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RESEARCH ARTICLE

Clinical Safety of Selected Ayurvedic Formulations in Osteopenia/Osteoporosis

¹Sunita, ²Shruti Khanduri, ³Pradeep Dua, ⁴Babita Yadav, ⁵Manohar Gundeti, ⁶Kishore Kumar, ⁷Anil Mangal, ⁸Govind Reddy, ⁹Sanjay K Giri, ¹⁰Vinod K Lavaniya, ¹¹V Rakesh Narayanan, ¹²Rakesh K Rana, ¹³Richa Singhal, ¹⁴Bharati, ¹⁵Madan M Padhi

ABSTRACT

Introduction: Osteopenia/osteoporosis is a condition characterized by decrease in bone mineral density. It is a major public health problem especially for women in India. The clinical picture of osteopenia/osteoporosis is similar to the condition of *Asthidhatukshaya* described in Ayurveda which is characterized by the loss of *saarata* of *Asthi dhatu* leading to increased predisposition to other bone-related pathologies. *Laksha Guggulu*, *Mukta-Shukti Pishti*, *Ashwagandha Churna*, and *Pravala Pishti* are some of the most common medicines used in the management of osteopenia/osteoporosis. However, safety data are not collected on these formulations.

Objective: To critically analyze and present clinical safety of classical Ayurvedic formulations, viz., *Laksha Guggulu*, *Mukta-Shukti Pishti*, *Ashwagandha Churna*, and *Pravala Pishti* in osteopenia/osteoporosis, through multicenter open-label studies at different Central Council for Research in Ayurvedic Sciences (CCRAS) centers.

Materials and methods: Data were collected from two different clinical studies executed in peripheral institutes of CCRAS and critically analyzed to assess the safety of four formulations: *Laksha Guggulu*, *Mukta-Shukti Pishti*, *Ashwagandha Churna*, and *Pravala Pishti* in osteopenia/osteoporosis. Safety assessments were done through liver function tests [LFTs; serum glutamate pyruvate transaminase (SGPT), serum glutamate oxaloacetic transaminase (SGOT), alkaline phosphatase (ALP), serum protein, albumin, globulin, and bilirubin] and kidney function tests (KFTs; serum urea and serum creatinine) before and after the trial period. Drug compliance and adverse drug reaction/adverse events, if any, were noted.

Conclusion: The finding in the two clinical studies indicated that *Laksha Guggulu*, *Mukta-Shukti Pishti*, *Ashwagandha Churna*, and *Pravala Pishti* are clinically safe, effective, and tolerable as participants belonging to different age groups, gender, geographical areas, and having different *prakriti* responded well to the trial medications without any adverse reactions or adverse events.

Keywords: *Ashwagandha Churna*, *Laksha Guggulu*, *Mukta-Shukti Pishti*, Osteopenia, Osteoporosis, Pharmacoepidemiology, *Pravala Pishti*, Safety.

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INTRODUCTION

Osteopenia/osteoporosis is a condition characterized by decrease in bone mineral density. According to the estimates, out of the 230 million Indians expected to be over the age of 50 years in 2015, 20%, i.e., almost 46 million, are women with osteoporosis. Thus, osteoporosis is a major public health problem especially for women in India.¹ It is also one of the major risk factors for fractures, especially among elderly women. Osteoporosis is a silent disease until it is complicated by fractures that occur following minimal trauma or, in some cases, with no trauma.² Dietary changes, supplementation of Vitamin D and calcium, use of antiresorptive agents, and hormonal therapies along with exercise, regular monitoring of bone mineral density, and assessment of biomarkers related to bone tumor are advised in the management of this condition.

The clinical picture of osteopenia/osteoporosis is similar to the condition of *Asthidhatukshaya* described in Ayurveda, which is characterized by the gradual loss of quality (*Saarata*) of *Asthi dhatu* leading to increased predisposition to other bone-related pathologies. It happens due to the *prakopa* of *Vata* that occurs in *Asthi*. *Prithvi*, *Ap*, and *Vayu mahabhutas* contribute to the formation and function of *asthi dhatu*. When qualities of *asthi dhatu* such as *guru*, *kathina*, *sthira*, etc. gets reduced due to vitiation

^{1-7,9-11}Research Officer (Ayurveda), ^{8,14}Assistant Director (Ayurveda), ¹²Statistical Officer (Ayurveda), ¹³Statistical Assistant (Ayurveda), ¹⁵Former Deputy Director General (Ayurveda)

