Research Protocol

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Ayurveda Section

Structural Vertebral Changes in Osteoporotic Women and Their Associations with *Prakriti* (constitution), *Agni* (digestive fire) and *Koshtha* (nature of bowels): A Research Protocol

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ABSTRACT

Introduction: The vertebral column is essential for supporting an upright posture. However, factors such as a sedentary lifestyle or other changes can alter its natural curvature, leading to issues like back pain, stiffness, and difficulty with movement. To prevent these symptoms, it is important to take an individual's *Prakriti* (constitution) into consideration.

Need of the study: Osteoporosis, marked by reduced bone density and weakened bone microarchitecture, significantly raises fracture risk. Using X-ray imaging and Ayurvedic questionnaires, research explores how individual constitutional traits may influence spinal degeneration. The findings aim to support personalised approaches to osteoporosis management based on Ayurvedic principles.

Aim: This study aims to evaluate the structural vertebral column changes in osteoporotic females based on *Prakriti* (constitution), *Agni* (digestive fire) and *Koshtha* (nature of bowels).

Materials and Methods: A cross-sectional study will be conducted from Jan 2025 to Dec 2025 at MGACH & RC and AVBRH, located in Sawangi (Meghe), Wardha. A total of 152 subjects will be included in the study. The study will include female participants who have been clinically diagnosed with osteoporosis. X-ray {Anterioroposterior (AP) & lateral view}, range of movement, *Naditarangini* for *Prakriti* (constitution) analysis and subjective parameter: *Sambhata*, Lower back pain (stiffness) will be assessed. Baseline characteristics will be summarised using descriptive statistics. Comparisons between groups will be made using the independent t-test or One-way ANOVA for normally distributed data, and Mann-Whitney U or Kruskal-Wallis tests for non-parametric data. The Chi-square test (or Fisher's exact test, when applicable) will be used to assess the association between *Prakriti*, Agni, *Koshtha* and structural changes in the vertebral column. Post-hoc analysis will be performed using Tukey's test or Benjamini-Hochberg correction. All tests will be two-tailed, with a p-value <0.05 considered statistically significant.

Keywords: Osteoporosis, Posture, Sedentary lifestyle

INTRODUCTION

Osteoporosis, a common skeletal disorder marked by a decline in bone density, presents a major global health challenge [1]. While conventional research primarily examines factors like genetics, hormones, and lifestyle, this study explores a new dimension by incorporating principles from Ayurveda, the ancient Indian system of medicine. Ayurveda categorises individuals into three distinct constitutions, or Doshas-Vata, *Pitta*, and *Kapha*, each reflecting a unique combination of physiological and psychological characteristics [2]. Osteoporosis involves a decline in Bone Mineral Density (BMD) along with structural weakening at the microscopic level, which significantly elevates the risk of fractures. The overall strength of bones is influenced by various elements, such as BMD, the rate of bone remodelling, bone size and surface area, the preservation of microarchitecture, and the degree of mineral content within the bone tissue [3]. In India, osteoporosis is highly prevalent, with an estimated 30 million women diagnosed with osteoporosis [4]. According to the World Health Organisation, a person is diagnosed with osteoporosis when their Bone Mineral Density (BMD) is 2.5 standard deviations below the mean value typical of healthy young adult women [5]. In Ayurveda, *Ayu* is defined as a balanced state of *Sharir* (body), *Indriya* (sense organs), *Satva/Manas* (mind), and *Atma* (soul) [6]. According to Ayurvedic principles, disease manifests when there is an imbalance or disequilibrium in any of these components. This ancient system offers a holistic understanding of health and longevity, exploring the effects of various lifestyles, the sources of joy and suffering, and the principles needed to maintain physical and mental balance [7]. In Ayurvedic terminology, *Kati* (lumbar region) refers to the waist, while *Kasheruka* (vertebrae) corresponds to *Merudanda (spinal column)*, the spinal column [8]. These anatomical concepts emphasize the importance of spinal health in maintaining overall well-being [9]. *Ayurveda* attributes bone health to the efficient functioning of *Agni* (digestive fire) and the proper transformation of *Dhatus* (tissues). Impaired *Agni*, or *Mandagni*, disrupts nutrient metabolism, leading to poor assimilation and defective formation of *Asthi Dhatu* (bone tissue) [10]. Classical Ayurvedic texts, including the *Charaka Samhita* and *Ashtanga Hridaya*, describe the progressive impact of chronic Vata imbalance on bone integrity, leading to *Asthi Kshaya* (bone tissue depletion). This ancient observation aligns with the clinical picture of osteoporosis in modern biomedicine [11]. Additionally, *Koshtha, which* represents the nature of the gastrointestinal tract- affects nutrient absorption. Individuals with a *Vata*-type *Koshtha* often exhibit irregular digestion and elimination patterns, potentially leading to suboptimal calcium absorption and poor bone nutrition [12].

