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Clinical Management of Osteoporosis with Panchatikta Ksheera Ghrita Basti - An Ayurvedic Medicinal Preparation

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ABSTRACT

Ageing is a process of physical, psychological, and social change in multidimensional aspects. Osteoporosis is one such age-related (generally) metabolic bone disorder where there is loss of bone tissue and its association with deterioration in skeletal micro-architecture. Bone fragility and bone fracture are the worst outcomes, therefore, effective medical treatment and therapy are its utmost need. In Ayurveda, it is mentioned that in vardhakya avastha, all dhatus undergo kshaya leading to dhatukshaya janya vata prakopa samprapti which can be understood as involvement of vata dosha (entity responsible for all kinds of neuro-hormonal activities in body) with ageing. Osteoporosis can be correlated with asthi sausrirya (porosity of bones). Asthisaurirya leads to asthikshaya. Vata vriddhi triggers Asthi kshaya because of a mutual bond held by both Ashrayashrayi bhava. In Charaka Samhita (chikista sthan ch.28), it is mentioned the usage of panchatikta dravya siddha ksheera basti (medicated enema) and sarpi in Asthi Vaha Srotodusti Chikitsa. Panchatikta ksheera ghrita is an ayurvedic preparation consisting of mainly five medicinal herbs having potency of increasing asthi dhatu (osteocytes) along with cow-milk and ghee. Following Ayurvedic principles, use of snehana dravyas (ghrita and milk) along with basti karma will pacify the vata involved in osteoporosis. As the tikta rasa-yukta dravya has property of kharata and soshana which are similar to property of asthi dhatu, so it reduces saushiryata (porosity) or kshaya of asthi dhatu by replenishing asthi dhatu. Ten patients who were diagnosed to be osteoporotic were taken into one experimental group, and one control group of 20 patients were taken. The treatment under experimental group is basti karma with panchatikta ksheera ghrita (72ml) for 14days and under control group, tab calcium500mg+vitD3 250mcg for 12weeks. Follow up was done during course of the treatment and after the completion of course. The treatment was more effective in the subjective parameters like low back ache (low thoracic and high lumbar vertebral pain), difficulty in walking, bone pain. Overall, the experimental group showed higher positive results. The drug may act as anti-oxidant, anti-inflammatory, anti-ageing. It can be treated easily in both OPD an IPD basis with zero surgical intervention, cost effective, no side effects and better outcomes.

Key Words *Osteoporosis, Asthikshaya, Asthisaurirya, Panchatikta Ksheera Ghrita, Asthivaha Srotas*

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INTRODUCTION

The principles of treatment of Ayurveda is shown to be successful against degenerative diseases (jarajanya vyadhi). Ageing is a real challenge. Osteoporosis is one of the degenerative disorders of bone where porosity develops and bone mineral density and bone mass decreases. Osteoporosis can be correlated with asthisaushirya (one cardinal sign of dushita majjavaha srota). Also signs and symptoms (both early and late) of osteoporosis justifies both asthivaha as well as majjavaha srota dusti lakshanas.. Over the past few years, a number of non-hormonal options have become available for prevention of osteoporotic fractures, yet no current available treatment modalities have potency to restore reduced bone density to normal. Therefore, to provide an effective treatment, an effort has been made through use of Ayurvedic siddhanta on management of osteoporosis (asthisausirya) by use of panchatikta ksheera ghrita basti (enema therapy).

DEFINITION OF OSTEOPOROSIS

World Health Organisation defines osteoporosis as a "progressive systemic skeletal disease characterized by low bone mass and micro architectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture".¹

Other definition is based mainly on bone mineral density (BMD) measurements of the hips and spine. Patients with BMD 1-2.5 standard deviations (SD) below peak bone mass

measurements are considered to be osteopenic and patients with BMD > 2.5 SD below peak bone mass measurements are osteoporotic.

