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Research Article

A CLINICAL STUDY TO EVALUATE THE EFFECT OF GUDUCHI SIDDA KSHEERA BASTI IN OSTEOPOROSIS

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ABSTRACT

Osteoporosis is the commonest form of metabolic bone disease and is a major public health problem. Osteoporosis is a condition characterized by reduced bone strength, which is prevalent more among post menopausal women. It also occurs in men and women with major risk factors associated with bone demineralization or decrease in the absolute amount of bone.

This condition can be coined as *Asthikshaya*. *Vata* is one of the important causative factors for *Asthikshaya* by its *Ashraya Ashrayi Bhava*. In Ayurveda, treatment of *Asthigata Vikaras* is explained as *Basti* with *Ksheera* and *Ghritha* processed with *Tiktaka Dravyas*. Drugs used in this study are *Tikta Rasa Pradhana Guduchi* which is having *Rasa*yana property and so is useful in the degenerative conditions as in *Asthikshaya*. To assess the effect of *Guduchi Ksheera Basti* in *Asthikshaya* or osteoporosis, the study was undertaken.

Total of 30 patients who were diagnosed to be osteoporotic on BMD test (bone mineral density), were taken in to a single group. *Guduchi Ksheera Basti* was given for duration of 15 days and follow up was done after one month and BMD test was done to see improvement. Treatment was more effective in subjective parameters like *Asthi Toda*, *Sparsha Asahyata* and moderately effective in objective parameters of BMD t -score.

INTRODUCTION

Osteoporosis is defined as a reduction in the strength of bone that leads to an increased risk of fractures. Exact numbers of people suffering are not known but on estimation 25 million Indians are affected by osteoporosis which increases in significance with the growing elderly population. Fractures related to osteoporosis are estimated to affect around 30% of women and 12-15% of men at some point in developed countries.

In old age, as a general rule all *Dhatus* undergo *Kshaya* leading to *Vata Prakopa* which might lead in to a disease. Equilibrium of all *Dhatus* are considered as health, any imbalance to this is considered as disease. *Vaishamyam* of *Dhatus* can be classified into 2 types as *Vruddhi* and *Kshaya*. "*Sharire Dharanat dhatavah*" here *Asthi* is one of the important *Sapta Dhatus* which provides stability i.e., it does *Dharana* of *Shareera* providing structure to the body. As *Asthi* and *Vayu* are having *Ashraya Ashrayi Bhava*, *Vata Vruddhi* leads to *Asthi Kshaya*[1]. Even the *Nidanas* (causative factors) which causes *Vata Vruddhi* acts as contributory factors for *Asthi Kshaya*. *Lakshanas* explained in the context of *Asthi Kshaya* in *Samhitas* are *Sandhi Shula*, *Asthi Toda*, *Sandhi Shaitilya*, *Kesha*, *Roma*, *Nakha Patana*, and *Rukshata*. [2]

In modern science "Osteoporosis is defined as reduced bone density, which causes a micro architectural deterioration of bone tissue and leads to an increase risk of fracture". It is also known as marble bone disease, refers to a rare group of rare genetic disease that is characterized by reduced bone resorption and diffuse symmetric skeletal sclerosis, due to impaired formation of osteoclasts.[3] The main etiological factors of osteoporosis are increasing age, hormone deficiency, inflammatory diseases, low calcium diet, smoking, alcohol and long standing corticosteroid treatment. Treatment is mainly aimed at preventing the further degeneration and further bone loss by administering calcium supplements, Vitamin D3 supplements and Selective Estrogen Receptor Modulators (SERMs).

In *Ayurveda*, line of treatment differs slightly. Formulations in the form of *Basti* have been explained in *Asthigata Vikaras*. The same principle is applied in

the present clinical study to evaluate the effect of *Guduchi sidda Ksheera Basti* in Osteoporpsis.

AIM OF THE STUDY

To evaluate the efficacy of *Guduchi Ksheera Basti* in the management of osteoporosis.

MATERIALS AND METHODS

The present study was an observational clinical study with pre and post test design.

