

Association between Menopause Status, With Gait Speed and Sagittal Curvature of Spine in Middle-Aged Females: A Protocol Study

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Original Article

Abstract

Introduction: Gait velocity and spinal alignment are two pivotal determinants of physical performance in women. Although the menopausal transition is hypothesized to influence both gait kinetics and sagittal spinal alignment, existing literature reports conflicting findings. Therefore, the primary objective of the present study is to investigate the correlations between menopausal status, serum estradiol concentrations, gait velocity, and the magnitudes of thoracic kyphosis and lumbar lordosis in middle-aged women. The secondary objective is to evaluate the interplay between specific musculoskeletal variables—including bone mineral density, skeletal muscle mass, and the strength and endurance of the back extensors—and their impact on gait speed and the curvatures of thoracic kyphosis and lumbar lordosis.

Materials and Methods: This analytical cross-sectional study protocol will involve a cohort of 135 healthy middle-aged women, aged 35 to 65 years. Serum levels of follicle-stimulating hormone (FSH) and estradiol will be quantified. Gait velocity, sagittal spinal alignment (thoracic kyphosis and lumbar lordosis), back extensor strength and endurance, and skeletal muscle mass will be assessed using the 10-meter walk test, a kyphometer, a tensile load cell device, and the InBody 270 bioelectrical impedance analysis system, respectively. These parameters will be compared between the two study groups. To analyze the concurrent influence of the independent variables on gait velocity, thoracic kyphosis, and lumbar lordosis, multiple linear regression models will be employed.

Keywords: Menopause; Gait velocity; Kyphosis; Lordosis; Back extensors

Citation: Fatehi F, Zafarbaksh A, Niknam H, Bokaei F, Tarkesh-Isfahani N, Abdollahpour I, et al. **Association between Menopause Status, With Gait Speed and Sagittal Curvature of Spine in Middle-Aged Females: A Protocol Study.** J Res Rehabil Sci 2023; 19: 123-9.

Received date: 31.12.2023

Accept date: 04.02.2024

Published: 05.03.2024

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Introduction

Menopause, characterized by the permanent cessation of menstrual cycles, is a quintessential physiological transition in the female lifespan (1). Given that the average age of natural menopause ranges between 46 and 52 years, women typically spend over one-third of their lives in the postmenopausal phase (2). The systemic impact of menopause and the associated depletion of serum estradiol on the musculoskeletal system during middle age may lead to deleterious consequences for physical function in later life (3). This transition is marked by profound endocrine shifts, specifically an elevation in pituitary gonadotropins—namely luteinizing hormone (LH) and follicle-stimulating hormone (FSH)—coupled with a precipitous decline in ovarian estradiol secretion (4, 5). Such physiological dysregulation is a well-established driver of musculoskeletal pathologies, including osteoporosis and sarcopenia (3), which can adversely affect gait velocity—now recognized as the sixth vital sign of aging (6). Moreover, these alterations elevate the susceptibility to age-related hyperkyphosis, a geriatric syndrome intrinsically linked to diminished physical performance (7, 8).

Contradictory information exists regarding the effect of menopause and serum estradiol deficiency on gait speed and sagittal spinal alignment in middle-aged women (9-12). In the study by Bandarev et al., which aimed to investigate differences in physical performance across various stages of menopause, maximum gait speed was evaluated in non-menopausal (233 individuals) and menopausal (299 individuals) women. The maximum gait speed in menopausal women was lower than in non-menopausal women, indicating an association between menopausal status and gait speed (9). In 2007, Sowers et al. evaluated the association between physical performance (measured using gait speed, grip strength, and the time required for stair climbing and sit-to-stand) and menopausal status in middle-aged women (mean age 44). The decline in gait speed was greater in menopausal middle-aged women compared to non-menopausal women (13).

On the other hand, in the study by Seeley et al., the effect of estrogen use on muscle strength and neuromuscular function in menopausal women was examined. Estrogen use status (never used/recent user/past user) was assessed via questionnaire, and gait speed was measured using a 6-meter walk test. As a result of this study, no significant difference in gait speed was observed between women who had recently used estrogen and those who had never used it, suggesting no association between this hormone and

gait speed (10). It is possible that other changes, especially age-related musculoskeletal changes, are responsible for the decrease in gait speed. In this regard, previous studies have investigated the effects of limb muscle mass and strength on gait speed in menopausal women (14-16). However, there is no evidence regarding the effects of trunk muscle strength and endurance on gait speed in middle-aged women.