CAUSES OF GENERALISED OSTEOPOROSIS¹

- Senility
- Post-immobilisation, eg a bed ridden patient
- Post-menopausal
- Nutritional and gastro-intestinal disorders- malnutrition, parenteral nutrition, malabsorption syndrome, severe liver disease
- Endocrine disorders – cushing syndrome, hyperparathyroidism, thyrotoxicosis
- Drug induced-long term steroid therapy, phenobarbitone therapy
- Hypogonadal states- turner syndrome, klinefelter syndrome

DIAGNOSIS OF OSTEOPOROSIS

Signs and Symptoms²

- Early
 - a) Episode of acute pain in middle to low thoracic or high lumbar region (low back ache).
 - b) Pain in knee joint
 - c) Bone pain
 - d) Difficulty in walking and sitting.
 - e) Pain in above mentioned regions while at rest or during routine daily activity is the earliest symptom of osteoporosis.
- Late signs and symptoms

Incremental loss in height

- a) Tenderness in bone
- b) Vertebral compression fractures, hip fracture

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- c) Diagnosis of osteoporosis (by investigation)²
- d) Radiographic findings
- e) Bone Mineral Density test (BMD-t score) GOLD STANDARD assessment
- f) BMD Score normal when +1 to -1 ,osteopenic -1 to -2.5 , osteoporosis -2.5 or lower
- g) Xray LS spine – Lumbosacral spondylosis , osteophytes , osteophytes osteoporosis , anterior wedge compression fracture .

Laboratory investigations. (biochemical markers)
Sr. Markers of bone formation-total alkaline phosphatase, sr. calcium,osteocalcin
Urine markers of bone resorption-urine calcium total pyridinates .

Limitations of biochemical markers – differ in response to specific osteoporosis therapies and may even vary in the same patient.

AIMS AND OBJECTIVES

- To study the concept of osteoporosis
- To manage cases of osteoporosis with panchatikta ksheera ghrita basti (an ayurvedic medicinal preparation)
- To compare the cases with the above mentioned therapy with modern medicine calcium and vit D.

MATERIALS AND METHODS

- A clinical trial is carried out with patients of osteoporosis diagnosed by investigations .
- Confirmatory period-1week

Experimental Group

- Treatment- Management with panchatikta ksheeraghrita basti (enema therapy)
- Treatment period- 14 days
- Age group – 40-70years
- Dose- 60ml
- Follow-up period-7th day, 14thday.
- Route of administration – per rectal
- No. of patients – 10
- Study centre- IPD and OPD of Govt. Ayurvedic College, Guwahati.

Control Group

- Number of patients. -10
- Age group – 40-70years
- Dose- Calcium 500mg+Vit D3 250mcg
- Route of administration- orally
- Treatment period - 12weeks .
- Follow up – after completion of course of treatment. Study centre- IPD and OPD of Govt. Ayurvedic College , Guwahati .

AYURVEDIC REVIEW OF OSTEOPOROSIS: DISEASE REVIEW

Ayurvedic: In Jaravastha, there is natural decline in quality and quantity of all dhatus (Ca.Vi.8/122). This gradual decline of all dhatus is attributed to the dominant Vata dosha in this stageAsthi vayu relationship

According to the principles of Ashrayashrayi Bhava, asthi dhatu is the seat of vata dosha. Asthi and vata dosha are inversely proportional to each other regarding vriddhi and kshaya. Vriddhi vata leads to kshaya of asthi (A.S.Su-20/1). So, if there is vata vriddhi that will lead to saushirta in

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asthi dhatu causing asthikshaya (loss of bone tissue)

Asthisausirya- While commenting on the word "Saushirya", the literal meaning of the word saushirya means porous bone, which is similar to osteoporosis. Acharya Charak has mentioned the symptoms of majja kshaya (Ca.Su.17/68) which means asthi becomes weak and light in weight.

Chikitsa / Treatment

The treatment of osteoporosis (an asthi asrayana vyadhi) is mentioned clearly in Charak Samhita sutra sthan chapter 28 sloka 27 where enema therapy vasti karma (a panchakarma) with ghrita and ksheera combined (or medicated) with tikta rasayukta dravya, which is considered as best therapy for asthi asrayana vayadhi .

