Original Article

A Survey on Relation of Menopause to Metabolic Syndrome - SAFOMS STUDY (South Asian Federation of Menopause Societies) - Interim Analysis

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ABSTRACT

Background: Metabolic syndrome (MS) is a spectrum of disorders that includes dysglycemia, dyslipidemia, central obesity, and hypertension. South Asian Indians are more prone to harbor MS at a younger age compared to Caucasians. However, there is a lack of large-scale data correlating menopause to MS in South Asian settings. **Aims and Objectives:** The study aimed to determine the prevalence of MS and its components in pre- and postmenopausal women. It also assessed the relationship of age, menopausal status, personal and family history, anthropometric parameters, and biochemical markers to MS. **Materials and Methods:** It was an interim analysis of a multicountry cross-sectional study in the South Asian Federation of Menopause Society (SAFOMS) countries: India, Pakistan, Bangladesh, Nepal, and Sri Lanka conducted through both online and physical methods. The survey questionnaire consisted of questions about details of personal history, demographics, and family history related to MS. Anthropometric measurements such as height, weight, basal metabolic index (BMI), waist circumference, and blood pressure readings were noted. Relevant history, history of polycystic ovarian syndrome, hypertensive disorders of pregnancy, and vasomotor symptoms were enquired. Biochemical evaluation of markers associated with MS was undertaken. **Results:** In this interim analysis, 638 women were recruited. Out of them, 406 (63.6%) women were premenopausal and 232 (36.4%) were postmenopausal. 392 (61.4%) women had MS, while 246 (38.6%) women did not have MS. Increasing age, BMI, and visceral adiposity (waist circumference) were significantly correlated with incidence of MS. Raised fasting blood sugar, hemoglobin A1C, total cholesterol, low-density lipoprotein, serum triglyceride, and reduced high-density lipoprotein levels were significantly associated with the incidence of MS in both pre- and postmenopausal women. Peri- and postmenopausal hot flashes, night sweats, and sleep disturbances were also significantly associated with MS. Personal history of hypertension, diabetes, and dyslipidemia were the strongest factors to be associated with MS with a significantly high odds ratio. **Conclusion:** The study has highlighted the role of BMI and waist circumference as the first warning signs, which will encourage to go for regular biochemical screening through lipid

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profile and fasting blood glucose measurements. Our study is a stepping stone for all future studies for relation of menopause to MS.

Keywords: *Cardiovascular disorders, Indian women, meaningful life management, menopause, metabolic syndrome, midlife*

Introduction

Metabolic syndrome (MS) is a complex disorder defined by a cluster of interconnected factors that increase the risk of cardiovascular atherosclerotic diseases and type 2 diabetes mellitus.[1] MS includes dysglycemia, dyslipidemia, central obesity, and hypertension.[1,2] The prevalence of MS has varied greatly in different populations. The prevalence of MS has ranged from 13.8% in premenopausal age to as high as 60% in postmenopausal women.[2] Several factors such as ethnicity, variations in the diagnostic criteria for defining MS, study designs, and sample sizes have led to the variation in this prevalence. MS is directly influenced by age, gender, genetic background, family history, diet, and level of physical activity.[3] Asian Indians, in general, are more prone to harbor MS, that too, at a younger age compared to their Western counterparts, which has resulted in greater morbidity and mortality.

South Asian women attain menopause at a much lower age compared to Caucasians.[4] Menopausal symptoms have been widely reported and analyzed in developing countries. Still, very little information is available from national registries. South Asian countries harbor a heterogeneous population belonging to different ethnic backgrounds and practicing different sociocultural norms. The main drivers for the surge in MS during the past few decades are changes in lifestyle and socioeconomic transitions due to ever-increasing urbanization, mechanization, sedentary behavior, and increased affluence.[5,6] Considering the controversial role of estrogen in the perimenopausal transition, it is very pertinent to have large data for risk factor stratification for cardiovascular disease and events. Hence, it is necessary to conduct a pan-South Asian large-scale population-based multicentric prospective observational study whereby data about the relation of menopause to MS can be properly analyzed.

