

A CLINICAL STUDY OF TIKTA KSHEERAVASTHI (KALAVASTHI) IN
OSTEOPOROSIS W. R. T. ASTHIGATAVATA

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ABSTRACT

The present study was aimed to evaluate the efficacy of *Tikta ksheeravasthi* in Osteoporosis w.r.t. *asthigata vata*. Osteoporosis can be correlated with *asthigata vata* in *Ayurveda*. In the treatment principle of *asthigata vata*, *snehan*, *swedan* and *mrudu shodhana* has been mentioned. 10 patients fulfilling the criteria for the osteoporosis were taken for the present study according to inclusion criteria. Initially *Deepana*, *Pachana*, *Rookshana* was done. Then *Jambeera pinda sweda* for 7 days was done. Then administration of *Tikta ksheeravasthi* in *kalavasthi* pattern for 16 days was done. Follow up was done after 32 days in which *guggultiktakam ghritam* was given as *shaman aushadhi*. Assessment was done before treatment and after follow up at clinical level and investigation level. After statistical analysis it can be concluded that *Tikta ksheeravasthi* was effective in reducing signs and symptoms of osteoporosis.

KEYWORDS: *Tikta ksheeravasthi*, *Asthigata vata*, Osteoporosis, *Guggultiktakam ghritam*,

INTRODUCTION

Osteoporosis, is burning health problem of this era. Osteoporosis is defined as a reduction in the strength of bone leading to an increased risk of fractures. WHO operationally defines osteoporosis as a bone density that falls 2.5 standard deviations (S.D) below the mean for young healthy adults of the same gender – also referred to as T – score of - 2.5. The word ‘Osteoporosis’ is a combination of two words – ‘Osteon’ meaning bone and ‘porosis’ meaning cavity formation. The symptoms includes restriction of joint movement, severe pain, fracture, abnormalities of nail and teeth etc. The etiological factors are right from metabolic to idiopathic and it usually generates along with senile and post menopausal changes in the body. India is one of the largest affected countries of the world with osteoporosis and the prevalence rate is 1 in 3 women and 1 in 12 men over the age of 50. Current WHO estimate that over 270 million people are likely to suffer from osteoporosis by 2020 in India and China alone.

Asthigata vata is one among the *dhatugata vata vyadhis* described in all *Ayurveda* classics. It comes under the category of *Gata vata* explained in *vatavyadhi prakarana*,^[1] of *charaka samhitha*. Instead of the word ‘Gata’ in *gata vata*, *acharyas* have mentioned various terminologies like *gate*, *sthite*, *avasthite*, *prapte* etc depending upon the gati of vitiated *vata* and *sthanasamsraya* on a particular site. In *Ayurveda* osteoporosis comes under the spectrum of *Asthigata vata*

in *Asthigata vata*, *vata* and *asthi* are predominantly affected due to *vata prakopa*. The causative factors are *vatala aahar vihar*,^[2] which produces *asthi kshaya lakshanas* and nowadays another causative factor is *virrudhha aahar* causing *dhatwa agni mandya*. The *vata dosha* and *asthi dhatu* are related to each other by *Asrayasrayibhava*,^[3] i.e they are reciprocally related. In the *Asthigata vata*, there will be *vata prakopa lakshanas* and *Asthi kshaya lakshanas*. The general line of treatment for *vata dosha* is *Snehana*, *swedana* and *mrudu shodhana*.^[4] In *Ayurveda* classics for *Asthi kshaya*, *acharya charaka* mentions treatment principle for *asthi ashrit vyadhi*,^[5] He mentions to use medicated *ksheera* and *ghrit* with *tikta rasa* for *panchakarma*. So based on this principle it is assumed that *tikta ksheera vasthi* are having pivoting role in osteoporosis. The present study was under taken to prove the efficacy of *tikta ksheera vasthi* in treating osteoporosis.

AIMS AND OBJECTIVES

1. To assess the efficacy of *Tikta ksheera vasthi* in reducing the signs and symptoms in patients with osteoporosis.
2. To evaluate the efficacy of *Tikta ksheera vasthi* in bone mineral density studies.

MATERIALS AND METHODS

Source of Data and Method of Collection

Patients were selected from the OPD and IPD of department of *Panchakarma*, CSMSS Ayurveda Hospital, Auranagabad. Patients were screened for Osteoporosis and were selected for study as per inclusion and exclusion criteria. Necessary investigations were carried out. Their details were recorded in a special proforma.