While the correlation between back extensor strength, bone mineral density, and sagittal spinal curvature is well established (17), the specific influence of menopausal status and serum estradiol levels on sagittal spinal alignment remains elusive, largely due to a paucity of evidence and conflicting findings in the existing literature. For instance, a 2018 cross-sectional study involving 1,063 older women examined the relationship between thoracic kyphosis and hormone replacement therapy patterns; the findings revealed that women who did not receive hormone therapy exhibited a significantly higher degree of kyphosis than those with intermittent or continuous use, suggesting a protective role of estradiol in mitigating thoracic kyphosis (11). Conversely, another study assessing the prevalence of kyphosis in a cohort of 140 women found no significant association between kyphosis and either advancing age, menopausal stage, or serum levels of estradiol and FSH (18). Furthermore, Pavolic et al. (2013) investigated the association between spinal curvature and bone mineral density in middle-aged women (aged 18-60 years), reporting no significant disparities in thoracic kyphosis or lumbar lordosis between menopausal and non-menopausal participants (12).

A synthesis of current literature reveals persistent discrepancies regarding the correlation between serum estradiol levels and gait velocity in middle-aged women, alongside a notable paucity of evidence concerning the influence of trunk musculature on gait performance. Consequently, further investigation into the impact of menopausal status on this critical vital sign is imperative. Moreover, given the musculoskeletal system's synergistic role in modulating gait velocity, evaluating the effects of menopause on musculoskeletal parameters—including kyphosis, back extensor strength and endurance, and bone mineral density—may yield more granular insights into the independent contributions of hormonal status and musculoskeletal integrity to gait speed. Accordingly, the primary objective of the present study is to examine the associations between menopausal status, serum estradiol concentrations, gait velocity, and the magnitudes of thoracic kyphosis and lumbar lordosis in middle-aged women. The secondary

objective is to elucidate the interplay between specific musculoskeletal variables—including bone mineral density, skeletal muscle mass, and back extensor strength and endurance—and their relationship with gait velocity and spinal curvatures in this population.

Materials and Methods

This study is an observational, analytical cross-sectional design. The target population consists of healthy middle-aged women who meet the inclusion criteria. The unit of analysis and sampling unit were defined as healthy middle-aged women. Inclusion criteria include: age between 35 and 65 years (19-21), the ability to stand and walk without assistive devices or any balance impairment (21), and a body mass index (BMI) of less than 30 kg/m². Exclusion criteria include: pregnancy, being within the six-month postpartum or breastfeeding period, interventions affecting ovarian function (bilateral oophorectomy, estrogen-containing hormonal medications, or any medication affecting ovarian function) (9), a history of hysterectomy (19), a history of spinal or lower limb fracture or surgery within the past year, the presence of upper or lower back pain at the time of assessment, or a history of upper or lower back pain in the last year requiring medical interventions (pharmacotherapy, bed rest, surgery, or orthosis use) (21), malignancy or undergoing chemotherapy (19), diseases or conditions affecting the sensory and motor systems (21), spinal abnormalities such as scoliosis, or the presence of hyperkyphosis since childhood (21), the use of medications affecting the central nervous system, balance, or muscle function in the last 12 months, and smoking or alcohol consumption (19). Additionally, women with depression, indicated by a score greater than 20 on the Patient Health Questionnaire-9 (PHQ-9), were excluded. The validity and reliability of the Persian version of this questionnaire are $r = 0.79$ and $ICC = 0.74$, respectively (22).

Following approval of the study protocol and receipt of the ethics code from the Ethics Committee of Isfahan University of Medical Sciences, middle-aged women will undergo a comprehensive assessment (including medical history and clinical examinations) by a rheumatologist and a physiotherapist to verify eligibility for inclusion and exclusion criteria. Eligible participants will be informed about the study process and assured that all personal and medical information will remain confidential. Women who provide consent will be asked to attend the Non-Communicable Diseases Research Institute of Isfahan University of Medical Sciences between 8:00 and 10:00 AM to complete the informed consent form. Subsequently,

participants will complete a personal information form. Sampling will be conducted among middle-aged women in Isfahan, recruited from health centers, health clinics, and municipal health houses across the city. Participants will be randomly selected from the household records registered at these centers using a table of random numbers.