Materials and Methods

It was an interim analysis conceptualized as a multicountry cross-sectional study in the South Asian Federation of Menopause Society (SAFOMS) countries: India, Pakistan, Bangladesh, Nepal, and Sri Lanka conducted over 9 months through both online and physical methods. It aimed to determine the prevalence of MS and its components in South Asian women (using the latest International Diabetes Federation criteria). It assessed the relationship of personal and family history, anthropometric parameters, and biochemical markers to MS. The study also aimed to analyze the relationship between age and menopausal status with the incidence of MS. Written informed consent was obtained from all participants before recruitment. All procedures in the study involving human participants were performed in accordance with the ethical standards of the Institutional Ethics Committee granting approval (TH/IEC/BHR/622/2022/MA/P1).

This was a South Asian study consisting of two arms: (i) online data collection through Google Forms by health-care professionals such as doctors and nurses and (ii) questionnaires being filled in outpatient departments of various hospitals and clinics.

Sample calculation: considering the study to have two independent arms for the prevalence of MS, i.e. the prevalence of MS in premenopausal (13.8%) and the prevalence of MS in postmenopausal women (60%), the sample size required in the study was 1200 for premenopausal women and 1075 for postmenopausal women. This is an ongoing study and the present publication is an interim analysis of the same with 638 participants.

All consecutive women from age 35 to 65 years consenting to the survey were eligible for recruitment. Women below 35 years and above 65 years, nonconsenting women, and mentally challenged women were excluded from the study. The survey questionnaire consisted of questions pertaining to details of personal history, demographics, and family history related to MS, diabetes, hypertension, cardiovascular disorders, and fragility fracture. All participants were subjected to general, systemic, and gynecological examinations to screen for the incidence of MS. The latest International Diabetic Federation (IDF) definition for MS was used in this study:

1. Central abdominal obesity: Waist circumference >80 cm (for South Asian women) or basal metabolic index (BMI) >30 kg/m^2; and any two of the following criteria
2. Hypertriglyceridemia: serum triglyceride level >150 mg/dl or under treatment of dyslipidemia

3. Reduced high-density lipoprotein (HDL): <50 mg/dl or under treatment of dyslipidemia
4. High blood pressure (BP): systolic blood pressure (SBP) >130 mm Hg and/or diastolic blood pressure (DBP) >85 mm Hg or on treatment of previously diagnosed hypertension
5. High fasting blood glucose: >100 mg/dl or on treatment for previously diagnosed diabetes.

Anthropometric measurements such as height, weight, BMI, waist circumference, and BP readings were carefully noted by trained health-care personnel. Body weight was measured with calibrated weighing machines (in kilogram), and participants were advised to wear light clothes and no footwear. Height was measured in centimeters using precalibrated stadiometers with the feet, buttocks, and head touching the wall and looking straight forward after exhalation. Waist circumference was measured (in centimeters) at a level midway between the bottom of the rib cage and the superior margin of the iliac crests during inspiration with the help of nonstretchable measuring tapes. BP readings of the participants were measured twice with standard barometers in a sitting position, and the average of the two readings was noted.

Relevant history such as age at menarche and menopause, duration of reproductive life, history of polycystic ovarian syndrome (PCOS), hypertensive disorders of pregnancy (HDP), changes in menstrual patterns, whether or not any history of menopausal hormone therapy, and reasons for initiation of the same were asked. Social history about diet and physical activity levels were also enquired. Biochemical evaluation of markers associated with MS was undertaken. Participants were subjected to venous blood sampling in the morning after overnight fasting of 12 h. Fasting blood sugar (FBS), hemoglobin A1C (HbA1C), total cholesterol, HDL, low-density lipoprotein (LDL), and serum triglycerides were collected, and the results were noted in their respective survey forms (either online or offline as per convenience).