DRUG REVIEW

In Ayurveda, in Asthivahasrota dusti chikitsa, use of basti karma with tikta dravyas with siddha ksheera and sarpi are mentioned (Ch.Su.28/27). Also, in majjavaha srota dusti chikitsa, use of tikta and swadu rasa are mentioned (Ch.S.u.28/28). Here, panchatikta ksheera ghrita has been taken for study the management of osteoporosis. Panchatikta ksheera ghrita is an ayurvedic preparation consist of Nimba (Azadirachta indica), Patola (Stereospermum suaveolens), Vasa (Adhathoda vasica), Guduchi (Tinospora cordifolia), Kantakari (Solanum xanthocarpum , triphala , go- ghrita (cow ghee) and go-dugdha (cow-milk).

METHODS OF ASSESSMENT

- General information including treatment for osteoporosis.
- Presenting symptoms as per modern medicine and Ayurvedic symptoms.
- Physical examination.
- Radiography (X-ray) Dorsal spine Lateral view.
- Bone Mineral Density test (BMD-t score) GOLD STANDARD assessment
- Laboratory investigations. Serum Calcium and Vit D assessed by us. method.Marker of bone formation (as serum).

Inclusion Criteria

- Patients presenting with the classical features of Asthi Kshaya (osteoporosis) were taken for the study.
- Postmenopausal women and osteoporotic men were taken for the study.
- Patients were selected between the age group of 40-60 years.
- Patients of osteoporosis diagnosed by BMD test.

Exclusion Criteria

The following patients were excluded from the study:

- Patients below the age of 40 years and above the age of 60 years were excluded.
- B.M.D.T. above -1 and less than -3.5
- Congenital disorders (Dysosteogenesis and Marfan's syndrome).
- Patients diagnosed with endocrine disorders (hyperthyroidism, hyperparathyroidism, untreated Cushing's syndrome).
- Patients with evidence of malignancy.

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- Patients suffering from major systemic illness necessitating long-term drug treatment.
- Prolonged immobilization.
- Long bone fracture in last six months .

Withdrawal Criteria

The patients were withdrawn from the trial when they developed any serious adverse or if there was noncompliance of treatment before three months.

Medicine preparation

Reference from chakradatt – panchatikta ghrita sloka 251-254

Susrut Chikitsa Sthan 17/19

Paribhasa Prakaran 1/10-11

- Ingredients – 5 medicinal herb collected locally.

Nimba (*Azadirachta indica*), Patola (*Stereospermum suaveolens*), Vasa (*Adhathoda vasica*), Guduchi (*Tinospora cordifolia*),

Kantakari (*Solanum xanthocarpum*), triphala, go-ghrita (cow ghee) and go-dugdha (cow-milk).

- Preparation site – State Ayurvedic Pharmacy (at Govt. Ayurvedic College)
- Quality test – Drug Testing Laboratory (DTL) , AYUSH, ASSAM

Gradation of symptoms (clinically)

- Low back ache
- Grade 0-No symptoms
- Grade 1-pain during lifting heavy objects
- Grade 2-bending forward and backward and standing after sitting posture
- Grade 3-standing for more than 10min or more
- Grade 4-bed ridden or inability to stand or even sit

RESULTS AND OBSERVATIONS

CLINICAL SIGNS AND SYMPTOMS

a) BONE PAIN AND TENDERNESS

GROUP A

Table 1 (a) Result for Bone Pain and Tenderness

Mean (BT)	Mean (AT)	Mean (BT)-Mean (AT)	SD	SE of mean	T-test (t9)	Probability	Remarks
3.5	1	2.5	0.85	0.27	2.17	P<0.05	Significant