The sample size was calculated using G*Power software (version 3.1.9.2, freeware; University of Düsseldorf, Düsseldorf, Germany) for a multiple regression model. In this model, gait speed was defined as the dependent variable. At the same time, age, body mass index (BMI), menopausal status, estradiol levels, mean bone mineral density, axial skeletal muscle mass, mean back extensor strength and endurance, and thoracic kyphosis and lumbar lordosis were considered as independent variables. Including the model intercept, a total of 11 independent variables were entered. With a significance level of 5%, a power of 80%, and a medium effect size ($f^2 = 0.15$), the required sample size was estimated to be 123. Accounting for a 10% attrition rate due to potential data inconsistencies, a total of 135 participants will be recruited (23).

Measurements

Determination of Menopausal Status and Serum Estradiol Levels: Menopausal status will be determined using questions about the menstrual cycle and the date of the last menstrual period. Women with regular menstrual cycles will be categorized as premenopausal, while those who have not experienced menstrual bleeding for more than twelve consecutive months will be categorized as postmenopausal (19). Additionally, serum estradiol (17 β Estradiol, E2) and follicle-stimulating hormone (FSH) levels will be measured from fasting blood samples. In women with active menstrual cycles, these measurements will be conducted between days 1 and 5 of the cycle [24]. Women will be classified as premenopausal if they have an FSH level below 9.5 IU/L and regular menstrual cycles, or an FSH level below 17 IU/L with regular cycles. Conversely, women will be classified as postmenopausal if they have had no menstrual bleeding in the last 6 months with $FSH > 30$ IU/L, or no bleeding in the last 3 months with $FSH > 39$ IU/L, or an extremely high FSH level (> 130 IU/L) (2).

Gait Speed Measurement: Gait speed will be assessed using the 10-meter walk test (10MWT). As shown in Figure 1, a 20-meter flat path will be marked on the test surface. The initial and final 5-meter sections will be designated for acceleration and deceleration, respectively. The stopwatch will be started immediately as the participant's foot crosses the 10-meter start line and stopped as they cross the 10-

meter finish line; the time will be recorded in seconds. Participants will be instructed to walk at their usual self-selected speed. This test will be repeated twice, and the average of the two trials will be recorded as the final gait speed ($ICC = 0.96-0.98$) (25).

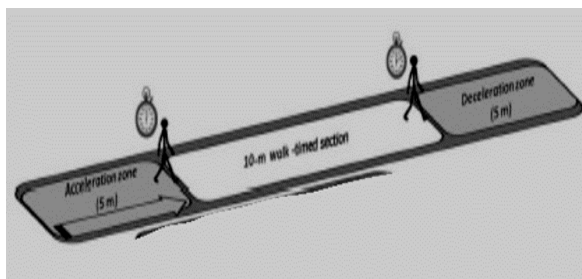


Figure 1. 10-meter walk test

Sagittal Spinal Alignment Measurement: Thoracic kyphosis and lumbar lordosis curvatures will be measured using a DeBrunner kyphometer (Ghamat Pooyan, Tehran, Iran). Evidence indicates high validity ($r = 0.95$) and reliability ($ICC = 0.98$) for this Iranian-made kyphometer, making it a recommended indigenous tool [26]. First, the spinous processes of the 2nd-3rd thoracic vertebrae (T2-T3), 11th-12th thoracic vertebrae (T11-T12), and 2nd-3rd sacral vertebrae (S2-S3) will be palpated and marked. Participants will stand barefoot in a relaxed, natural position, gazing at a marker on the wall at eye level, with feet shoulder-width apart, knees straight, and arms hanging comfortably at their sides. To measure thoracic kyphosis, the upper arm of the kyphometer will be placed between the spinous processes of T2 and T3, and the lower arm between T11 and T12, to measure the Cobb angle of kyphosis. For lumbar lordosis, the upper arm will be placed between T11 and T12, and the lower arm between S1 and S2 to measure the lumbar Cobb angle (27). Measurements for each region will be repeated three times at intervals of one to two minutes, and the mean value will be recorded in degrees. Existing evidence shows very high intra-rater ($ICC = 0.98$) (28) and inter-rater ($ICC = 0.96$) (29) reliability for the kyphometer in measuring thoracic kyphosis and lumbar lordosis. Furthermore, a significant correlation has been reported between the kyphosis angle measured via radiography and the kyphometer ($p < 0.001$, $r = 0.58$), as well as between radiographic and kyphometer-measured lordosis ($p < 0.001$, $r = 0.40$) [30].

