue in old age group due to the sedentary lifestyle and dietary habits of the developed world (1,2). It is marked by a micro architectural deterioration of bone tissue associated with low bone mass and progressive bone fragility and susceptibility to fracture (3). Usually, the loss of bone mineral density begins at the age of 30–40 years in both men and women. In women of menopausal age, there is an immediate decline in bone mass and density within a year and this reduction continues until 10 years after menopause, coming to a steady rate as the age progresses (4). It is estimated that 1 in 3 women and 1 in 5 men above the age of 50

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experience osteoporotic fractures worldwide (5). India has a population of around 1.2 billion people, with approximately 10% population (more than 100 million) over the age of 50 years (6). It is observed that around 50 million people in India suffer from osteoporosis or have a low bone mass (7). Osteopenia is a clinical term used to describe a decrease in bone mineral density below the normal reference values, but not low enough to be considered osteoporotic (8). Individuals with Osteopenia or Osteoporosis may not present with any complaints until they suffer a bone fracture leading to pain and disability. The conventional approach to Osteopenia/Osteoporosis is supplementation of Calcium and Vitamin D as these are the two primary nutrients related to bone health and play an important role in bone metabolism (9).

ISSN No: 0976-5921

According to Ayurveda, Asthi (bone tissue) is one of the seven Dhatu's (tissues) of the body which performs the function of Dharana(support) (10,11). The Asthivaha Srotas (System) regulates the metabolism of Asthi dhatu in the body and factors like excessive physical exertion, jerky movements of the body,



Varghese Jibi et.al., Effect of Panchatikta Ksheera Basti and Praval Panchamrut Vati in Asthikshaya

increased friction between bones subject to Vata vitiating factors causes derangement of Asthivaha Srotas leading to Asthi Pradoshaja Vikara (diseases of the bony tissue)(12,13). The relation between Asthi and Vata is inversely proportional whereby increase of Vata causes Asthi Kshaya or decrease in Asthi dhatu (14). An individual with Asthi Kshaya suffers from pricking pain in bones, hair fall, brittleness of nails and erosion or fracture of teeth (15). Hence, the etiological factors for *Vata* vitiation also present as the etiological factors for Asthi kshaya. The vitiated Vata either due to dhatu kshaya (degeneration or undernutrition) or margaavrodha (obstruction) enters Asthidhatu and leads to Asthi kshaya. As per Charaka Samhita, the treatment for Asthipradoshaja vyadhi is Panchakarma wherein basti prepared with tikta dravya (bitter herbs), ksheera (Cow Milk) and ghrita (Cow Ghee) along with the use of Swayonivardhak dravya (medicines having similar qualities of bone tissue) is indicated. The Pakvashaya or large intestine is the main site of *Vata dosha* in the body and Basti acts directly on the same, thereby regulating Vata dosha in the body (16). Owing to this specific property of basti, it is designated as Ardha Chikitsa (half treatment) for all diseases and especially those affecting the Musculoskeletal System (17). Ayurveda has already woven the interconnection between the atmospheric changes occurring in the nature and living beings. In Varsha ritu (rainy season), the Vata dosha tends to get aggravated with simultaneous accumulation of Pitta dosha in the body. This aggravated Vata dosha is best balanced by the Basti treatment and the aforementioned Tikta Ksheera Basti has been specifically advocated for vitiation of Vata with respect to Asthi Dhatu.

Ayurveda has clearly explained Asthi Kshaya, its associated symptoms and its management and hence this study was undertaken to evaluate the efficacy of Ayurveda management in symptoms of Asthi kshaya (Osteopenia/Osteoporosis). Panchatikta Ksheera basti is a type of Brimhana basti which pacifies the aggravated Vata dosha and Pitta dosha whereas Praval Panchamrut vati is a source of organic calcium and also complies as Parthiva component required for bone growth and repair. This study was conducted before the Varsha ritu ascends which aids both as a preventive and curative measure to condense the excess vitiation of Vata dosha in patients who were already having the symptoms. To compare this Ayurveda management with conventional therapy, a control group with oral calcium and vitamin D supplementation was assigned in parallel.

Materials and Methods

A Pilot Randomized Controlled Clinical study was conducted at Dr. D.Y. Patil College of Ayurved & Research Centre, Pimpri, Pune- 18, Maharashtra, India between January 2021 to June 2021 with Institutional Ethics Committee approval (DYPV/EC/12/18). The study was registered prospectively in CTRI with Registration Number (CTRI/2019/08/020840). The CONSORT (2010) guidelines were followed for reporting the outcomes of the study.