The formulations selected were

1. *Tiktadya Ghritha* 65ml for *Anuvasana Basti.* [4]
2. *Guduchi siddha Ksheera* -500ml for *Asthapana Basti* [5]. This was administered in *Kala Basti* pattern.

SAMPLE SIZE

Total 30 patients diagnosed to have *Asthi Kshaya* (Osteoporosis) were selected incidentally from the OPD, IPD and special camps conducted at JSS Ayurveda medical college hospital Mysore. Patients were registered and treated as in patients for the present study. Special case sheet proforma was prepared for entering the data.

DIAGNOSTIC CRITERIA

Subjective criteria: The clinical presentation of patients according to the signs and symptoms of *Asthi Kshaya* vis-a-vis osteoporosis.

Objective criteria: Bone mineral density test (BMD, T score < -2.5).

INCLUSION CRITERIA

- Patients between the age group 30-65 years
- Patients who are fit for *Basti* procedure
- Pre and post menopausal women
- Patients with the confirmed diagnosis of osteoporosis by means of BMD values

EXCLUSION CRITERIA

- Traumatic, infective, endocrinal disorders (Hyper /Hypoparathyroidism) and secondary to other diseases and systemic disorders which interferes with the course of treatment.
- Patients contraindicated for *Basti.*

ASSESMENT CRITERIA

The improvement in the subjective parameters and objective parameters were assessed by scoring method (Mc Gail Pain Scoring method). Clinical and functional parameters were made out to assess the clinical response in the total number of patients. All the grades used for the assessment of subjective parameters were clearly documented.

Subjective symptoms were assessed before treatment and after treatment and again after 15 days of the treatment as follow up. Objective symptoms i.e. BMD was done before the treatment and after 30 days of the treatment. i.e. on the follow up day.

A) SUBJECTIVE PARAMETERS

1) *Asthi Toda* : Grading for *Toda*

Grade 0 : No *Toda*
Grade 1 : Mild *Toda*
Grade 2 : Moderate *Toda*
Grade 3 : *Toda* felt on pressure
Grade 4 : Severe *Toda*

2) *Sandhi Shula* : Grading for pain

Grade 0 : No pain
Grade 1 : Mild pain
Grade 2 : Discomforting pain
Grade 3 : Distressing pain
Grade 4 : severe pain

3) *Sparsha Asahyata*: Grading for tenderness

Grade 0 : No tenderness
Grade 1 : Mild tenderness without response on pressure
Grade 2 : Wincing of face on pressure
Grade 3 : Wincing of face and withdrawal of affected part
Grade 4 : Resist touch due to tenderness

B) OBJECTIVE PARAMETERS

Table 1: Bone Mineral Density (BMD)

S.No.	Category	Bone Mineral Density ('t'-score)
1.	Normal	A value of BMD (t-score) within '1' standard deviation of young adult reference mean, i.e. t-score < -1
2.	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.
3.	Osteoporosis	A value of BMD more than 2.5 standard deviation below the young adult reference mean. i.e. t-score <-2.5.

OBSERVATION S AND RESULTS

Among 30 patients Maximum number of patients i.e., 16 (53.33%) patients were female and 14 (46.22%) patients were male. 22 patients (73.33%) had *Vatapitta Prakruti*, followed by 7 (23.33%) patients had *Vata kapha*, and 1(3.33%) had *Pittavata Prakruti*.

Among 16 female patients 13 (81.25%) patients had already attained menopause, followed by 3 (18.75%) were in pre menopausal state.

Among 30 patients, maximum number of patients, i.e. 13 (43.33%) were between the age group of 60-65 years, followed by 5 (16%) patients were of age group of 55-60 years, 4 (13.33%) were of age group 45-50 years, 3 (10%) patients each were of 40-

45 years and 50-55 years respectively and 2 (6.66%) patients were of age group 35-40 years.

Among 30 patients, 21 patients (70%) had sedentary life style, followed by 6 patients (20%) had executive life style and 3 (10%) patients were from labor class. Among 30 patients maximum number of patients i.e. 18 (60%) had chronicity of 1-5 years, followed by 11 (36.66%) had chronicity of less than 1 year, 1 (3.3%) patient had chronicity of 6-10 years.