Statistical analysis

Data collected through Google Forms were analyzed at an aggregate level after compiling them into a Microsoft Excel sheet. We carried out statistical analysis using the statistical package StataCorp. 2023. Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC. Categorical data were represented in the form of frequencies and proportions. The Chi-square test was used for the categorical data. Unadjusted odds ratio (OR) with 95% confidence limits was presented in the 2 × 2 by the Chi-square tests. We tested continuous variables for normality assumptions using the Kolmogorov–Smirnov test. Descriptive measures such as mean, standard deviation, and range values were computed for normally distributed data. We compared the mean values either using a *t*-unpaired test or a one-way analysis of variance test. For all the statistical tests, a two-sided probability of $P < 0.05$ was considered to be statistically significant.

Results

In this interim analysis, a total of 638 eligible women were recruited from various tertiary care teaching hospitals, medical colleges, and health clinics during the study time frame. Questionnaires were submitted through both online mode (104 participants) and offline physical mode (534 participants). Out of them, 406 (63.6%) women were premenopausal and 232 (36.4%) were postmenopausal. Considering the IDF criteria, 392 (61.4%; 95% confidence interval [CI]: 57.5%–65.2%) women were classified as having MS, while 246 (38.6%) women did not have MS. Figure 1 shows the flowline of events during the study time frame.

A detailed comparison was done between the factors responsible for MS in the study population, as shown in Table 1. The mean age of the participants was 43.78 ± 7.85 years and 46.73 ± 7.92 years in the no-MS and MS groups, respectively ($P < 0.001$). Increasing age was significantly correlated with the incidence of MS. In our study, age at menarche ($P = 0.532$) and profession of the participants ($P = 0.109$) were not significantly correlated with the incidence of MS. However, since this is an interim analysis, we look forward to more data from all South Asian countries in the final analysis before coming to a conclusion regarding the relation of

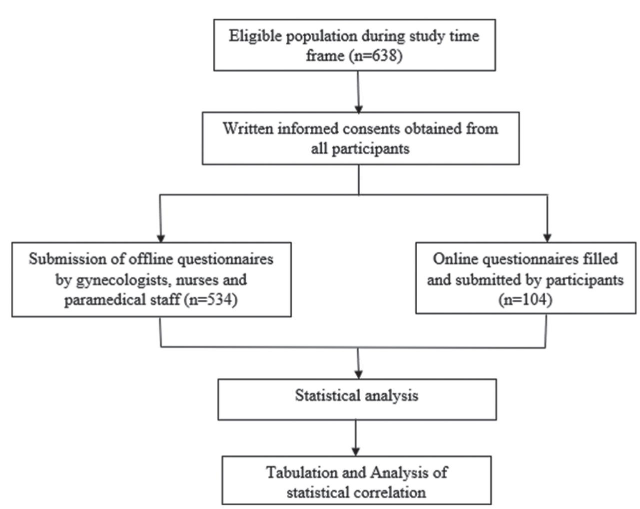

Figure 1: Flowline of events during the study time frame

age at menarche to the incidence of MS. BMI played a major role in the development of MS in our study population ($P < 0.001$). Visceral adiposity was strongly correlated with MS as evidenced from the significant increase in waist circumference ($P < 0.001$). Both raised SBP and DBP were also positively correlated with the development of MS (SBP $P < 0.001$; DBP $P = 0.013$, respectively). Certain biochemical parameters were also useful in predicting MS in midlife women. Raised FBS, HbA1C, total cholesterol, LDL, serum triglyceride, and reduced HDL levels were significantly associated with the incidence of MS in both pre- and postmenopausal women ($P < 0.001$) as evident from Table 1.

Personal history and clinical symptoms play a vital role in the prediction of MS. Participants were asked about the history of PCOS and HDP, and their correlation with MS was assessed. The present study did not find any significant association of these history parameters with MS (PCOS $P = 0.572$; HDP $P = 0.687$). However, individual factors such as waist circumference, weight, BMI, and LDL in patients with PCOS have been found to have a significant correlation with MS [Table 2]. Since it is an interim analysis of SAFOMS data, we look forward to the final analysis of more incoming data before drawing a solid conclusion.