REVIEW OF LITERATURE

Ayurvedic literature conceptualises health as the harmonious interaction of structural and functional elements of the body, wherein constitutional attributes such as Prakriti and *Koshtha* modulate the activity of *Agni*, the central metabolic force. Chouragade NB et al.,

correlated the status of *Agni* with *Koshtha*, Prakriti, and *Sama-Nirama Mala Parikshan,* suggesting that metabolic responsiveness and physiological functioning differ among individuals, thereby influencing disease susceptibility. This study concluded that *Krura Koshtha*, *Vata*-dominant Prakriti, and *Nirama Mala* were present in the greatest number of *Vishamagni* participants. Participants with *Mandagni* had *Sama Mala*, *Kapha*-dominant Prakriti, and *Madhyam Koshtha*. Participants with *Tikshanagni* had *Pitta*-dominant Prakriti, *Sama Mala*, and *Mrudu Koshtha*. With *Pitta*-dominant Prakriti, *Nirama Mala*, and *Madhyam Koshtha*, *Samagni* participation was extremely uncommon [12]. When considered alongside biomedical models, these findings imply that inherent metabolic characteristics may interact with structural features, including vertebral morphology, to shape overall health outcomes. In modern musculoskeletal research, vertebral morphology assessment has been pivotal for characterising osteoporotic changes. Genant HK et al., introduced a semiquantitative system that standardised the identification of vertebral deformities, improving consistency in recognising wedge, biconcave, and crush patterns. The study concluded that a semiquantitative approach can be applied reliably in vertebral fracture assessment when performed using well-defined criteria [13]. Recent scientific evidence has begun to link the Ayurvedic concepts of *tridosha* and *prakriti* with modern biology, including metabolic pathways, chronic diseases, and genetic variations [14]. Expanding this understanding, Bouxsein ML highlighted that bone fragility is determined by structural geometry, microarchitecture, and material composition in addition to density, underscoring the multifactorial nature of vertebral strength [15]. Every individual can be categorised into various combinations of *vata*, *pitta*, and *kapha prakriti* depending upon the predominance of each dosha. It is independent of race, ethnicity, language, and geography, which will be specific for each individual. The susceptibility to different diseases depends upon the type of *prakriti* constitution in an individual [11]. Both constitutional factors and structural vertebral characteristics are integral to evaluating musculoskeletal integrity and vulnerability to degenerative or osteoporotic changes. These findings suggest that *prakriti* may represent distinct phenotypes associated with certain genotypes, highlighting the universality of Ayurvedic principles. One important implication is the potential for newborns to be screened for their *prakriti* through genetic testing. Such early identification could allow preventive strategies, dietary, lifestyle, and behavioural modifications to be implemented from childhood, reducing the risk of chronic diseases and promoting healthier, more productive lives. This approach represents a step beyond personalised medicine, offering the possibility of personalised preventive health, a novel concept with significant long-term impact that is not currently available in Western medical systems. Therefore, this study aims to evaluate the structural Vertebral column changes in osteoporotic females based on *Prakriti* (constitution), *Agni* (digestive fire) and *Koshtha* (nature of bowels)

Primary objectives: To evaluate the anatomical and structural changes in the vertebral column among osteoporotic female patients with their respective *Prakriti* (constitution), *Agni* (digestive fire), and *Koshtha* (nature of bowels) types.

Secondary objectives: To evaluate the association the structural Vertebral column changes in osteoporotic females based on *Prakriti* (constitution), *Agni* (digestive fire) and *Koshtha* (nature of bowels).

MATERIALS AND METHODS

This study will be a cross-sectional study conducted at MGACH & RC and AVBRH, Sawangi (Meghe), Wardha, from Jan 2025 - to December 2025, IEC NO. MGACHRC/IEC/Jun -2024/850. Informed consent will be obtained from the participants.