Among 30 patients maximum of 25 (83.33%) patients did not had history of any fracture or trauma, followed by 5 (16.6%) patients had history of fracture and trauma. Among 30 patients maximum patients i.e. 22 (73.33%) were having BMI of 20-25, followed by 5 (16.66%) patients had BMI of 25-30, and 3 (10%) patients had BMI below 20.

RESULTS

The results obtained for the parameter *Asthi Toda* was statistically highly significant with 59.90% improvement, *Sandhi Shula* was statistically highly significant with 76% improvement. *Sparsha Asahyata* was statistically highly significant with 76.60% improvement with the P value 0.000. The Mean difference of BMD 't' score before treatment was -2.9033 with S.D of .44527 and is reduced to -2.5067 with S.D of .38321. The Paired difference of mean was -.3967 with P value .000 which was highly significant after the treatment.

Table 2: Showing the results of *Asthi Toda*

			SESSION		Total
			Before	After	
ASTHI TODA	**Nil**	**Count**	0	15	15
		% of SESSION	.0%	50.0%	25.0%
	Mild	**Count**	23	14	37
		% of SESSION	76.7%	46.7%	61.7%
	Moderate	**Count**	5	1	6
		% of SESSION	16.7%	3.3%	10.0%
	Pain with Pressure	**Count**	1	0	1
		% of SESSION	3.3%	.0%	1.7%
	Severe pain	**Count**	1	0	1
		% of SESSION	3.3%	.0%	1.7%
Total		**Count**	30	30	60
		% of SESSION	100.0%	100.0%	100.0%

Table 3: Showing the results of *Sandhi Shula*

			SESSION		Total
			Before	After	
SANDHI SHULA	**Nil**	**Count**	0	13	13
		% of SESSION	.0%	43.3%	21.7%
	Mild	**Count**	3	16	19
		% of SESSION	10.0%	53.3%	31.7%
	Discomforting pain	**Count**	13	1	14
		% of SESSION	43.3%	3.3%	23.3%
	Distressing pain	**Count**	10	0	10
		% of SESSION	33.3%	.0%	16.7%
	Severe pain	**Count**	4	0	4
		% of SESSION	13.3%	.0%	6.7%
Total		**Count**	30	30	60
		% of SESSION	100.0%	100.0%	100.0%

Table 4: Showing the results of *Sparsha Asahyata* (Tenderness)

			SESSION		Total
			Before	After	
SPARSHASYATA	**Nil**	**Count**	8	21	29
		% of SESSION	26.7%	70.0%	48.3%
	Mild without Pressure	**Count**	7	8	15
		% of SESSION	23.3%	26.7%	25.0%
	Wincing on pressure	**Count**	10	1	11
		% of SESSION	33.3%	3.3%	18.3%
	Withdrawal of affected part	**Count**	4	0	4
		% of SESSION	13.3%	.0%	6.7%
	Resist touch due to	**Count**	1	0	1

	severe Tenderness	**% of SESSION**	3.3%	.0%	1.7%
Total		**Count**	30	30	60
		% of SESSION	100.0%	100.0%	100.0%

Table no 5: Showing the results of BMD Test: Paired Stats...

		Mean	**N**	**Std. Deviation**	**Std. Error Mean**
Pair 1	**BMD PRE**	-2.9033	30	.44527	.08129
	BMD POST	-2.5067	30	.38321	.06996

Paired Samples Test

		Paired Differences	**T**	**Df**	**Sig (2-tailed)**
		Mean			
Pair 1	**BMD PRE – BMD POST**	-.3967	-10.071	29	.000

DISCUSSION

In the present study the age group was divided into 03 groups i.e. 13 patients (43.33%) were from the age group 60-65 years which shows more evidence of old age where *Asthi Kshaya* is more predominant. Even patients with age group of 50-60 years around 5 patients were observed. 5 patients with age group of 35-45 years were observed. This can be inferred that after 45 years, degenerative condition prevails may be because of life style disorders.