Table 2 shows the relationship of PCOS with parameters contributing to MS. Anthropometric measurements such as weight, BMI, and waist circumference are significant markers of MS in women with a history of PCOS (P = 0.002, 0.029, and 0.011 respectively). Among the biochemical markers, serum LDL was found to be significantly raised in women with PCOS compared to their counterparts ($P = 0.046$).

There was a strong association of clinical signs and symptoms of menopause to MS. Peri- and postmenopausal hot flashes ($P = 0.032$; OR: 1.460; 95% CI: 1.03–2.07), night sweats ($P = 0.008$; OR: 1.808; 95% CI: 1.16–2.82), and sleep disturbances ($P = 0.001$; OR: 1.908; 95% CI: 1.28–2.85) were significantly associated with MS. However, mood changes were not significantly associated with MS in the present study ($P = 0.100$). Personal history of hypertension ($P < 0.001$; OR: 6.719), diabetes ($P < 0.001$; OR: 8.023), and dyslipidemia ($P < 0.001$; OR: 4.084) were the strongest factors to be associated with MS with significantly high OR as shown in Table 3 and Figure 2. A family history of hypertension, diabetes, cardiovascular diseases, and fragility fracture was not statistically significantly related to MS in the present study. It is noteworthy that eliciting proper history with meticulous accuracy needs great effort in our clinical setting. Owing to the time constraints in our outdoor setup, detailed history taking with a high index of suspicion will help to yield a proper relationship between family history and the risk of MS in the South Asian context.

Table 4 shows the relationship of physical activity level and the prevalence of MS. In our study, the majority

Table 1: The correlation of various demographic, anthropometric, and biochemical parameters with the prevalence of metabolic syndrome (*P* values were based on the *t*-unpaired test for means and the Chi-square test for frequencies)

Parameters	No MS (*n*=246), *n* (%)	MS (*n*=392), *n* (%)	*P*
Age (years)	43.78±7.85	46.73±7.92	<0.001
Age at menarche (years)	13.52±1.75	13.68±3.51	0.532
Profession of participants			
Doctor	32 (13.01)	68 (17.35)	0.109
Nurse	22 (8.94)	19 (4.85)	
Others	192 (78.05)	305 (77.81)	
BMI (kg/m^2)			
Underweight - (<18.5)	16 (6.50)	5 (1.28)	<0.001
Normal - (18.5–24.9)	62 (25.20)	50 (12.76)	
Overweight - (25–29.9)	49 (19.92)	58 (14.79)	
Obese - (>30)	119 (48.37)	279 (71.17)	
Waist circumference (cm)	86.14±13.75	95.86±9.99	<0.001
SBP (mm Hg)	114.11±13.94	123.44±17.21	<0.001
DBP (mm Hg)	75.68±8.64	82.52±42.38	0.013
FBS (mg/dL)	89.97±21.45	99.02±31.51	<0.001
HbA1C (%)	5.31±0.77	6.02±2.79	<0.001
Total cholesterol (mg/dL)	164.97±38.23	182.96±39.96	<0.001
HDL (mg/dL)	50.27±10.66	44.33±7.99	<0.001
LDL (mg/dL)	95.08±35.29	107.36±41.28	<0.001
Triglyceride (mg/dL)	122.45±49.63	164.15±50.91	<0.001

LDL: Low-density lipoprotein, HDL: High-density lipoprotein, FBS: Fasting blood sugar, DBP: Diastolic blood pressure. SBP: Systolic blood pressure, HbA1C: Glycated hemoglobin, BMI: Basal metabolic index, MS: Metabolic syndrome

Table 2: Association of cardiometabolic risk factors of metabolic syndrome in women with or without polycystic ovarian syndrome