^{1-4,7,10-13,15}Central Council for Research in Ayurvedic Sciences New Delhi, India

^{5,8}Raja Ramdeo Anandilal Podar Central Ayurveda Research Institute for Cancer, Mumbai, Maharashtra, India

^{6,9}Regional Ayurveda Research Institute for Metabolic Disorders Bengaluru, Karnataka, India

¹⁴Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi, India

Corresponding Author: Sunita, Research Officer (Ayurveda) Central Council for Research in Ayurvedic Sciences, New Delhi India, Phone: +918010529320, e-mail: sunita.dr@rediffmail.com

of *Vata*, *asthi soushirya* occurs resulting in the inability of *asthi dhatu* to perform its normal function of *deha dharana*. Complex treatment approaches including medication, purification techniques including *Panchakarma*, diet and lifestyle advices, etc., are useful in the management of this condition. *Laksha Guggulu*, *Mukta-Shukti Pishti*, *Ashwagandha Churna*, and *Pravala Pishti* are few among the multitudes of medicines that are currently prevalent in use for the management of osteopenia/osteoporosis.

OBJECTIVE

The objective of this study was to critically analyze and present clinical safety outcomes of classical Ayurvedic formulations, viz., *Laksha Guggulu*, *Mukta-Shukti Pishti*, *Ashwagandha Churna*, and *Pravala Pishti* in osteopenia/osteoporosis, through multicenter open-label studies at different CCRAS centers.

MATERIALS AND METHODS

Open-label multicenter clinical trials were done in selected peripheral institutes of CCRAS to evaluate the safety and efficacy of *Laksha Guggulu*, *Mukta-Shukti Pishti*, *Ashwagandha Churna*, and *Pravala Pishti* in osteopenia/osteoporosis, and the details are briefed in Table 1. Follow-up was done every 2 weeks to record the onset of any adverse reaction during the intervention.

The formulations fulfilling the physicochemical standards and quality parameters, and prepared as per standard operating procedures, were procured from good manufacturing practices-certified companies for all the studies. These two different clinical studies were approved by institutional ethics committee of all the participating centers and done in accordance with World Health Organization Good Clinical Practice guidelines. The data obtained from the completed clinical studies were analyzed retrospectively to assess the safety profile of the drugs through assessment of LFTs and KFTs. The data thus generated were analyzed to evaluate the safety of these formulations in the case of osteopenia/osteoporosis.

Statistical Analysis

Laboratory parameters at the beginning and at the end of the trial period were compared using paired t-test. A p-value <0.05 was considered significant. All statistical analyses were performed using Statistical Package for the Social Sciences, version 15.0.

DRUG PROFILE

The ingredients of the formulations used in the two clinical trials are described in Tables 2 to 5.

OBSERVATION AND RESULTS

Study I: Clinical Evaluation of *Laksha Guggulu* and *Mukta-Shukti Pishti* in the Management of Osteopenia/Osteoporosis

Among the total 88 patients who completed the trial, most of the patients, i.e., 71 (80.7%), were females and remaining 17 (19.3%) were males. Majority of the patients, 68 (77.3%), were literate and only 8 (9.1%) hailed from lower socioeconomic stratum. Maximum numbers of patients, i.e., 53 (60.2%), were housewives. Eighty-five (96.6%) were from urban population, and maximum number of patients, i.e., 41 (46.6%), followed a sedentary life. Maximum number of patients were of *Pitta-kapha* (66, 75%), followed by *Vata-pitta prakriti* (19, 21.6%). *Asthisula* was the major symptom present in 85 (96.5%) patients mostly along the dorsolumbar region (in 65.9% cases) of intermittent (51.1%) or continuous nature (45.5%). The symptom *kesa loma pata* was observed in 58 (65.9%) cases, and feeling of comfort with hot fomentation and local massage was observed in 68 (77.3%) cases. Serum bilirubin, SGPT, SGOT, serum ALP, serum protein, albumin, globulin, blood urea, and serum creatinine were within normal limits during the entire period. The values were compared with paired t-test after the trial and were found to be within the normal range. No significant adverse events could be identified due to drug during the study.