GROUP B

Table 1 (b) Result for Bone Pain and Tenderness

Mean (BT)	Mean (AT)	Mean (BT)-Mean (AT)	SD	SE of mean	T-test (t9)	Probability	Remarks
3	1.2	1.8	0.44	0.32	1.37	P<0.05	significant

CLINICAL SIGNS AND SYMPTOMS

b) LOW BACK ACHE

GROUP A

Table.2(a) Result for Low Back Ache

Mean (BT)	Mean (AT)	Mean (BT)-Mean (AT)	SD	SE of mean	T-test (t9)	Probability	Remarks
2.7	0.6	2.1	0.567	0.18	11.66	P<0.01	Highly Significant

GROUP B

Table 2(b) Result for Low Back Ache

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Mean (BT)	Mean (AT)	Mean (BT)-Mean (AT)	SD	SE of mean	T-test (t9)	Probability	Remarks
2.2	1.6	0.6	0.393	0.124	9.95	P<0.01	Highly Significant

CLINICAL SIGNS AND SYMPTOMS

c) DIFFICULTY IN WALKING AND SITTING

GROUP A

Table 3(a) Result for Difficulty in Walking and Sitting

Mean (BT)	Mean (AT)	Mean (BT)-Mean (AT)	SD	SE of mean	T-test (t9)	Probability	Remarks
2.7	0.4	2.3	0.482	0.152	15.13	P<0.01	Highly Significant

GROUP B

Table 3(b) Result for Difficulty in Walking and Sitting

Mean (BT)	Mean (AT)	Mean (BT)-Mean (AT)	SD	SE of mean	T-test (t9)	Probability	Remarks
2.3	1.4	0.9	0.482	0.152	5.92	P<0.01	Highly Significant

COMPARATIVE STUDY

TABLE 4 Low Back Ache

(Mean) BT-AT Group A	(Mean) BT-AT Group B	SD	SE of Mean	t-test (t18)	Probability
2.1	0.6	0.48	0.217	6.9	<0.01

t18 =6.9,P<0.01, hence result is highly significant, moreover the effect of group A is better than group B in low back ache.

Table 5 Difficulty in Walking And Sitting

(Mean) BT-AT Group A	(Mean) BT-AT Group B	SD	SE of Mean	t-test (t18)	Probability
2.3	0.9	0.482	0.215	6.51	<0.01

Table 6 Bone Pain and Tenderness

(Mean) BT-AT Group A	(Mean) BT-AT Group B	SD	SE of Mean	t-test (t18)	Probability
2.5	1.3	0.73	0.32	3.75	<0.01

DISCUSSION

We see that osteoporotic cases are highly prevalent in developing and developed countries and its increased risk of complications are witnessed if not managed at early stage . The treatment of established bone loss is difficult. The place of hormonal replacement therapy as gold standard treatment for osteoporosis is now challenged as an evidence for its effectiveness has come under great scrutiny and uncertainties about long term effects on coronary heart disease

has emerged. The use of Aledronate, Ibandronate, Zoledronic acid have complains of oesophagitis, oesophageal ulcers and the latest modern drug Teriparatide 20mcg SC has played a great role but researchers point out chances of osteosarcoma. Therefore, by applying ayurvedic principles picked up frm from samhitas written by great scholars, effort has been made to manage this metabolic, generally age related disease. The results and observations shown in Table. 1(a),1(b),2(a),2(b),3(a),3(b),4,5 and 6

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gives a positive outcome from its inference. This therapy has been shown cost effective, non invasive and also good in feasibility and accessibility. In future, pilot study can be done taking more number of patients and prove beneficial for the scholars and researchers .

CONCLUSION

Ayurveda is a science where all the siddhants are inscribed by ancient great scholars after many repeated discussions , proofs, validations and experiences over the years and their final results . Every siddhant has its own uniqueness in understanding and specific in its applications . As Ayurveda is boon for management of chronic , degenerative diseases. (jara chikitsa) and enhancing Ayu(longevity) . Therefore , here effort has been made in osteoporosis (jarajanya vyadhi) and its chikitsa aspect .

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