



## A CLINICAL STUDY TO EVALUATE THE EFFECT OF ELEG FEM CAPSULES (ASTHISHRINKHALAADI YOGA) IN THE MANAGEMENT OF OSTEOPOROSIS

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**ABSTRACT** Osteoporosis is an alarming issue in the society today. It is continuously increasing its significance with increasing elderly population and is affecting both the sexes at different degrees. It is characterized by low bone mass with microarchitectural deterioration of bone leading to enhanced bone fragility, thus increasing the susceptibility to fracture. Taking into account the references available in various Ayurvedic classics it can be correlated to Asthikshaya. Asthikshaya occurs due to decrease in strength of Asthi Dhatu chiefly due to Kala, Swabhava and Vata Prakopa. International Osteoporosis Foundation estimated that the annual direct cost of treating osteoporotic fractures has increased grossly. In India the general population is not much aware about the hazardous complications of osteoporosis. The modern pharmacological treatment is long and beyond the financial reach of common people. Therefore the best way to deal with it is to prevent this as early as possible. To achieve this aim a clinical study was conducted to evaluate the effect of an Ayurvedic Formulation known as Eleg Fem capsules (Asthisrinkhalaadi Yoga) in osteoporotic patients. In the clinical trial 30 patients above the age of 40 years with low BMD T-Score were registered from OPD and IPD of Kayachikitsa department of Rajiv Gandhi Govt. Post Graduate Ayurvedic College and Hospital Paprola, Kangra. Out of 30 patients, 27 completed the trial and 3 patients were drop out. Criteria of assessment of patients was change in bone mineral density (BMD T-Score) and change in the score of Quality of Life Index Questionnaire for Osteoporosis (QUALEFFO-41). All the registered patients were given the formulation for 6 weeks. Improvement was observed with statistically significant results on mean BMD T-Score and moderately significant result on Quality of Life Index scoring. The study revealed that the Eleg Fem capsules (Asthisrinkhalaadi Yoga) is a safe and effective therapy in the Osteoporotic patients.

**KEYWORDS :** Eleg Fem capsules, Asthisrinkhalaadi yoga

### INTRODUCTION

*Asthikshaya* means decrease in *Asthi Dhatu*. The decline of all *Dhatus* occurs naturally in *Jarawastha* mainly due to *Kala* and *Swabhava* but when *Kshaya* occurs more than normal it leads to *Vyadhi*. *Vatadosha* predominance occurs with advancing age which further leads to *Asthi Dhatu Kshaya*. Similarly *Vata* which is lodged in *Asthi Dhatu* predominates in *Jarawastha* leading to its more *Kshaya* especially because of their unique relationship. *Asthikshaya* typically occurs after 60 to 70 years of age in both male and female. Females are more prone to Osteoporosis after the menopause. Female mostly land into *Asthi Saushirya* as they have *Alpa Bala* and *Alpa Samhanana* in their bones. *Asthi Kshaya* further leads to *Uttarottar Dhatu Kshaya* leading to *Majja Kshaya*.

Osteoporosis is characterized by decreased bone strength, is prevalent among post menopausal women but also occurs in men and women with underlying conditions or having major risk factors associated with bone demineralization. Its chief clinical manifestations are vertebral and hip fractures<sup>1</sup>. It is defined operationally as a bone density that falls 2.5 standard deviation below the mean also referred as T-Score of -2.5. Based on various data an estimated 25 million Indians are affected by this disease. Indians have low BMD as compared to the western Caucasians. This could be attributed to difference in skeletal size, however the high prevalence of Vitamin D deficiency is a major factor in low BMD and poor health of Indians. Considering the magnitude of the problem of Osteoporosis prevention is the only cost effective approach. The treatment advocated in the contemporary science like calcium supplementation, bisphosphonates, hormone replacement therapy, selective estrogen receptor modulators and anabolic steroids may lead to serious adverse effects. Estrogen replacement therapy is of maximal value in preventing Osteoporosis when it is begun at or within a few years after menopause and continued for at least 15 to 20 years. But because of the potential adverse effects of estrogen and because of the high cost of necessary surveillance while it is being administered it is important to identify those perimenopausal women who are at the greatest risk of future fracture<sup>2</sup>. Hence there is a need to find safe and effective measure to treat Osteopenia /Osteoporosis. Taking into consideration these aspects the present study was carried out to evaluate the effect of a herbal combination in its treatment.

*Ayurvedic* texts clearly mention *Samshodhana Chikitsa* in *Bahu Doshawastha* of the disease. *Panchkarma* is the definite treatment in disease of *Asthi* therefore *Basti* prepared with combination of *Ksheera Ghrita* having *Snigdha Guna* and *Dravyas* having *Tikta Rasa* are used in management of *Asthikshaya*<sup>3</sup>. Therefore combination of such *Dravyas* are given which have *Snigdha* and *Shosana Gunas* that produce *Kharatva* and *Vridhhi* in *Asthi Dhatu*. Secondly in *Samshamana chikitsa* the *dravyas* that possess the *Gunas* similar to *Asthi Dhatu* are used. According to texts in all *Vridhhi Janya Vikaras Langhana* is the line of management but this statement is contradictory in case *Vata Prakopak Vikaras* such as *Asthikshaya* thus in *Vata Vridhhi Janya Roga Bringhana* is done<sup>4</sup>. Therefore *dravyas* which possess *gunas* such as *Guru, Kathina, Khara, Sthira* and *Murtimad* are used that bring about *Bringhana* in *Asthi Dhatu*. Thus such drug that bring about *Bhringana* in *Asthi Dhatu* as Eleg fem capsules (*Asthisrinkhalaadi Yoga*) can be effective in treatment of Osteoporosis. Six weeks clinical trial has shown improvement in BMD T-Score of the patients and brought relief in symptoms mentioned in Quality of life index questionnaire score. Results show that Eleg fem capsules (*Asthisrinkhalaadi Yoga*) has beneficial effects on patients of Osteopenia/ Osteoporosis.