Study II: Clinical Evaluation of *Ashwagandha Churna* and *Pravala Pishti* in the Management of Osteopenia/Osteoporosis

Among the total 90 patients who completed the trial, 67 (74.4%) of the patients were females and remaining 23 (25.6%) were males. Majority of the patients (85, 94.4%) were literate and 20 (22.2%) were from lower socioeconomic stratum. Maximum numbers of patients (58, 64.4%) were housewives. Eighty-seven (96.7%) were urban from population. About 44 (48.9%) did moderate exercises, whereas 38 (42.2%) followed a sedentary life. Maximum number of patients were of *Vata-pitta* (38, 42.2%) followed by *Pitta-kapha prakriti* (35, 38.9%). *Asthitoda* was found to be the major symptom which was found in 87 (96.7%) followed by *Shrama* 79 (87.8%) and *Sandhishaitilya* 46 (51.1%). Serum bilirubin, SGPT, SGOT, serum ALP, serum protein, albumin, globulin, blood urea, and serum creatinine were within normal limits during the entire period, and the values were compared with paired t-test after the trial. The values were found to be within the normal range. No significant adverse events could be identified due to drug during the study.

The data regarding demographic profile, efficacy of safety obtained from both the studies are given in Tables 6 and 7 and Graphs 1 to 4.

Table 1: Brief description of studies conducted in the management of osteopenia/osteoporosis

Name of study	Study period	Study design	Number of centers	Name of the center/ centers	Sample size	Study intervention	Dosage schedule	Duration
Clinical Evaluation of <i>Laksha Guggulu</i> and <i>Mukta-Shukti Pishti</i> in the Management of Osteopenia/Osteoporosis (CTRI/2012/03/002533)	18 months	Open clinical trial	2	1 Regional Ayurveda Research Institute for Drug Development, Gwalior 2 Raja Ramdeo Anandilal Podar (RRAP) Central Ayurveda Research Institute for Cancer, Mumbai	88	<i>Laksha Guggulu</i> <i>Mukta-Shukti Pishti</i>	<i>Laksha Guggulu</i> Dose: 1 gm twice daily Dosage form: 500 mg tablet Route of administration: oral Time of administration: twice a day after food Anupana: lukewarm water <i>Mukta-Shukti Pishti</i> Dose: 250 mg twice daily Dosage form: 250 mg capsule Route of administration: oral Time of administration: twice a day after food Anupana: lukewarm water	12 weeks
Clinical Evaluation of <i>Ashwagandha Churna</i> and <i>Pravala Pishti</i> in the Management of Osteopenia/Osteoporosis (CTRI/2015/01/005406)	12 months	Open-label prospective multicenter study	2	1 Regional Ayurveda Research Institute for Metabolic Disorders, Bengaluru 2 RRAP Central Ayurveda Research Institute for Cancer, Mumbai	90	<i>Ashwagandha Churna</i> <i>Pravala Pishti</i>	<i>Ashwagandha Churna</i> Dose: 3 gm twice daily Dosage form: powder Route of administration: oral Time of administration: twice a day after food Anupana: lukewarm water <i>Pravala Pishti</i> Dose: 250 mg twice daily Dosage form: capsule of 250 mg Route of administration: oral Time of administration: twice a day after food Anupana: lukewarm water	12 weeks

Table 2: Ingredients of *Laksha Guggulu*³

Sanskrit name	Latin name	Part used
<i>Laksha Guggulu</i>		
<i>Laksha</i>	<i>Laccifer lacca</i>	Gall
<i>Asthisamhrt</i>	<i>Cissis quadrangularis</i>	Stem
<i>Kakubha (Arjuna)</i>	<i>Terminalia arjuna</i>	Stem bark
<i>Asvagandha</i>	<i>Withania somnifera</i>	Root
<i>Nagabala</i>	<i>Sida veronicaefolia</i>	Root
<i>Pura (Guggulu)—suddha</i>	<i>Commiphora wightii</i>	Oleo resin

Table 3: Ingredients of *Mukta-Shukti Pishti*⁴

Sanskrit name	Latin name	Part used
<i>Mukta-Shukti Pishti</i>		
<i>Mukta—suddha</i>	Purified pearl	
<i>Gulab arka (Satapatrika)</i>	<i>Rosa damascena</i>	Flower

Table 4: *Ashwagandha Churna*

Sanskrit name	Latin name	Part used
<i>Ashwagandha Churna</i>		
<i>Ashwagandha</i>	<i>Withania somnifera</i>	Root powder