Inclusive criteria:

1. Diagnosed osteoporotic female patients;
2. Age between 40 years and 60 years;
3. Working female patients whose working hours are around six to eight hours.
4. Minimum job experience of five years is required.
5. Those who are willing to give consent for the research study.

Exclusive criteria:

1. Male patient;
2. Patients having a history of spinal or vertebral column surgery;
3. Accidental injury at vertebral column.
4. Any type of disease related to the spinal cord and vertebral column;
5. An individual taking a calcium supplement for three months before recruitment in the study.

Sample size calculation:

$n=Z^2\times P\times(1-P) / d^2$

In this formula, n denotes the required sample size, Z is the standard normal value corresponding to a 95% confidence level (1.96), P represents the estimated prevalence of vertebral structural alterations in osteoporotic females (11.1% or 0.111) [16], and d refers to the acceptable margin of error (5% or 0.05). After substituting the values, the calculation proceeds as follows:

$n=(1.96)^2\times0.111\times(1-0.111)/(0.05)^2$

$n=3.8416\times0.111\times0.889/0.0025$

$n=0.3792/0.0025$

$n=152$

Therefore, the total sample size required for the present study is 152 subjects.

Outcomes

Ayurvedic Assessment Tools:

Prakriti (body constitution) will be determined using a validated Ayurvedic *Prakriti* evaluation tool (*Nadi tarangini*). An advanced device known as *Nadi Tarangini* is designed to capture the real-time *tridosha* (*Vata*, *Pitta*, *Kapha*) pressure wave patterns of individuals. The device uses three pressure sensors strategically positioned on the wrist to detect the pulse as per traditional Ayurvedic methods. It effectively replicates how an Ayurvedic practitioner manually assesses the *nadi* (pulse). The information will be securely stored on a centralised cloud server. A full year's worth of *Nadi* data and reports will be available on the server [17].

To identify whether participants predominantly exhibit *Vata*, *Pitta*, or *Kapha* traits.

Classical *Agni* (digestive strength) will be screened through appetite, post-meal comfort, digestive regularity, and bowel tendencies, following the classical Ayurvedic types *Sama*, *Tikshna*, *Manda*, and *Vishama Agni*. A stable appetite and comfortable digestion indicate *Sama Agni*, while strong hunger and rapid digestion suggest *Tikshna Agni*; low appetite with heaviness denotes *Manda Agni*; and fluctuating appetite with irregular digestion indicates *Vishama Agni* [18,19]. These criteria are derived from *Charaka Samhita* and the *dosha* associations described in *Ashtanga Hridaya*.

Koshtha (bowel habit) will be assessed through stool consistency, frequency, ease of evacuation, and laxative response, classifying individuals into *Mridu*, *Madhyama*, or *Krura Koshtha*. Loose or frequent stools indicate *Mridu Koshtha*, regular once-daily stools indicate *Madhyama Koshtha*, and hard or infrequent stools suggest *Krura Koshtha*, based on descriptions in *Charaka Samhita* and *Ashtanga Hridaya* [20,21].

Range of movement- The assessment of the spine's range of movement will focus on how far each spinal region-cervical, thoracic, lumbar, and pelvic- will move during specific motions. The process will usually begin with active movements, where the individual will perform each motion independently, followed by passive movements

if further evaluation will be required. For flexion and extension, the person will bend forward and backward, and observations will be made regarding the degree of movement, smoothness, and any discomfort. Side bending (lateral flexion) will be evaluated by asking the individual to lean left and right without rotating the trunk, allowing comparison of movement on both sides. Rotation will be assessed by having the individual twist their upper body or turn their head, depending on the spinal region being evaluated.

Subjective parameters:

- *Sthambhata*
- Back pain (using the visual analogue scale)

While the objective parameters will be assessed based on findings of X-ray of the vertebral column and spine

STATISTICAL ANALYSIS

R Software and SPSS version 17 will be used for statistical evaluation.

The relationships between Ayurvedic parameters and changes in the vertebral column will be examined using both paired and unpaired t-tests. Baseline characteristics will be described through summary statistics. The analysis will adopt an intention-to-treat approach, meaning that all participants will be analysed within the groups to which they were originally assigned, regardless of their adherence to the study protocol. A p-value of less than 0.05 will be regarded as statistically significant.

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