Participants

Individuals of both genders aged between 40 to 70 years were examined for classical signs and symptoms of *Asthi kshaya* along with Bone Mineral Density (BMD).

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Inclusion Criteria

Individuals of either gender aged between 40 to 70 years with any 2 classical signs and symptoms of *Asthi kshaya* like *Asthishula, Keshapata, Nakha vikara and* Bone Mineral Density (BMD) (T-score)

=<-1 were enrolled with due written informed consent.

Exclusion Criteria

Individuals with known case of Bone Cancer, Osteomalacia, Rheumatoid Arthritis, Gouty Arthritis, Diabetes Mellitus, Thyrotoxicosis, Hyperparathyroidism, Addison's disease, Paget's disease, Cushing's Syndrome, Chronic Renal, Hepatic or Cardiac ailments, those not willing to participate were excluded from the study.

Screening Methods

All recruited patients were thoroughly examined clinically and their data were recorded on various subjective and objective parameters. Laboratory investigations for Serum Calcium, Vitamin D, Serum Phosphorus levels and BMD were done at Day 0 and Day 30.

Research Design

This study was conducted by the Department of Kayachikitsa, Dr. D. Y. Patil College of Ayurved & Research Centre, Pimpri, Pune with Institutional financial support with the aim to prove the clinical efficacy of ayurveda intervention in Osteoporosis/Osteopenia. A special BMD camp was organized wherein a total of 100 patients with signs and symptoms of *Asthikshaya* were screened with physical examination and Bone Mineral Density (Calcaneal bone) by using Ultrasonic Bone Densitometer. During the BMD screening,30 patients with BMD (T-score) =<-1 were selected and then randomized by Computer generated randomization table - block method into Trial Group A and Control Group B with 15 patients in each.

Intervention

Group A patients were given *Hingvashtaka Churna* 1 gm orally twice a day for first 3 days along with *Praval Panchamrut Vati* 250mg twice a day and administration of *Panchatikta Ksheera basti* 300ml once in a day for 30 days. Local *Snehan* (Oleation) by *Tila taila* (Sesame Oil) and *Nadi Sweda* (Fomentation) was given at abdomen and lower back before administering *Basti* per rectum.

The raw drugs were procured from FDA approved and GMP certified Sudhatatva Pharmacy of Dr.D.Y.Patil College of Ayurved & Research Centre, Pimpri, Pune and subjected for authentication and standardization at the Institutional Quality Control Laboratory as per Ayurveda Pharmacopeia of India (API) guidelines.



Preparation of *Praval Panchamruta Vati* was done by grinding all the ingredients *Mauktika* (Pearl), *Shankha* (Conch Shell), *Shukti* (Pearl Oyster), *Kapardika* (Cowries) and *Praval* (Coral) *bhasma* in *khalva yantra* (mortar and pestle) to obtain a fine powdered mixture which was then triturated by Cow milk and then further processed to obtain granules. The granules were then transformed into tablets. The trituration by cow milk is a modification from the classical guideline where milk of *Calotropis Procera* has been indicated (18).

Panchatikta Ksheera Basti preparation was freshly done every day as per classical guidelines. 25 gm of Panchatikta churna (5 gm equal quantity of each herb) was added to 200 ml of cow milk and 800 ml of water. The mixture was boiled on low flame with continuous stirring until only 200 ml milk remained in the vessel. This remaining milk decoction (Ksheera Paka) was filtered and used for further process. Honey (30ml), Panchatikta Ghrita (50 ml), Panchatikta kalka (paste) (20 gms) and the obtained Ksheera Paka (200 ml) were sequentially mixed to obtain the final mixture of 300 ml (≈6 pala) as Uttam Matra of Sneha Basti (19).

The Control Group B patients were given oral organic Calcium and Vitamin D for 30 days once in a day. A standard combination of Organic Calcium Carbonate 1250mg (equivalent to elemental Calcium 500mg) and Vit.D 250 IU in tablet form was procured from Institutional Pharmacy Store.

ISSN No: 0976-5921

Criteria of Assessment Primary Outcome Criteria

Patients of both the groups were assessed on basis of *Asthishula*, *Kesha pata*, *Nakha vikara* and Visual Analogue Scale (VAS). The parameters were graded and scored from 0 to 4 according to severity (Table1) and assessed on day 0, in between treatment on day 15 and last day of treatment on day 30. *Asthishula* was assessed by bony tenderness on the shin of tibia bone and the spine. Visual Analogue Scale where the participant can rate the intensity of pain by two endpoint line scoring 0-10, one end representing 'no pain' and the other representing 'worst pain'.