Inclusion Criteria

- Patients with Osteoporosis and patients at the risk of Osteoporosis.
- Age group 35 – 60 years
- Sex: Female and Male
- Patient fit for *Vasti*
- Patient with written informed consent.

Exclusion Criteria

- Patient below Age group 35 and above 60 yrs.
- Heritable diseases of connective tissue like Osteogenesis imperfecta.
- Metabolic disorders like Hyperthyroidism and Hyperparathyroidism, Diabetes mellitus and other systemic illnesses like Chronic Rheumatoid Arthritis, complicated hypertension
- Other gross metabolic Bone disorders.
- Patients who are on long term treatment with corticosteroids.
- Contraindications for *vasti*.

Research Design

10 patients were selected for study as per inclusion and exclusion criteria after screening for osteoporosis by BMD test. The BMD Test and required haematological investigations were done before and after the study and trial was conducted on selected patients. An informed written consent of patient was taken prior to study. Concerned datas were recorded and periodic evaluations were done accordingly. Results were statistically analysed at the end of study.

Intervention

Maharasnadi Kashayam 90ml bd morning and evening - 3 days

Shaddharana churnam 5gm bd with lukewarm water before food -3 days

Jambeera pinda sweda - 7days

Ksheeravasthi done as *Kalavasthi* - 16 days.

MATERIALS AND METHODS

Jambeera pinda Sweda

Lemon, garlic, saindhav, rasna choorna, deodar choorna, haridra choorna, methika choorna All fried in eranda tailam and tila tailam. And the pottali was prepared and used.

Vasthi

Shuddha Bala taila (for abhyanga) - Q. S.

Drugs for *Ksheeravasthi*

- *Panchtiktasheerapaka* - 200ml.
- *Guggulutiktaka gritha* - 100ml.
- *Lakshadi taila* - 100ml.
- *Madhu* - 100ml.
- *Yavanyadikalka* - 30g.
- *Saindhava* - 5g.

Drugs for *Anuvasana Vasthi*

Lakshadi taila - 120ml.

Saindhava - 1g.

ShatapushpaChurna - 1g.

Preparation of trial drugs

Maharasnadi Kashaya and *Shaddharana Choorna*, *Lakshadi Taila*, *Guggulutiktaka Ghrita*, *Shuddha Bala Taila*, *Madhu* were used of the GMP Certified *Arya Vaidya Shala Kottakal Pharmacy*, Kerala. Materials required for *Jambeera Pinda sweda*, *Panchatikta Bharad Kalka Dravya* were collected from Market.

Preparation of *Ksheeravasthi*

Initially *madhu* and *Saindhava* were added and mixed properly. *Lakshadi taila* was added followed by liquefied *guggulutiktaka gritha* in thin stream with continued grinding. Then *Yavanyadi Kalka* was added little by little and mixed together until the uniform mixture is obtained. Finally *panchatikta ksheerapaka* was added in thin streams while continuing the grinding. Then all the contents were mixed to form a uniform mixture, it was filtered through a clean cloth and made lukewarm over boiling water vapour. Then this mixture is churned with the help of a churner for few minutes. The mixture obtained was slightly thick, uniformly mixed and lukewarm. This was put into a clean and sterile, thick plastic cover (*Vasthi putaka*) and *vasthinetra* made of plastic was tied to it, and was plugged with cotton.

Preparation of *Anuvasana vasthi*

Lakshadi Taila was added with fine powder of *Shatapushpa choorna* and *saindhava* 1g each, and stirred properly. It was filtered and filled in *Vasthiputaka*. *Vastinetra* was tied properly and plugged with cotton.

Procedures

Jambeera Pinda sweda: For 7 days, this was done for whole body by using *shuddha bala taila* for 30 minutes in 7 different position. Patient was asked to take rest for 1 hour Then bath with luke warm water.

Kalavasthi: The 16 *vastis* were done. First two *anuvasana* then 6 *ksheeravasthi* and *anuvasana* alternately followed by last three *anuvasana*.

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Administration of Anuvasana Vasthi

Poorvakarma - *Abhyanga* with *Shuddha Bala taila* in the morning and *bashpasweda*.

Blood pressure and pulse rate were recorded.

Pradhana Karma - Administration of *anuvasana vasthi* in 120 ml quantity.