Table 5: Ingredients of *Pravala Pishti*⁵

Sanskrit name	Latin name	Part used
<i>Pravala Pishti</i>		
<i>Pravala—suddha</i>	Purified coral	
<i>Gulab arka (Satapatrika)</i>	<i>Rosa damascena</i>	Flower

Table 6: Demographic profile of the patients in two clinical trials

	<i>Laksha Guggulu and Mukta-Shukti Pishti (n = 88)</i>	<i>Ashwagandha Churna and Pravala Pishti (n = 90)</i>
Demographic profile		
Sex		
Male	17 (19.3%)	23 (25.6%)
Female	71 (80.7%)	67 (74.4%)
Education		
Unable to read and write	20 (22.7%)	5 (5.6%)
Literate	68 (77.3%)	85 (94.4%)
Socioeconomic status		
Below poverty line	8 (9.1%)	20 (22.2%)
Above poverty line	80 (90.9%)	70 (77.8%)
Diet		
Vegetarian	41 (46.6%)	31 (34.4%)
Nonvegetarian	47 (53.4%)	59 (65.6%)
Prakriti		
<i>Vataja</i>	—	7 (7.8%)
<i>Pittaja</i>	—	6 (6.7%)
<i>Kaphaja</i>	—	—
<i>Vata-Pittaja</i>	19 (21.6)	38 (42.2%)
<i>Pitta-Kaphaja</i>	66 (75%)	35 (38.9%)
<i>Vata-Kaphaja</i>	3 (3.4%)	4 (4.4%)
Patients completing the trial from different geographical locations		
Madhya Pradesh (Gwalior)	58 (65.9%)	—
Maharashtra (Mumbai)	30 (34.1%)	45 (50.0%)
Karnataka (Bengaluru)	—	45 (50.0%)

Values are expressed as n (%)

Table 7: Safety profile of the patients in two clinical trials

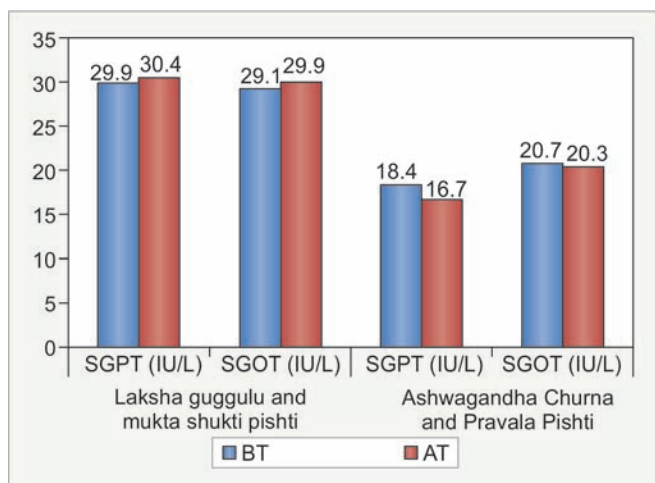
Parameters	<i>Laksha Guggulu and Mukta-Shukti Pishti (n = 88)</i>			<i>Ashwagandha Churna and Pravala Pishti (n = 90)</i>		
	BT	AT	p-value	BT	AT	p-value
Liver function test						
Serum bilirubin (conjugated) (mg/dL)	0.29 (0.191)	0.26 (0.159)	<0.05	0.15 (0.065)	0.16 (0.090)	>0.05
Serum bilirubin (unconjugated) (mg/dL)	0.48 (0.192)	0.45 (0.158)	<0.05	0.39 (0.207)	0.40 (0.252)	>0.05
SGPT (IU/L)	29.90 (15.546)	30.46 (19.555)	>0.05	18.41 (9.290)	16.73 (8.014)	<0.05
SGOT (IU/L)	28.15 (9.415)	29.13 (13.100)	>0.05	20.74 (7.054)	20.30 (6.612)	>0.05
Serum ALP (IU/L)	80.59 (19.138)	81.17 (21.017)	>0.05	73.08 (20.464)	73.23 (19.483)	>0.05
Total protein (gm/dL)	6.74 (0.537)	6.79 (0.541)	>0.05	7.00 (0.388)	6.96 (0.429)	>0.05
Albumin (gm/dL)	4.13 (0.264)	4.11 (0.329)	>0.05	4.28 (0.220)	4.24 (0.197)	>0.05
Globulin (gm/dL)	2.63 (0.375)	2.69 (0.406)	>0.05	2.72 (0.381)	2.71 (0.398)	>0.05
Kidney function test						
Blood urea (mg/dL)	22.02 (6.602)	22.02 (5.578)	>0.05	19.58 (5.144)	19.31 (4.924)	>0.05
Serum creatinine (mg/dL)	0.88 (0.167)	0.82 (0.116)	<0.01	0.79 (0.179)	0.78 (0.183)	>0.05
Uric acid (mg/dL)	4.52 (1.092)	4.59 (1.135)	>0.05	4.73 (1.258)	4.74 (1.323)	>0.05