Parameters	No history of PCOS	History of PCOS	*P*
BMI (kg/m^2)	26.33±4.53	28.17±6.15	0.002
Weight (kg)	62.34±11.51	65.38±10.64	0.029
Waist circumference (cm)	91.87±12.45	96.77±12.87	0.011
FBS (mg/dL)	95.55±29.11	95.55±22.70	0.999
HbA1C (%)	5.74±2.41	5.79±0.65	0.866
Total cholesterol (mg/dL)	175.87±40.47	176.73±38.80	0.860
LDL (mg/dL)	94.11±36.68	103.68±39.71	0.046
HDL (mg/dL)	47.59±7.70	46.52±9.77	0.358
Triglyceride (mg/dL)	147.50±53.56	150.75±58.79	0.622

BMI: Basal metabolic index, LDL: Low-density lipoprotein, HDL: High-density lipoprotein, FBS: Fasting blood sugar, HbA1C: Glycated hemoglobin, PCOS: Polycystic ovarian syndrome of the study population had a sedentary lifestyle with <30 min of physical activity daily. Although no statistical significance was found between the level of physical activity and MS, we wish to reserve judgment till the final results from all countries of South Asia (SAFOMS data) are analyzed.

Menopausal transition also played a major role in the incidence of MS ($P < 0.001$). While 47.8% of reproductive-age women <40 years had MS, this prevalence raised to 68.9% during the first 5 years after menopause and up to 75.3% after 5 years of menopause ($P < 0.001$). Menopause, which is marked by a drastic decline in estradiol level, is a strong contributory factor to the development of MS [Table 5 and Figure 3].

Discussion

Menopausal transition, due to the hypoestrogenic state, contributes toward the development of insulin resistance and MS.[7,8] Age at menopause being earlier in the South Asian population is perhaps one of the prime causes of higher incidence of MS. Our study has also shown menopausal age to be around 46 years, which is around 5 years earlier than Western data.[3]

Besides age, genetic predisposition, female gender, central obesity, low fiber intake, history of PCOS, smoking, excessive alcohol intake, and lack of physical activity also play significant roles in determining the risk of developing MS in midlife.[8-10]

MS is the result of a complex etiopathogenesis involving both genetic and acquired factors.[11] Of all these, insulin resistance and chronic inflammation as vascular endothelium appear to be the major factors in the progression of MS. In the first 5 years after menopause, women gain half a kilogram per year and start becoming obese due to fat deposition in the central body compartments.[12] Lack of physical activity and a sedentary lifestyle due to urbanization and mechanization have promoted it further. Hypoestrogenic state results in intra-abdominal deposition of fat (apple-shaped android fat and pear-shaped gynecoid fat), which has emerged as an independent risk factor for cardiovascular morbidity.[13] A recent meta-analysis has concluded that menopause adversely affects all components of MS, including triglycerides, HDL, LDL, and BPs.[14] Similarly, our study also shows a strong relationship of derangement in lipid profile with the incidence of MS. They are

Table 3: The association of personal history and vasomotor symptoms with metabolic syndrome

Parameters	No MS (*n*=246), *n* (%)	MS (*n*=392), *n* (%)	*P*	OR
History of PCOS	32 (13.01)	45 (11.48)	0.572	0.870
History of HDP	36 (14.63)	62 (15.82)	0.687	1.096
Hot flashes	68 (27.64)	140 (35.71)	0.032	1.460
Mood changes	66 (26.83)	129 (32.91)	0.100	1.343
Night sweats	32 (13.01)	83 (21.17)	0.008	1.808
Sleep disturbances	41 (16.67)	108 (27.55)	0.001	1.908
Hypertension	39 (15.85)	219 (55.87)	<0.001	6.719
Diabetes	65 (26.42)	291 (74.23)	<0.001	8.023
Dyslipidemia	45 (18.29)	259 (66.07)	<0.001	4.084

PCOS: Polycystic ovarian syndrome, OR: Odds ratio, MS: Metabolic syndrome, HDP: Hypertensive disorders of pregnancy