Paschat Karma - Patient was asked to lie down in supine position with all the limbs relaxed, counting up to 100. Then was asked to take rest and advised to evacuate the bowel as soon as the urge comes. At night was asked to take light food.

Administration of Ksheera vasthi

Poorva Karma - Patients was given *abhyanga* with *Shuddha bala taila* and *baspasweda* at 10.30 am. Their blood pressure and pulse rate were recorded.

Pradhana Karma - Administration of *Ksheera vasthi* in left lateral position.

Paschat Karma - Patient was asked to lie in supine position till the urge of defecation occurs. Then was asked to clear the bowels and take bath with hot water. Then light food like rice was given with *mudga yusha* was asked to take rest and light food was given at night.

Post Vasthi Regime - After *Kalavasthi* patient was advised to follow *parihara kala* for a period of 32 days. During follow up patient was advised to take the *Guggulutiktakam Ghritam* as *shamana* drug at bedtime after food for 6 months.

Duration of the study

The study includes 26 days of intervention and 180 days of follow-up.

Assessment Criteria

Assessment was done at two levels

Clinical level

A) Pain: It was assessed by visual analogue scale and graded as follows.

Table 1: Pain assessment.

Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
No pain	Mild pain	Moderate pain	Severe pain	Impossible to tolerate

B) Stiffness

Table 2: Stiffness assessment.

Grade 0	Grade 1	Grade 2
Absent	< 15 minutes	> 15 minutes

C) Tenderness

Table 3: Tenderness assessment.

Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
No tenderness	Patient say joint is tender	Patient winces	Patient winces and withdraws the affected part.	Patient won't allow touching the affected part.

D) Crepitus

Table 4: Crepitus assessment.

Grade 0	Grade 1	Grade 2
Absent	Palpable	Audible

E) Walking Difficulties

Table 5: Walking difficulties are assessed by inspection and assessed as follows.

Ability to Climb up a standard flight of 10 stairs	Easily with mild difficulty with moderate difficulty marked difficulty Impossible	Grade 0 Grade 1 Grade 2 Grade 3 Grade 4
Ability to climb down a standard flight of 10 stairs	Easily with mild difficulty with moderate difficulty with marked difficulty Impossible	Grade 0 Grade 1 Grade 2 Grade 3 Grade 4
Ability to bend or squat the knee	Easily with mild difficulty	Grade 0 Grade 1

	with moderate difficulty	Grade 2
	with marked difficulty	Grade 3
	Impossible	Grade 4

F) Investigation level

BMD test done before and after study was the prime investigative tool. Routine blood tests, TFT, Serum Alkaline Phosphatase and serum calcium were assessed before and after treatment.

Interpretation of Bone Density Values

WHO has established diagnostic guidelines of T-score as follows

- Normal Bone : T-score at or above -1SD
 Osteopenia : T-score between -1.0 and -2.5 SD
 Osteoporosis : T-score at or below -2.5 SD

Statistical analysis

The efficacy of treatment was analyzed by calculating the mean, standard deviation of the parameters; t and p values were found using Paired 't' test.

OBSERVATION AND ANALYSIS**Data related to response to treatment**

The response to the treatment was assessed by statistical methods during admission of the patient and after follow up of 6 months.

Table 6: Response of treatment on joint movements.