Values are reported as mean (standard deviation), compared using paired t-test, p-value <0.05 has been considered as significant; BT: Before test; AT: After test

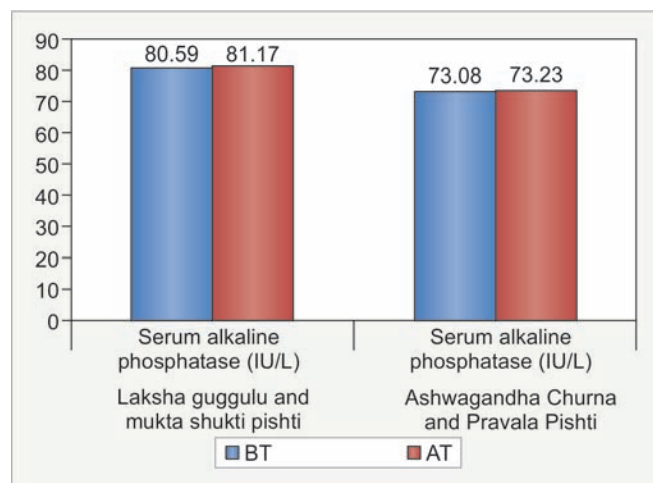
DISCUSSION

Osteopenia/osteoporosis is a growing health challenge especially in elderly women population. Vitiating of *Vatadosha* is an important feature of old age, and *Vatadosha* has an inverse relationship with *Asthidhatu* itself. Therefore, *Vataprakopa* and diseases related to *Asthi* are

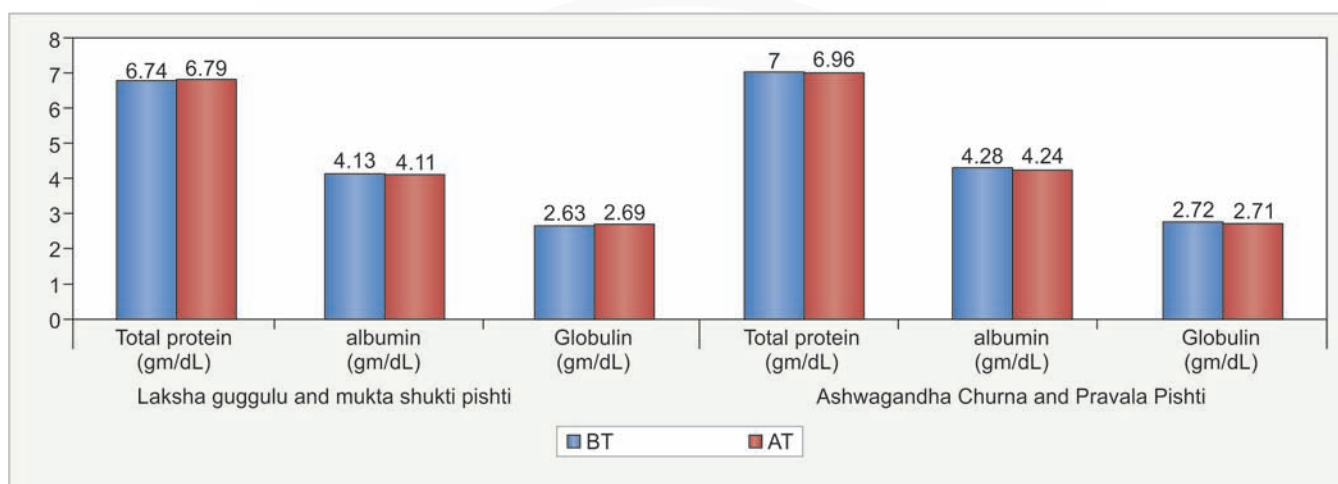
very common in old age. Even though it is not easy to reverse these conditions, various preventive measures are available to reduce the speed of degeneration. The formulations like *Mukta-Shukti* and *Pravala Pishti* have *Prabhava* on *Asthi*, as they are rich source of calcium which helps in nourishing the osteoporotic bone tissue. *Laksha*



