

The association between shift working behaviour and metabolic syndrome among employees in a hospital setting: protocol for a comparative cross-sectional study

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Abstract

Background

Strong evidence exists that shift workers are more susceptible to metabolic syndrome (MetS), with most of this research coming from Western countries. However, South Asians who exhibit an inherently higher risk for the MetS due to their unique body composition and lifestyle factors have not been widely studied.

Objectives

This study aims to determine the association between shift work and MetS in a South Asian population and to assess whether their lifestyle behaviours and body composition have an additional detrimental effect on the disease.

Methods

The study will be conducted as a comparative cross-sectional study at the Nawaloka Hospital, Colombo, Sri Lanka. A sample of 74 regular day workers and shift workers will be recruited for the study. Firstly, the shift workers group (n=37) will be selected using a stratified random sampling technique. Then a comparison group of day workers (n=37) will be selected after matching for age and gender in a 1:1 ratio. Data will be collected through blood tests, anthropometric measurements, and interviewer-administered questionnaires. MetS will be diagnosed based on the International Diabetes Federation (IDF) criteria. The prevalence of MetS between day and shift workers will be evaluated as the primary outcome. Secondary outcomes are the differences in anthropometric, clinical, biochemical parameters, and other lifestyle behaviours between the day workers and shift workers. Data will be analyzed using SPSS version 23.0.

Conclusion

This article presents a study protocol to investigate the association between shift working behaviour and MetS. The result of the present study will be useful in formulating occupational policies, as well as serve as a starting point for future research on shift work and the risk of chronic diseases.



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Introduction

Rapid global industrialization has led to an increase in the need for shift work throughout the world. It often encompasses work outside the conventional daytime and thereby covers fixed evening and night work, roster work, and ordinary three-shift work [1]. It is highly prevalent in service industries, particularly in the healthcare sectors, retail, and transportation [2]. The proportion of shift workers is now estimated to be around 20% of the entire working population in developed countries [3]. In the European Union in 2018, 18.1% of employees worked shifts and 13.2% of the total working population worked night shifts [4]. It is expected that this situation will soon be mirrored in other nations which are still in the process of acquiring an industrial base of their own [5]. Even though the introduction of shift work could offer more employment opportunities and can be advantageous to businesses, the health and social costs implications cannot be ignored.

Shift work is accompanied by a greater incidence of several health disorders, such as cardiovascular [6], metabolic [7], gastrointestinal [8, 9], and mental diseases [10]. In recent years, it was found that shift workers are more prone to metabolic syndrome (MetS) than day workers [11]. MetS is referred to a cluster of cardiometabolic risk factors such as obesity, specifically central obesity as measured by waist circumference, hypertension, dyslipidemia, and insulin resistance [12]. There is strong evidence suggesting that the presence of MetS increases the risk of cardiovascular mortality and morbidity [13]. In addition, MetS is also found to be associated with other disorders such as thrombotic and inflammatory conditions, fatty liver disease, and reproductive disorders [14]. Moreover, studies indicate that common genetic variants are associated with the development of MetS [15] and South Asians have an unusually high tendency to develop MetS compared to Caucasians [16].

According to the study by Katulanda *et al.* the age-adjusted prevalence of MetS was 24.3% among Sri Lankan adults. Pakistan and India also have shown a higher prevalence of 34.8% and 25.3% respectively [17]. In addition, it has been reported that MetS is twice more common amongst South Asian immigrants living in the US compared to the native Caucasian population [18]. The increased disease burden is partly due to the Asian Indian or South Asian phenotype, which refers to a combination of characteristics that predisposes South Asians to the development of insulin resistance, type-2 diabetes, and cardiovascular disease [19]. South Asians are physically less active [20] and also consume high carbohydrates and fat, along with fewer fruits and vegetables compared to other ethnic groups [21, 22]. In addition, Sri Lankan adults are also reported to have a higher body fat percentage, at a lower body mass index

(BMI) and waist circumference making them more prone to MetS [23].

As the prevalence of MetS is high and continuously rising in the Asian region and developing countries like Sri Lanka, it is suspected that the shift working pattern may worsen the risk for the disease. Although there is a plethora of literature on Western countries regarding different shift systems and their effect on employees' health, no prior research has been carried out in developing countries to identify the impact under local working conditions [24]. The present paper describes the study protocol for a comparative cross-sectional study which aims to determine the association between night shift work and MetS in a South Asian population and assess whether their lifestyle and body composition have an additional detrimental effect on the disease.

Objectives and hypothesis

Hypothesis: The main hypothesis derived for the study is that shift workers are more prone to MetS than regular day workers. Further, it is also hypothesized that lifestyle is associated with developing MetS among shift workers.