Measurement of Static Strength and Endurance of Back Extensors: Static strength and endurance of the back extensor muscles will be assessed using an S-type load cell (H3-C3-100 kg-3B-D55, Zemic, China)

attached to a vertical bar in a seated position (Figure 2). This device has demonstrated very high and high reliability for measuring maximum isometric force ($ICC > 0.95$) and trunk extensor endurance ($ICC > 0.80$), respectively (31, 32). Additionally, a strong correlation between the load cell and calibrated external forces indicates the high validity of this tool ($r = 0.99$, $p < 0.001$) (31).

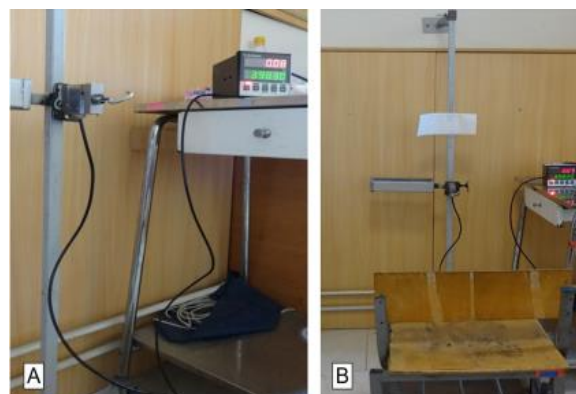


Figure 2. Device for measuring back extensor strength and endurance: S-type load cell attached to a vertical base.

Measurement of Back Extensor Muscle Function: Participants will be instructed to sit on a stool such that the hip and knee joints are flexed at 90 degrees, the thighs are parallel to the horizon, and the arms are crossed over the abdomen. Each individual will be positioned in their usual posture in front of the load cell. A strap will be placed over the abdomen and secured to the backrest. Another strap will be placed at the top of the thighs, at the level of the ASIS, and tightened to prevent vertical or forward movement of the hip joints during the test. The examiner will adjust the load cell on the vertical base to align it with the superior edge of the manubrium at the midline. Four rigid, non-elastic cords will be attached to the load cell hook and secured to the vest's rings. These cords will be shortened based on the participant's height and distance from the vertical bar to prevent any backward movement (21, 33). After the procedure is explained, each participant will be asked to pull their trunk backward within 1-2 seconds, attempt to exert and maintain maximum force for 3-5 seconds, and then slowly release this force over 1-2 seconds. The generated force will be displayed on a digital monitor. Following one practice trial, the maximum pulling force will be recorded three times. A rest period of approximately 60 seconds will be provided between repetitions (Figure 3). The maximum force achieved

will be recorded as the isometric strength of the back extensors in kilograms (34).

To measure muscle endurance, after a 30-minute rest to ensure the absence of fatigue, the participant will be repositioned on the stool and connected to the device as in the previous stage. Each individual must maintain 50% of their previously recorded maximum pulling force. The test will terminate, and the time will be recorded, as soon as the force drops below 90% of this baseline. This measurement will be repeated 3 times at 30-second intervals, and the maximum recorded time will be the static endurance of the back extensors in seconds (35).

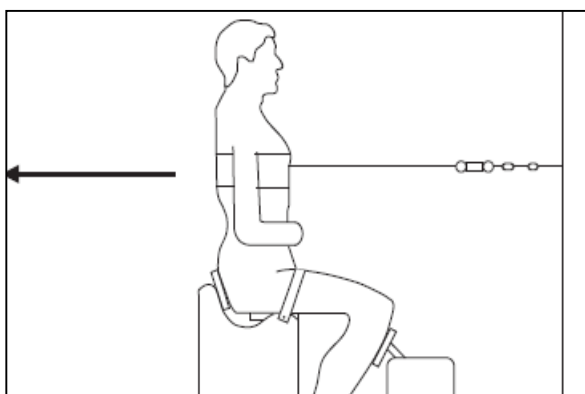


Figure 3. Assessment of maximum static back extensor force in the seated position: The load cell is aligned at the midline at the level of the superior border of the manubrium, and the participant pulls the trunk backward with maximum force.