Among 30 patients 14 (46.6%) were male and 16 (53.3%) were females. This shows the greater incidence of the disease is more in females compared to males. The reason is the peak bone mass achieved in males is late than females, when the bone desorption starts as a natural consequence of aging, women tend to have less bone mass compared to men.

Among 30 patients 16 patients were female, out of which 14 (96.6%) patients had already attained menopause which indicates that incidence of osteoporosis in post menopausal is more evident. Osteoblastic activity is stimulated and the inhibition of the osteoclastic activity is done by the Estrogens in females thereby maintaining the bone mass. There is a progressive decrease in the sex hormones after menopause either natural or surgical. This leads to decrease in the bone mass and hence causes osteoporosis.

PROBABLE MODE OF ACTION OF *KSHEERA BASTI*

In *Guduchi sidda Ksheera Basti*, the main ingredient *Guduchi* acts as the *Rasa*yana, *Tridosha shamaka*, and it possesses *Katu Tikta Rasa*, *Ushna Veerya* and *Madhura Vipaka* which helps in mitigating *Vata* by virtue of its qualities. *Ksheera* used in this study acts as *Dhatu Vardhana* and *Poshana* again by its *Gunas*.

The concept of *Ksheera paka* is selected because it is *Upakalpana* of *Kwatha* and this is used for *Basti* by which *Doshavaishamyata* is recovered and *Balavardhana* is achieved. The *Virya* of *Basti Dravya*, due to its *Anupravana Bhava* is transmitted all over the body by the *Apanadi Vata*s and thus has its systemic effect. According to Acharya Paraashara, *Guda Bhaga* is considered as the *Mula* of *Siras* (veins) and hence there will be increase in rate of absorption of *Oushadi Dravyas*. The morbid *Doshas* from all over the body will be drawn out from *Sarva Shareera* by the *Virya* (potency) of *Basti Dravya* and then expels out through *Guda Marga*.

The absorption of the *Basti Dravya* is higher in the lumen of the rectum and lowers in the cells surrounding the rectum. Hence the molecules of *Basti* move from the higher concentration to the lower concentration i.e., from the rectum to the surrounding cells and gets absorbed in to the rectal veins. The temperature of the *Basti Dravya* is lukewarm which brings about the vasodilatation and aids in the faster absorption. Since the *Basti Dravya* is in the lipoidal form due to the presence of *Ksheera* and *Ghritha*, they are absorbed across the mucous membrane of the rectum.

The main ingredients used in the *Ksheera Basti* is *Ksheera* which is rich in minerals like calcium, phosphorous, magnesium etc., and vitamins like A, D, K. These contents help in the bone formation. Apart from this the *Ghritha* contains the phospholipids which play an important role in the mineralization of the bones.

Ghritha is *Vata Pittashamaka*, *Balya*, *Agnivardhaka*, *Madhura*, *Soumya*, *Sheetavirya, Shulahara*, *Jwarahara*, *Vrishya* and *Vayasthapaka*. Thus it pacifies the *Vata*, improves the general condition of the body and to a certain extent acts as a rejuvenator of the body.

CONCLUSION

Osteoporosis results from bone loss due to age related changes in bone remodeling as well as extrinsic and intrinsic factors that exaggerate this process. *Tikta Dravya Siddha Ghritha Sadhita Ksheera Basti* is the treatment principle for *Asthi Vikaras*. *Guduchi Ksheera Basti* taken for this study is found effective and can be practiced safely without any complications unless patient is diagnosed properly and is fit for the procedure. Overall there is significant improvement in the subjective parameters when compared to the objective parameter like BMD. The procedure should be continued for longer duration since osteoporosis is the degenerative condition which cannot be reversed but can be prevented from the further degeneration. The probable mode of action of these drugs are anti inflammatory, immunomodulatory and anti arthritic

and all the drugs used in the present study have *Vedanasthapana*, *Sandhaniya*, *Rasa*yana, *Brimhana* and *Vatanulomana* properties which has helped to a maximum extent in the patients of osteoporosis in the present study.

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