### AIMS AND OBJECTIVES

- To Evaluate the Effect of Eleg Fem capsules (*Asthisrinkhalaadi Yoga*) in the patients of Osteopenia/ Osteoporosis.
- To assess the effect of drug in improving the BMD T-Score in the patients of Osteopenia/ Osteoporosis.
- To assess the effect of drug in improving the symptoms mentioned in Quality of life index score questionnaire for Osteoporosis (QUALEFFO-41).
- To evaluate the safety of drug.

### MATERIAL AND METHODS

#### Source of Data

30 patients fulfilling the inclusion criteria were registered from OPD and IPD of Kayachikitsa department of Rajiv Gandhi Govt. Post Graduate Ayurvedic College and Hospital Paprola, Kangra, Himachal Pradesh during July 2015 to January 2016. Out of 30 patients there were 6 male and 24 female, 27 completed the trial and 3 patients were drop out as they did not come back for followup. The patients were enrolled on the basis of BMD T-Score. Patients below 40 years of age,

have chronic liver, renal and endocrine disease, lactating and pregnant women, have undergone chemotherapy and radiotherapy, have evidence of malignancy, taking drugs which affect bone metabolism like corticosteroids, bisphosphonates for more than three months were excluded.

#### Design of trial

Clinical trial was designed as single group trial of 30 patients. All the registered patients were advised to take 550 mg Eleg Fem capsules (*Asthishrinkhalaadi Yoga*) orally one in morning and one at bedtime with water for 6 weeks. There was a routine follow up after 15 days.

#### RESULT

Levels of BMD T-Score found in the patients after therapy was statistically significant at  $p < 0.05$  and effect of therapy on total score of QUALEFFO-41 was statistically moderately significant at  $p < 0.01$ .

#### Effect of therapy on objective criteria / BMD T-Score

BMD	Mean BT	Mean AT	Mean Daifference	S.D.	S.E.	T value	P value
t score	-2.004	-1.833	0.159	0.377	0.072	2.208	<0.05

#### Effect of therapy on subjective criteria/ Quality of life index score questionnaire for Osteoporosis (QUALEFFO-41)

(A)

DOMAINS	Mean BT	Mean AT	Mean Difference	% of relief	SD	SE	T value	P value
Pain	15.25	12.81	2.44	16.01 %	1.76	0.33	7.29	<0.01
Activity of daily living	12.85	11.37	1.44	11.2 %	1.45	0.27	5.17	<0.01
Jobs around the house	15.14	13.29	1.85	12.21 %	1.72	0.33	5.57	<0.01
Mobility	21.74	19.92	2.18	10.05 %	2.63	0.50	4.31	<0.01
Leisure social activity	16.74	15.44	1.29	7.74 %	1.68	0.32	4.00	<0.01
General Health perception	12.00	10.14	1.92	15.94 %	0.99	0.19	10.02	<0.01
Mental function	26.92	27.20	0.33	1.22 %	1.49	0.28	1.16	>0.05
Total Score	120.88	108.77	12.25	10.13 %	6.19	1.19	10.25	<0.01

(B)

Overall improvement in pain	16.01%
Overall improvement in activity of daily living	11.2%
Overall improvement in jobs around house	12.21%
Overall improvement in mobility	10.05%
Overall improvement in leisure and social activities	7.74%
Overall improvement in general health perception	15.94%
Overall improvement in mental function	1.22%
Overall improvement in QUALEFFO-41	10.13%

#### DISCUSSION

*Cissus quadrangularis* contains high amount of Carotene A, anabolic steroidal substances and calcium. The phytogetic anabolic steroid may be the main constituent which helps in fracture healing<sup>5</sup>. *Asthishrinkhala* is *Sthambhaka* and *Sandhaniya* therefore helps in fracture healing<sup>6</sup>. Ethanolic extract of *Terminalia arjuna* containing tannins, saponins and tripenoid contents may have definite action on bone regeneration, calcium and alkaline phosphatase metabolism thus playing important role in osteoblastic activity<sup>7</sup>. In treatment of fractures and Osteoporosis decoction of *Arjuna* bark with milk and *Ghrita* is used<sup>8</sup>. *Dioscorea bulbifera* has active principle *Diosgenin* which may have pharmacological action similar to DHEA and estrogen<sup>9</sup>. The roots of *Asparagus racemosus* are rich in phytoestrogens, a group of natural compounds that have structure similar to estrogen<sup>10</sup>. Estrogen helps to prevent Osteoporosis in women especially in perimenopausal period. The ligans and flavanoids present in bark of *Saraca asoca* contain phytoestrogen which act on estrogenic receptor and may produce pharmacological response similar to estrogen. This stimulates the osteoblast activity and decreases the osteoclast activity<sup>11</sup>. *Vanshlochan* contains more Silicon dioxide as compared to other silica plant sources. Organic silica may provide

collagen and assists in healing of bones<sup>12</sup>.

#### CONCLUSION

Constituents of the trial drug chiefly have *Vata Shamaka*, *Srotoshodaka*, *Brighanan karaka*, *Balya* and *Rasayana* properties therefore have beneficial role in the treatment of *Asthikshaya*. The ingredients also play a significant role in improving the bone mineral density by providing the trigger factors which are necessary for bone formation. Thus Eleg Fem Capsules (*Asthishrinkhalaadi Yoga*) is effective in the management of Osteoporosis. No adverse effect of therapy was noted during the trial and in the follow up period.

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