Parameters	Stage	Mean	SD	N	Mean Difference	Paired t	P
Neck movements	BT	2.60	0.70	10	2.1	11.7	p<0.001
	AT	0.50	0.53	10			
Shoulder mobility (left and right)	BT	2.80	0.63	10	2.2	16.5	p<0.001
	AT	0.60	0.70	10			
Elbow mobility (right)	BT	2.44	0.73	9	2.0	12.0	p<0.001
	AT	0.44	0.53	9			
Elbow mobility (left)	BT	2.22	0.67	9	2.0	12.0	p<0.001
	AT	0.22	0.44	9			
Arm mobility (right)	BT	1.80	0.79	10	1.7	8.0	p<0.001
	AT	0.10	0.32	10			
Arm mobility (left)	BT	1.44	0.53	9	1.3	8.0	p<0.001
	AT	0.11	0.33	9			
Wrist mobility (right and left)	BT	1.56	0.53	9	1.4	8.2	p<0.001
	AT	0.11	0.33	9			
Hip mobility (right and left)	BT	2.70	0.48	10	2.3	15.1	p<0.001
	AT	0.40	0.52	10			
Knee mobility (right)	BT	2.80	0.42	10	2.4	14.7	p<0.001
	AT	0.40	0.52	10			
Knee mobility (left)	BT	2.60	0.52	10	2.3	15.1	p<0.001
	AT	0.30	0.48	10			
Ankle mobility (right)	BT	1.90	0.99	10	1.5	9.0	p<0.001
	AT	0.40	0.52	10			
Ankle mobility (left)	BT	1.70	0.82	10	1.5	9.0	p<0.001
	AT	0.20	0.42	10			
Foot mobility (right)	BT	1.88	0.64	8	1.6	8.9	p<0.001
	AT	0.25	0.46	8			
Foot mobility (left)	BT	1.75	0.71	8	1.5	7.9	p<0.001
	AT	0.25	0.46	8			
Difficulty to climb up a standard flight of 10 stairs (right)	BT	2.80	0.42	10	2.4	14.7	p<0.001
	AT	0.40	0.52	10			
Difficulty to climb up a standard flight of 10 stairs (left)	BT	2.70	0.48	10	2.4	14.7	p<0.001
	AT	0.30	0.48	10			
Difficulty to climb down a standard flight of 10 stairs based on group (right)	BT	2.80	0.42	10	2.4	14.7	p<0.001
	AT	0.40	0.52	10			
Difficulty to climb down a standard flight of 10 stairs (left)	BT	2.60	0.52	10	2.3	15.1	p<0.001
	AT	0.30	0.48	10			
Difficulty to bend or squat at the knee (right)	BT	2.80	0.42	10	2.4	14.7	p<0.001
	AT	0.40	0.52	10			
Difficulty to bend or squat at the knee	BT	2.60	0.52	10	2.3	15.1	p<0.001

(left)	AT	0.30	0.48	10			
Tenderness (right)	BT	2.70	0.48	10	2.3	15.1	p<0.001
	AT	0.40	0.52	10			
Tenderness (left)	BT	2.60	0.52	10	2.2	16.5	p<0.001
	AT	0.40	0.52	10			
Crepitus (right)	BT	1.50	0.53	10	1.3	8.5	p<0.001
	AT	0.20	0.42	10			
Crepitus (left)	BT	1.40	0.52	10	1.3	8.5	p<0.001
	AT	0.10	0.32	10			
Morning stiffness (right)	BT	1.83	0.41	6	1.8	11.0	p<0.001
	AT	0.00	0.00	6			
Morning stiffness (left)	BT	1.83	0.41	6	1.8	11.0	p<0.001
	AT	0.00	0.00	6			
BMD test score	BT	-2.3	0.5	10	2.0	8.2	p<0.001
	AT	-0.3	1.2	10			
ESR	BT	31.9	12.2	10	15.0	4.8	p<0.01
	AT	16.9	7.3	10			
Serum alkaline phosphatase	BT	106.4	7.9	10	8.0	5.2	p<0.001
	AT	114.3	7.4	10			
Serum calcium	BT	8.0	0.9	10	0.7	6.2	p<0.001
	AT	8.7	0.7	10			
Serum haemoglobin	BT	10.7	1.4	10	1.3	5.5	p<0.001
	AT	12.0	0.8	10			

DISCUSSION

Osteoporosis can be correlated with *Asthigata vata* which is included under the spectrum of *vatavyadhi*. *Vatavyadhi* is included under *Mahagadas* due to *uttarothara dhatu avaghatwam* (progressive affection of deep dhatus) and *deerkhakalanubandhatwam* (prolonged disease duration). *Asthigata vata* is caused by *vata prakopa* which in turn leads to *Asthi kshaya*.

The present study was under taken to prove the efficacy of *Tikta ksheera vasthi* in treating osteoporosis and to evaluate the efficacy of *Tikta ksheera vasthi* in bone mineral density studies. 10 patients were undertaken for this study and the observations were systematically recorded.