Secondary Outcome Criteria

BMD, Sr. Calcium, Sr. Phosphorus and Vitamin D were done only on Day 0 and Day 30 and values were recorded.

Table 1: Assessment Criteria of Subjective parameters

			g I							
Symptoms	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4					
Asthishula (Pain in bones)	No pain	Mild pain	Moderate pain	Severe pain not affecting regular activities	Severe pain affecting regular activities					
Kesha Pata (Hair fall)	No hair fall	Hair fall once in morning during washing/combing	Hair fall every time during combing	Hair fall without combing & raised hairline in frontal region of head	Visible or significant baldness in frontal/vertex region (caput)					
Nakha Vikaras (Nail deformities)	No Nakhavikaras (Nail deformities)	Mild loss of natural texture & elasticity of nails	Moderate loss of natural texture & elasticity of nails	Visible brittleness of nails	Brittle nails					

Statistical Methods

The statistical analysis was carried out as within the group analysis and between the group analysis by using SPSS software version 21(Table 2-5). For within the group analysis, Wilcoxon Signed Rank test was used for observations on ordinal scale and paired t-test for quantitative data. For the analysis of data between the groups, Mann Whitney test was applied for observations on ordinal scale and unpaired t-test for quantitative data. All tests were considered statistically significant at p < 0.05.

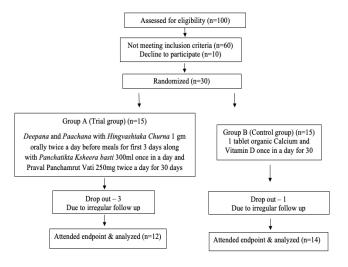
Observation and Results Patient Profile

Gender - Total number of male patients enrolled were 50% and 21.4% while females were 50% and 78.6% in Group A and Group B respectively.

Age – The patients enrolled in the age group 40-49 years were 41.7% in Group A and 57.2% in Group B. In the age group 50-60 years total number of patients were 58.3% and 21.4% in Group A and Group B respectively. Total of 21.4% patients in Group B were from 60-70 years of age group.

During the study, 3 patients from Trial Group A and 1 patient from Control Group B were dropped from the study due to irregular visits for treatment and follow up.

Figure 1 Consort Flow Chart



ISSN No: 0976-5921



Varghese Jibi et.al., Effect of Panchatikta Ksheera Basti and Praval Panchamrut Vati in Asthikshaya

Table 2: Statistical analysis for within the group observations on ordinal scale (For Group A, n=12 and Group B, n=14)

Parameters	Group	Before		After		Wilcoxon signed	
		Mean	SD	Mean	SD	Rank Test	p value
Anthinhala	Group A	2.33	1.07	0.42	0.51	-2.980	0.003 (S)
Asthishula	Group B	2	0.78	1.43	0.94	-2.828	0.005 (S)
V1 + -	Group A	1.92	1.38	1.08	1.08	-2.887	0.004 (S)
Kesha pata	Group B	1.5	0.85	0.64	0.63	-2.972	0.003 (S)
Nakha vikara	Group A	0.17	0.39	0.08	0.29	-1.00	0.317 (NS)
	Group B	0	0	0	0	0	1 (NS)
Visual Analogue Scale	Group A	5.33	1.50	2.08	1.16	-3.108	0.002 S
(VAS)	Group B	6	1.24	3.71	1.27	-3.332	0.001 S

Statistically significant results were observed in both the groups for *Asthishula* and Visual Analogue Scale (VAS). Pain relief was better in Study group A. The symptom of *Kesha Pata* though showed significant results wherein the patients reported a drop in their hair fall but it is relatively premature to draw a concrete inference in a short duration.

Table 3: Statistical analysis for quantitative observations (within the group)

Danamatana	C	Before		After		Daim d 4	1
Parameters	Group	Mean	SD	Mean	SD	Paired t	p value
BMD	Group A	-1.76	0.45	-1.33	0.86	-1.783	0.102 (NS)
DMD	Group B	-1.81	0.58	-1.21	0.67	-2.810	0.015 (S)
Serum Calcium	Group A	8.75	0.82	9.47	0.75	-2.869	0.015 (S)
Serum Calcium	Group B	8.36	0.83	9.44	0.42	-4.743	0.000 (S)
Common Diagonal common	Group A	3.39	0.76	3.67	0.28	-1.602	0.138 (NS)
Serum Phosphorus	Group B	3.34	0.60	3.30	0.58	0.265	0.795 (NS)
Vitamin D	Group A	15.69	10.83	19.12	13.63	-0.776	0.454 (NS)
Vitamin D	Group B	16.72	11.26	17.53	9.34	-0.462	0.652 (NS)

BMD score – The values of BMD score <-1 to <-2.5 (Osteopenia) was observed in 14 patients in Group A and 13 patients in Group B while BMD score <-2.5 (Osteoporosis) was observed in 1 patient in Group A and 2 patients in Group B.