Measurement of Muscle Mass: Total skeletal muscle mass will be measured using a Body Composition Analysis (BCA) device (Inbody 270, Inbody Co., Seoul, Korea). BCA utilizes Bioelectrical Impedance Analysis (BIA) technology, which estimates muscle mass based on total body electrical conductivity rather than direct measurement (36). For the measurement of total and segmental skeletal muscle mass, this device demonstrates repeatability ($ICC > 0.95$ and > 0.69 , respectively) and validity ($r > .$). The device features eight tactile electrodes. The hand electrodes will be in contact with the fifth finger, and the heels will be placed on the foot electrodes. Participants will be requested to stand barefoot on the device and remain motionless during the measurement [38]. The recorded variables will include skeletal muscle mass (SMM) and the skeletal muscle index (SMI), defined as SMM normalized to height squared (SMM/H^2) (37).

Measurement of Bone Mineral Density: Currently,

dual-energy X-ray absorptiometry (DXA) is the most widely used imaging technique for measuring bone mass in both clinical and research settings. This quantitative method provides regional bone mass measurements in grams per square centimeter (g/cm^2). The advantages of DXA include a significantly lower radiation dose compared to CT scans, the ability to measure bone mass in areas prone to osteoporotic fractures—such as the lumbar spine and the proximal femur—excellent repeatability (with a coefficient of variation ranging from 1% in the spine to 2% in the femoral neck), and a short scanning time (1–3 minutes). In this study, the bone mineral density (BMD) of the lumbar region will be measured based on the mean of the first to fourth lumbar vertebrae and reported in g/cm^2 (39).

Statistical Analysis

Data analysis will be conducted at two levels: descriptive and inferential. Descriptive statistics will include means, standard deviations, frequency distribution tables, and statistical charts. For inferential analysis, after verifying the normality of data distribution using the Kolmogorov-Smirnov test, independent t-tests will be used to compare the mean gait speed, thoracic kyphosis, and lordosis between the postmenopausal and premenopausal groups. To investigate the simultaneous effects of independent variables on gait speed, thoracic kyphosis, and lordosis, a multiple linear regression model will be employed. All tests will be performed at the 5% significance level ($\alpha = 0.05$) using SPSS (version 24; IBM, Armonk, USA).

Limitations

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Recommendations

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Conclusion

Physiotherapists strive to employ evidence-based perspectives for the treatment of physical functional impairments. Given the musculoskeletal system's contribution to gait speed, investigating the effects of menopausal status on musculoskeletal factors, kyphosis, back extensor strength and endurance, and bone mass can provide more accurate information about the independent influence of menopause and musculoskeletal factors on gait speed. It is expected that the results of the present study will contribute to understanding the factors involved in the decline of gait speed, particularly in relation to menopausal status. These findings may assist in prioritizing

preventive strategies and designing rehabilitation programs focused on gait speed and spinal alignment (kyphosis and lordosis) for middle-aged and older women, thereby enhancing the health of this significant population.

Acknowledgments

This study is related to the project NO 299266 from Research Institute for Primary Prevention of Non-Communicable Diseases of Isfahan University of Medical Sciences, Isfahan, Iran. We also appreciate the “Research Institute for Primary Prevention of Non-Communicable Diseases” in Isfahan University of Medical Sciences for their financial supports.

The authors acknowledge the use of AI-assisted translation and linguistic refinement to improve the overall flow and readability of the English manuscript.

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Funding

The present study was based on the proposal of Master's theses in Physical therapy by Faezeh Fatehi (Scientific Code: 299266, Ethical code: IR.MUI.MED.REC.1400.002), with financial support from Isfahan University of Medical Sciences. The University did not interfere in data collection, analysis and reporting, manuscript preparation and final approval of the study for publication.

Conflict of Interest

The authors did not have a conflict of interest.

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