The treatment principle was based on *vatavyadhi chikitsa* viz *snehan*, *swedan* and *mrudu shodhana*.^[6] Initially *deepana*, *pachana* and *rookshana* were done for attaining *agnibala*.^[7] For this purpose *maharasnadi kashaya* and *shaddharana churna* was used. *Jambeera pinda sweda* using *Shuddha Bala taila* was done. *Snehana* and *swedana* is against the *seetha* and *rooksha guna* of *vayu* so pacify the *vata*. Then patients were given *ksheeravasthi* in form of *kalavasthi* which included *6 niroohas* and *10 anuvasanas*. *Ksheeravasthi* consisted of *panchatikta ksheerapaka*, *lakshadi taila* and *guggulu tiktaka gritha* which was according to *chikitsa sootra* of *asthivaha srotodushti*. *Yavanyadi kalka* was added as per the directions of *Arundatta*. *Ksheera vasthi* is *mrudu nirooha* mentioned particularly for the, *vatashamana bala vardhan*, and it is *snigdha* in property.^[8] It expels the *doshas* from the *pakwasaya*,^[9] thus removes the *roga karana* from the root. Patients were discharged after *vasthi Karma*. They were advised to follow *vasthi*

parihara kala of 32 days viz *dwipariharakala*¹⁰. *Parihara kala* is necessary to increase *bala* of patient after *shodhana karma*. The remaining *doshas* in body are been treated with *shaman aushadhis*. *Guggulutiktakam ghritam* was used as *shaman aushadhis* with is very effective in *asthisandhi gata vyadhis* for a period of six months. Patients were advised to be in contact with respect to treatment just to notice the changes that occurred.

Interpretation of response to the treatment

The clinical assessment were done on parameters like pain on joint mobility, difficulty in walking, tenderness, crepitus, morning stiffness, BMD test and haematological investigations After treatment highly significant changes were obtained in all parameters.

BMD: Highly significant changes were seen in BMD which suggest that treatment is very effective in increasing bone mineral density.

ESR: Highly significant changes were seen in ESR which can be known by enhanced joint mobility with reduced pain and stiffness.

Serum Alkaline Phosphatase: Highly significant changes were seen in Serum Alkaline Phosphatase levels. It indicates the increased osteoblastic activity and increased bone formation.

Serum Calcium level: Highly significant changes were seen in Serum calcium level which is suggestive of enhanced osteoblastic activity and strengthening of bone.

These highly significant improvements were because of the treatment done in this study *Ksheeravasthi* in form of *kalavasthi* has proved to be effective in reducing signs and symptoms of *asthigata vata* and also proved effective in enhancing bone mineral density.

Probable action of Tikta ksheera vasthi in osteoporosis
Ksheera vasthi is such a *vataghna yoga* that induces *bala*, *snehana* and when used with *tikta ksheera* and *gritha*, it acts specifically on *asthidhatu*. According to *Arundatta* commentary – Any *dravya* having *snigdha* and *shoshan* property and the *dravya* which produces *kharatva* in body is beneficial for *asthikshaya* as the *asthi dhatu* has *khara* property. In the universe there is not a single drug having these combined property. *Tikta* is the *rasa* which produces *kharatva* because of most *shoshana swabhava*, and *kharatva* is *pradhana guna* of *Asthidhatu*. *Tikta rasa* when combined with *ksheera* or *gritha* will improve the *dridatha* of *asthidhatu*, resulting in *asthiposhana* and *asthivardhana*. *Tikta rasa* aggravates *vata*, but when its processed with *ksheera*, and *grithas* it promotes osteogenesis. Hence because of such combination this *vasthi* though *vatahara* by nature, produces *kharatva* in the *shareera*, but does not cause *vataprakopa* because of *snighatva* of *ksheera* and *gritha*. *Ksheera* and *gritha* are very useful and effective *dravyas* in degenerative conditions. *Sushruta* says that *vasthi* stays in *pakwasaya*, where *pureesha dhara kala* exists and does its action.^[11] *Dalhana* in his commentary mentions that *pureeshadhara* and *Asthidhara kalas* are one and the same,^[12] so when *vasthi* is given, it acts on *asthidhara kala* It means *kharatva* produced in *pakwashaya* by *Tikta ksheera vasthi* helps in normal formation of *asthidhatu* in *shareera*, and hence improves the condition.

CONCLUSION

1. Osteoporosis can be well treated with *tikta ksheera vasthi* (*Kalavasthi*) without any complications.
2. *Tikta ksheera vasthi* is very effective in reducing signs and symptoms of osteoporosis.
3. The *vasthi* improves the general health status of patients and thereby brings well-being.
4. *Tikta ksheera vasthi* also helpful in increasing bone mineral density in patient.

LIMITATIONS

- Sample size was very small.
- The period of study was limited in this study.
- Still longer follow up can be done.

RECOMMENDATION FOR FURTHER RESEARCH

- Larger sample size can be taken
- Longer follow up should be done.
- Effect on other immunological parameters can be done.

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