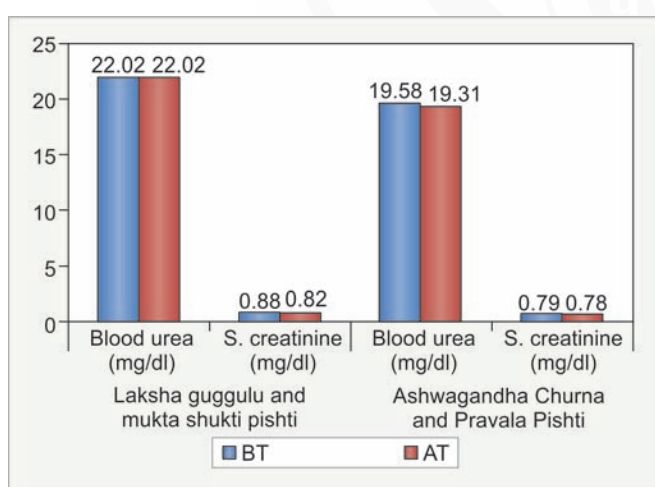
Graph 1: Comparison of LFTs (SGOT and SGPT) before and after the trials



Graph 2: Comparison of LFTs (serum ALP) before and after the trials



Graph 3: Comparison of LFTs (total protein, globulin, and albumin) before and after trials



Graph 4: Comparison of KFTs (blood urea and serum creatinine) before and after the trials

Guggulu has components which have *Madhura* and *Tikta rasa* which act by qualitative improvement of *Asthisara*. It has ingredients, such as *Laksha* and *Asthisamhrt* which are

having *Sandhaniya* properties and also *Nagabala* which is a *Rasayana*. Earlier studies have evaluated *Laksha Guggulu* for anti-arthritis and chondroprotective properties.⁶ The pharmacological activity of *Ashwagandha* has been attributed to two main withanolides: withanolide A and withanolide. It has anti-stress and rejuvenating properties.⁷ These drugs combined may act as *Dhatuposhaka* and *Asthisandhanakara*. Medical systems like Ayurveda have taken up the challenge to develop safe and effective remedies for their management.

Both the interventions were found to be safe, and at the end of 84 days of intervention, no clinically significant changes were observed regarding various hematological parameters or in LFT or KFT. However, the analysis of the study results showed statistically highly significant reduction in the serum creatinine value in *Laksha Guggulu* and *Mukta-Shukti Pishti* group and significant reduction in SGPT value in *Ashwagandha* and *Pravala Pishti* group. Wherever statistically signifi-

cant changes were observed regarding these parameters, the values were found to be within the clinically normal range. No adverse events or adverse reactions were noted during the trial period.

CONCLUSION

Evaluation of safety and efficacy of *Laksha Guggulu*, *Mukta-Shukti Pishti*, *Ashwagandha Churna*, and *Pravala Pishti* was done through studies conducted at peripheral institutes of CCRAS spread throughout various biogeographical areas of India. The analysis of outcome of these scientifically planned studies demonstrates that in spite of the differences in gender, socioeconomic status, age group, *Prakrati*, and geographic region, *Laksha Guggulu*, *Mukta-Shukti Pishti*, *Ashwagandha Churna*, and *Pravala Pishti* proved to be safe in the management of osteopenia/osteoporosis. No adverse reactions were noticed during the trial period.

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हिंदी सारांश

ओस्टियोपीनिया/ओस्टियोपोरोसिस रोग में चयनित आयुर्वेदिक योगों की चिकित्सकीय सुरक्षा

¹सुनीता, ²श्रुति खंडूड़ी, ³प्रदीप दुआ, ⁴बबीता यादव, ⁵मनोहर गुण्डेटी, ⁶किशोर कुमार
⁷अनिल मंगल, ⁸गोविन्द रेड्डी, ⁹संजय के. गिरी, ¹⁰विनोद के लवानिया, ¹¹वी. राकेश नारायणन
¹²राकेश के. राणा, ¹³रिचा सिंघल, ¹⁴भारती, ¹⁵मदन एम पाढी