Table 4: Association of physical activity level and metabolic syndrome

Parameters	No MS (*n*=246), *n* (%)	MS (*n*=392), *n* (%)	*P*
Physical activity level			
Sedentary lifestyle and <30 min of exercise per day	160 (36.4)	279 (63.6)	0.104
>30 min of exercise per day	86 (43.2)	113 (56.8)	

MS: Metabolic syndrome

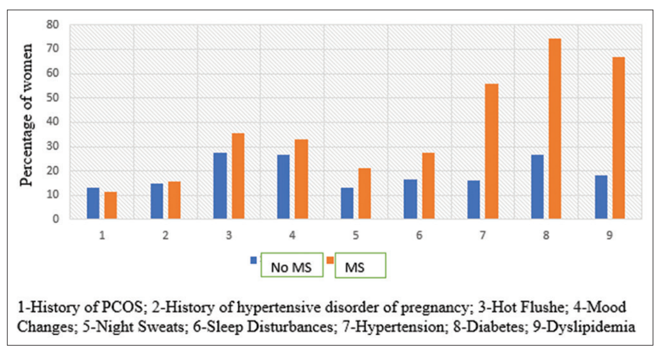

Figure 2: Relationship of personal history, vasomotor symptoms, and biochemical markers to metabolic syndrome. PCOS: Polycystic ovarian syndrome

Table 5: Association of age and menopause to metabolic syndrome

Parameters	No MS (*n*=246), *n* (%)	MS (*n*=392), *n* (%)	*P*
Relationship of age and menopause to MS			
Reproductive-age women <40 years	97 (52.2)	89 (47.8)	<0.001
Women above 40 years till menopause	82 (37.3)	138 (62.7)	
Postmenopausal for <5 years	47 (31.1)	104 (68.9)	
Postmenopausal for >5 years	20 (24.7)	61 (75.3)	

MS: Metabolic syndrome

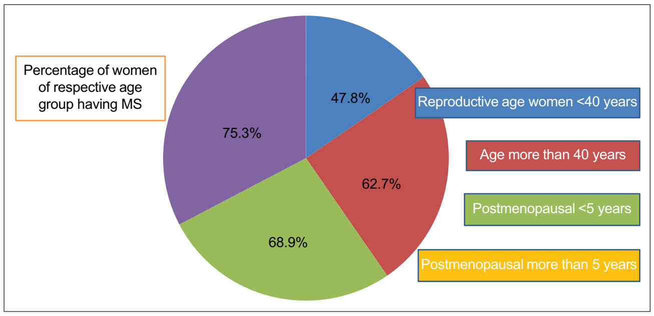

Figure 3: Association of age and menopause to metabolic syndrome

an important marker of screening for MS in women entering their menopausal transition.

Vasomotor symptoms such as hot flashes and night sweats up to 7–10 years after menopause have been associated with MS.[15] In a recent cross-sectional study on 675 women from an urban setting, hot flashes were an independent risk factor for determining the onset of MS after adjusting age and menopausal status with an OR of 1.98.[16] Similar findings were observed in the present study from South Asian women where the odds of having MS in women with vasomotor symptoms, particularly hot flashes, was found to be 1.46. However, unlike other observational studies, mood swing was not found to be significantly associated with MS in our interim analysis.

A prospective study from North India concluded that abnormal waist circumference was the most prevalent component (87%) of MS, followed by BMI, DBP total cholesterol, and triglycerides. FBS and HDL were proportionally similar in both groups.[17] In this study, no increase in MS was noted from pre- to postmenopause, while our study has shown an increase in MS, which was age and menopause related [Figure 3]. Our study has also shown a strong correlation of waist circumference, BMI, DBP, total cholesterol, and triglycerides with the incidence of MS. Moreover, SBP and other biochemical markers such as FBS, HbA1C, LDL, and HDL were also highly associated with MS in peri- and postmenopausal women in our study. In our study the most correlated factors for MS are raised triglycerides (≥150 mg/dL) with Odds ratio 8.7 (95% CI: 5.9-12.8) followed by Diabetics (FPG≥100 mg/dL or HBA1c>5.6 mmol/L) with Odds ratio 8.0 (95% CI: 5.6-11.5) and Hypertension (systolic BP≥130 or diastolic BP≥85 mm Hg) with Odds ratio 6.7 (95% CI: 4.5- 10.0).