Objectives: The study's primary objective is to investigate the association between shift work and MetS in a selected work setting. The secondary objectives are to investigate the differences between anthropometry, body composition, and metabolic and biochemical profiles between shift workers and day workers.

Methods

Study design and setting

This study will be a comparative cross-sectional study to compare the prevalence of MetS between day workers and shift workers. It will be conducted at the Nawaloka Hospital, Colombo, Sri Lanka which is a leading tertiary care private healthcare institution in the country with 400-500 employees working on different working schedules. The two groups will be 1:1 age and sex-matched to investigate the association between the above-mentioned parameters.

Sample size

The sample size was calculated based on the literature on the prevalence of MetS among Sri Lankan adults [25], and the prevalence of MetS among daytime workers in prior studies. As the study population will mainly consist of young people mostly below the age of 40 years, a prevalence level of 15% is expected among daytime workers. The expected prevalence among shift workers is 45% [26]. The sample size calculation was done using the "OpenEpi Version 4.04.15" with a statistical power of 80% and maintaining the type one error (α) at 0.05. Therefore, the required sample size for each sub-group will be 37 and the total sample size will be 74.

Study population

Our study population will be regular day workers and shift workers at the Nawaloka Hospital, Colombo, Sri Lanka. The day workers will be the employees who generally work during daylight hours within the week and do not engage in any kind of night work. Shift workers are the ones who perform night duties and day duties rotationally. To be included in this study a shift worker should engage in at least 3-night shifts per week. Participants will be recruited voluntarily and written informed consent will be obtained from all study participants before the study. Details of inclusion and exclusion criteria are given below.

Inclusion and exclusion criteria

Inclusion criteria

- Age 18-65 years
- Being permanent employees
- Remained in the same shift schedule for at least 1 year
- Day workers should have not engaged in any type of night work for the last 1 year
- Shift workers should be working at least 3-night shifts per week

Exclusion criteria

- Pregnant and lactating mothers
- Having known chronic conditions such as cancers and renal diseases

- Had a history of any type of minor or major surgical procedure in the past 6 months
- Participating in healthy lifestyle programmes such as diet prescriptions and yoga class
- Heavy drinkers and smokers
- Any condition that, in the opinion of the primary investigator, would contraindicate the patient’s participation

Recruitment

The participants for the study will be recruited by circulating a standard email invitation among the staff of the hospital and also by invitations through department heads. If participants express interest, they can directly contact the principal investigator to take part in the study. The employees who are interested in taking part in the project will be given an appointment and will be invited to visit the study center in the hospital. Those who visit the study center will be given a self-administered baseline screening questionnaire to ensure their suitability for the study. After basic screening potentially suitable participants will be provided with a printed information package in their native language which will include a research participant information statement as well as consent and withdrawal of consent forms. If the potential participants indicate their agreement to take part in the study after having read these documents, they will be asked to sign the consent form. In addition, the participants will also be informed of their right to withdraw their consent at any time. Figure 1 shows a flow chart of the recruitment process.