परिचय: ओस्टियोपीनिया/ओस्टियोपोरोसिस बोन मिनरल डेनसिटी की कमी से उत्पन्न होने वाली एक अस्थि सम्बन्धी व्याधि है जो आज के परिपेक्ष्य में, विशेषकर महिलाओं की एक प्रमुख व्याधि के रूप में उभर के आ रहा है। ओस्टियोपीनिया/ओस्टियोपोरोसिस रोग के लक्षणों की तुलना आयुर्वेद में वर्णित 'अस्थि धातु क्षय' की अवस्था से की जा सकती है। लाक्षा गुग्गुलु, मुक्ता-शुक्ति पिष्टी, अश्वगंधा चूर्ण एवं प्रवाल पिष्टी सामान्य रूप से इस रोग की चिकित्सा में प्रयुक्त होने वाले प्रमुख औषधियां हैं। हालांकि अब तक इन औषध योगों पर चिकित्सकीय सुरक्षा जानकारी उपलब्ध नहीं है।

उद्देश्य: शास्त्रीय आयुर्वेदीय योगों यथा लाक्षा गुग्गुलु, मुक्ता-शुक्ति पिष्टी, अश्वगंधा चूर्ण एवं प्रवाल पिष्टी का ओस्टियोपीनिया/ओस्टियोपोरोसिस के रोगियों में चिकित्सकीय सुरक्षात्मक एवं प्रभावकारिता परिणामों का विश्लेषण सीसीआरएस के विभिन्न परिधीय केंद्रों पर किये गए बहुकेंद्रीय, खुले स्तरीय अध्ययनों के आकड़ों के आकलन से करना।

सामग्री व विधि: ओस्टियोपीनिया/ओस्टियोपोरोसिस रोग प्रबंधन की चार औषधियों यथा लाक्षा गुग्गुलु, मुक्ता-शुक्ति पिष्टी, अश्वगंधा चूर्ण एवं प्रवाल पिष्टी का विशिष्ट रूप से सुरक्षात्मक प्रोफाइल जांच करने के लिए सीसीआरएस के विभिन्न परिधीय संस्थानों में पूर्ण किये गये दो विभिन्न चिकित्सकीय अध्ययनों से एकत्रित किये गये आंकड़ों के पूर्वव्यापी विश्लेषण से यह अध्ययन किया गया है। यह सुरक्षात्मक आंकलन यकृत कार्य परीक्षण (एल. एफ. टी) यथा एस. जी. पी. टी., एस. जी. ओ. टी., एल्कलीन फास्फोटेज, सीरम प्रोटीन, एल्ब्यूमिन, ग्लोब्यूलिन, बिलिरुबिन एवं वृक्क कार्य परीक्षण (के.एफ.टी.) यथा सीरम यूरिया व सीरम क्रिएटिनिन के परीक्षण अवधि से पूर्व व पश्चात किये गये आंकड़ों से किया गया है। अध्ययन प्रारम्भ दिन से अध्ययन अवधि पूर्ण होने पर औसत परिवर्तन में तुलना करने के लिये युग्मित टी-परीक्षण प्रयुक्त किया गया। इस अध्ययन से यह ज्ञात हुआ कि सभी मापदंड पूरी अध्ययन अवधि के दौरान निर्दिष्ट सीमाओं के भीतर थे। <0.05 का पी-मान महत्वपूर्ण माना जाता है। औषध अनुपालना, प्रतिकूल औषध प्रतिक्रिया या प्रतिकूल घटनायें सम्बन्धी आकड़ें लिपिबद्ध किये गए।

निष्कर्ष: दो विभिन्न नैदानिक/चिकित्सकीय अध्ययनों का निष्कर्ष स्पष्ट रूप से इंगित करता है कि लाक्षा गुग्गुलु, मुक्ता-शुक्ति, अश्वगंधा चूर्ण एवं प्रवाल पिष्टी चिकित्सकीय रूप से सुरक्षित, प्रभावी तथा सहनीय है। विभिन्न आयु समूहों, लिंग, भौगोलिक क्षेत्र व प्रकृति से जुड़े प्रतिभागियों में किये गए नियोजित अनुसंधान अध्ययनों के परिणामों के माध्यम से समझा जा सकता है कि परीक्षण औषध ने समान रूप से सभी में अच्छा परिणाम दिया।