A systematic review on the history of PCOS and MS in menopausal women has concluded that menopause *per se* increases the incidence of MS due to an increase in central obesity, deranging lipid profile, and hypertension, more pronounced in women with PCOS.[18] In our study, besides biochemical markers like LDL, anthropometric measurements such as weight, BMI, and waist circumference were the significant markers of MS in women with PCOS.

This opens a window of opportunity where clinical weight and waist circumference can be used as effective screening tools for preventing MS in women with and without PCOS. Waist circumference is probably the first and most cost-effective parameter that can be easily measured in low-resource setup which will signal us to triage further with biochemical markers.

The World Health Organization (WHO) and the United Nations have declared this decade (2021–2030) as the "Decade of Healthy Aging." Keeping in line with this theme, various researchers around the globe have focussed on the concept of healthy aging of the WHO.[19-23] Thus, it becomes very important to elicit personal history like age at menarche, history of PCOS, and stressful pregnancy conditions such as hypertensive disorder and gestational diabetes during the antenatal period.

Family history plays a significant role in determining the risk of MS.[24] In our study, we tried to assess the relationship of these parameters with the prevalence of MS. It was very difficult to get a true temporal relationship of family history with the incidence of MS in our study population as there is no proper documentation of health history in the registry of these low-middle income countries. Although no statistically significant association was observed in this interim analysis, we look forward to a larger sample size which will be soon obtained for the final analysis.

Regular workouts with moderate-intensity aerobic exercises for 30 min a day for at least 5 days a week (150 min in a week) are advisable to burn out central adipocytes for the generation of energy.[21-24] In 2018, the World Health Assembly agreed on a global target to reduce physical inactivity by 15% by 2030 and align with the Sustainable Development Goals (SDG). The commitments made by world leaders to develop ambitious national SDG responses provide an opportunity to refocus and renew efforts at promoting physical activity. Although no statistically significant association was found between the duration of physical activity and MS in the interim analysis of the present study, we wait for the final results of the study to come to a concrete assumption.

The study had a few limitations. This is the interim analysis of the SAFOMS multicountry study. Data included in this interim analysis has been largely contributed from India. Data from other South Asian countries are being collected. Uniform collection of data from pan-South Asia will help to draw conclusions regarding the risk of MS in this diverse population. In sample size calculation, general population estimates were considered for the calculation rather than region-specific population estimates. The lack of detailed elicitation of family history has resulted in the nonuniformity of data. We look forward to overcome these shortcomings in the final analysis of the complete data from all the South Asian countries.

Conclusion

Our study is a stepping stone for all future studies for relation of menopause to MS. It is beyond doubt that MS has increased risks of cardiovascular diseases and diabetes. This, in turn, has increased morbidity, mortality, and public health burden on middle-income countries of South Asia such as India, Pakistan, Nepal, Bangladesh, and Sri Lanka. The study has highlighted the role of BMI and waist circumference as the first warning signs, which will encourage to go for lifestyle changes and regular biochemical screening through lipid profile and fasting blood glucose estimation. In our study, we found an increase in biochemical markers and anthropometric figures, which were age and menopause related. Other factors that have been highlighted are the role of history taking of early menarche, adverse pregnancy outcomes, and family history, although we could not establish a significant relationship due to lack of documentation. In our study, PCOS *per se* was not associated with MS, but individual factors such as waist circumference, weight, BMI, and LDL in patients of PCOS have been found to have a significant correlation with MS. Another important finding is the association of vasomotor symptoms such as hot flashes, night sweats, and sleep disturbances with MS. Future studies should be in collaboration with physicians and cardiologists so that a comprehensive picture can emerge.

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Conflicts of interest

There are no conflicts of interest.

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