Statistically significant results were noted in both the groups for Serum Calcium levels, while significant changes were seen for BMD in study group B after intervention.

Table 4: Statistical analysis for observations on ordinal scale (between the groups)

Parameters	Group	Mean Difference score	SD	Mann Whitney U test	Test Statistics Z	p value
Asthishula	Group A	1.92	1.08	27	-3.133	0.002 (S)
Asinisnuia	Group B	0.57	0.51	21		
	Group A	0.83	0.58	85	-0.02976	0.976 (NS)
Kesha pata	Group B	0.75	0.62			
	Group B	0.21	0.43			
Nakha vikara	Group A	0.08	0.29	77	1.003	0.316 (NS)
wakna vikara	Group B	0	0	//		
Visual Analogue	Group A	3.25	0.87	40	-2.2374	0.020 (S)
Scale (VAS)	Group B	2.29	0.99			

Statistically significant results were observed for *Asthishula* and Visual Analogue Scale (VAS) with the Study Group A showing better outcome than Control Group B.

Table 5: Statistical analysis for quantitative observations (between the groups)

Table 5. Statistical analysis for quantitative observations (between the groups)							
Parameters	Group	Mean Difference score	SD	SEM	Unpaired t	p value	
DMD	Group A	-0.43	0.83	0.238	0.540	0.589 (NS)	
BMD	Group B	-0.60	0.80	0.214	0.548		
C C-1-:	Group A	-0.72	0.87	0.250	1.055	0.302 (NS)	
Serum Calcium	Group B	-0.07	0.85	0.226			
C Dl l	Group A	-0.28	0.60	0.174	-1.370	0.183 (NS)	
Serum Phosphorus	Group B	0.04	0.59	0.157			
Wite in D	Group A	-3.43	15.29	4.415	0.502	0.5(5.(NIC)	
Vitamin D	Group B	-0.81	6.54	1.747	-0.583	0.565 (NS)	

Statistically non-significant difference was observed between the groups for all the parameters.



Primary Outcomes

Within the group analysis showed statistically significant results in both the groups for *Asthishula*, *Kesha Pata* and Visual Analogue Scale (VAS). However, relief in *Asthishula* was better in Study Group A.

Statistically significant results were observed for *Asthishula* and Visual Analogue Scale (VAS) with the Study Group A showing better outcome than Control Group B in between group analysis.

Secondary Outcomes

Within the group analysis showed statistically significant results were noted in both the groups for Serum Calcium levels, while significant changes were seen for BMD in study Group B after intervention.

Statistically non-significant difference was observed between the groups for all the parameters.

Discussion

Bone metabolism is regulated by the action of Osteoclasts and Osteoblasts which in turn are tightly controlled by action of modulators such as Estrogen, Thyroid and Parathyroid hormones (20, 21). Osteoporosis is the condition that arises during increased bone resorption along with decreased bone formation due to imbalance in hormonal functions (22). Osteopenia is a pre-cursor of Osteoporosis where the bone mineral density is below normal values but may not be present with any sign or symptom (23).

According to Ayurveda, Asthi Dhatu (Bone tissue) undergoes Kshaya (loss/degeneration) due to Vata vitiating Ahara (diet) and Vihara (lifestyle). Absence of Sneha (oleation) and at the same time increase in Ruksha (dry), Laghu (light), Sheeta (cold) and Chala (rapid) gunas (properties) in the body leads to Asthi Kshaya. This loss in Asthi dhatu is presented not only in the form of Asthishula (pain in bones), Asthi toda (pricking pain in bones) but also danta-nakha-kesha sadanam (brittleness or breaking of teeth, hair and nails) as the same are Mala's (by-products) of Asthi. Osteoporosis/Osteopenia can be correlated to the condition of Asthi Kshaya due to the common mechanism of loss in bone tissue and also presenting signs and symptoms (24,25).

Sedentary lifestyle, faulty dietary habits and premature ageing are the main causes of Osteopenia/ Osteoporosis (26,27). In the quest for tasty foods, majority of the people are consuming fast foods and processed foods like pizza, burger, French fries etc. which lack proper nutrients leading to conditions like Osteoporosis (28). The incidence is comparatively more prevalent in females than males with the ratio being 3:1. The increased risk can be attributed to the onset of menopause during which females undergo rapid physiological transitions due to hormonal imbalance (29).

Even though *Asthi Kshaya* and Osteoporosis are two different entities told by two sciences, their etiology coincides with the fact that both are involving deficiency of *Asthi dhatu* (bony tissue) either due to metabolic or degenerative causes. Factors like ageing,

degeneration, nutritional deficiency etc. ultimately lead to *Vata* vitiation in the body accompanied by *Dhatu Kshaya* (tissue loss). Faulty dietary habits, obesity and sedentary lifestyle adversely affect *dhatu poshana* and *Utpatti* (tissue growth and metabolism) due to accumulation of *Meda* (adipose tissue) in the body leading to *Srotorodha* (obstruction of channels in the body). Hence it is evident that there is an etiological as well as pathological linkage between *Asthi Kshaya* and Osteopenia/Osteoporosis and the therapeutic approach to them also aims at correcting the deficiency and metabolic derangement.

ISSN No: 0976-5921

Acharya Charaka has advised Tiktka Ksheera Basti where Ksheera (Milk) serves as Sneha whereas the Tikta Rasa acts as vehicle to deliver the Sneha to Asthi Dhatu due to its dominance of Akasha (Space) and Vayu (Air) Mahabhoota (Element) and property to reach the Asthi dhatu. Tikta Rasa also helps in faster absorption of the Sneha and does not cause Agnimandva (appetite loss), which may appear due to prolonged administration of Sneha. Additionally, milk also acts as a source of Vitamin D and calcium, thus supporting the conventional therapeutic approach too. The ingredients of Praval Panchamruta Vati are all basically made up of the same compound Calcium Carbonate. As per their classical properties, majority of the contents of Praval Panchamruta Vati are Shoolaghna (analgesic) and deepana (activating the digestive fire), making it a good therapeutic choice for Asthi Kshava. Additionally, it also suffices the complimentary approach of supplementing oral calcium in Osteopenia/ Osteoporosis.

The result shows that *Panchatikta Ksheera Basti* along with *Praval Panchamruta Vati* in Group A showed better results than the Control Group B which was supplemented with Organic Calcium and Vitamin D. It also improved the functional and physical activities of the patient thus improving the daily lifestyle of the patient.

Conclusion

Basti (Medicated Enema) has been indicated by Ayurveda as the most effective intervention for vitiated Vata due to its holistic action on the Koshtha (gut) and Dhatu (tissues). Praval Panchamruta replenishes the Asthi dhatu in accordance with the dominance of Prithvi Mahabhoota through similar elements as all its contents are marine shell forms composed of Calcium Carbonate. The present study has established that Panchatikta Ksheera Basti and Praval Panchamruta Vati have an equal or better therapeutic potential (for some parameters) in Asthi Kshaya (Osteopenia/ Osteoporosis) in comparison to conventional approach. Association between Gastro-intestinal disorders and Osteoporosis is a known fact (30) and throws light on relation between gut health and bone metabolism. The action of basti on the hind gut and its holistic action in Asthi Kshaya is documented in Ayurveda but needs to be explored further with respect to its long-term outcomes and additional benefits.



Varghese Jibi et.al., Effect of Panchatikta Ksheera Basti and Praval Panchamrut Vati in Asthikshaya

There were no adverse events noted throughout the study. Although the cost of Ayurveda intervention is comparatively more than the conventional treatment for Osteopenia/Osteoporosis.

Limitations

The present work was a pilot study and hence had its limitations with respect to sample size and duration of the study and hence it is a challenge to draw a concrete inference.

Acknowledgement

The authors acknowledge the support provided by the management of Dr. D.Y.Patil Vidyapeeth (Deemed to be University), Pimpri, Pune-18. We also acknowledge the help of Vrushali Wayal (Biostatistician).

Source of Funding

Dr. D.Y.Patil Vidyapeeth (Deemed to be University), Pimpri, Pune-18.

Conflict of interest

The authors declare that they have no known competing financial or personal interests that could influence the work for publication.

Declarations of generative Artificial Intelligence (AI) in scientific writing – The authors declare that No Artificial Intelligence was used during the scientific writing.

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