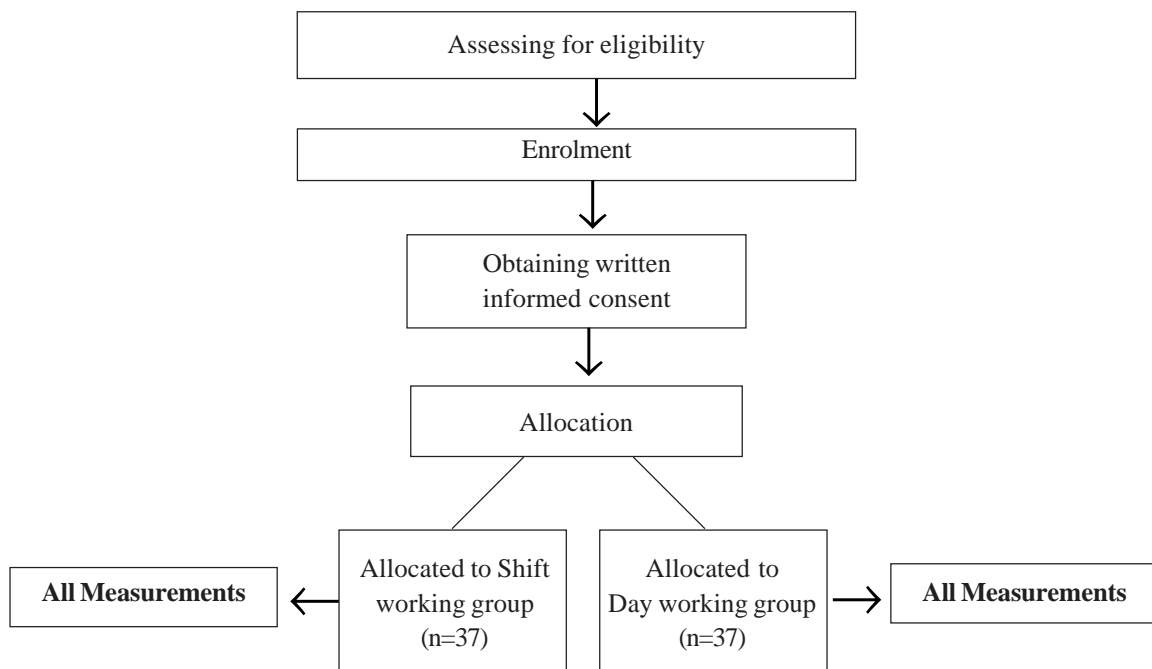


Figure 1. Flow chart of the recruitment process.

Sampling

First, the group of shift workers will be selected using a stratified random sampling technique. For selecting the shift work group, the shift working population will be first divided into subgroups (strata) based on gender and age. Then a random sample from each subgroup (stratum) will be taken in a number proportional to the stratum's size when compared to the population. These subsets of strata will be then pooled to form a random sample of shift workers. Later in the day working population, age, and sex-matched participants for the already selected shift work group will be assigned. Computer-generated random numbers will be used for randomization.

Study period

It is expected that the study will take a period of around 2 months.

Procedure

During the study period, the participants will be given a set of interviewer-administered questionnaires to collect information regarding demographic, lifestyle, medical history, work patterns, physical activity, sleep-related information, and dietary intake. Participants' anthropometric measurements, body composition, and blood pressure measurements will also be taken. For determining MetS, criteria defined by the International Diabetes Federation (IDF) will be used [27].

Outcomes and measures

Primary outcome: Prevalence of MetS in day workers and shift workers.

Secondary outcomes: Following variables will be measured in day workers and shift workers,

- i. Lipid profile – total cholesterol (TC), high-density lipoprotein (HDL) – cholesterol, low-density lipoprotein (LDL)-cholesterol, triglycerides (TG), and very low-density lipoprotein (VLDL)
- ii. Fasting plasma glucose and glycated haemoglobin (HbA1c)
- iii. Measurements of full blood count.
- iv. Systolic blood pressure (SBP) and diastolic blood pressure (DBP)
- v. Anthropometric measurements such as body weight, waist circumference, and hip circumference
- vi. Body composition parameters such as skin-fold thickness, fat mass, fat-free mass, and muscle function

In addition, level of physical activity (International Physical Activity Questionnaire-short form), dietary intake (validated Food Frequency Questionnaire) and sleep quality (Pittsburgh Sleep Quality Index) would be assessed in both groups as they are confounding factors affecting MetS.

Measurement Tools

Anthropometric measurements

Height will be measured using a calibrated stadiometer (Seca 213 portable stadiometer) to the nearest 0.1cm. Body weight is to be measured in light, indoor clothing to the nearest 0.1kg using a calibrated digital weighing scale (Seca 813, Hamburg, Germany). Waist circumference will be measured at midway between the iliac crest and the lower costal margin at the end of normal expiration using a nonelastic measuring tape (Seca 201, Germany) to the nearest 0.1cm. Similarly, the HC (hip circumference) will be measured at the widest part of the buttocks at the intertrochanteric level to the nearest 0.1cm. All anthropometric measurements will be made by trained personnel adhering to international recommendations.

Body composition

Total body water, percentage body fat, and fat-free mass will be assessed using a bio-electrical impedance analyzer (Bodystat, Douglas, Isle of Men, UK). The muscle function of the hand and forearm is to be measured using the handgrip dynamometer. Furthermore, body composition will also be assessed using a Harpenden skin fold calliper (British Indicators, West Sussex, UK) at the following sites: triceps and biceps [28]. All measurements are expected to be taken to the nearest 0.1mm by the same investigator to maintain consistency and inter-rater reliability. Each skin fold measurement will be taken in duplicate on the non-dominant side, and the average of two readings is to be recorded following the standard International Society for the Advancement of Kinanthropometry (ISAK) protocols using a consistent technique.

Metabolic and biochemical parameters

Blood pressure: The blood pressure of the subjects will be measured after five minutes of rest, with the back supported and the legs uncrossed. Constructive clothes will be removed from the upper arm, and it will be rested on a table at the heart level. Blood pressure will generally be recorded to the nearest 2 mmHg using digital blood pressure monitors (Omron Healthcare, Singapore). Optimal systolic and diastolic blood pressure will be considered as 120 mmHg and 80 mmHg respectively. Two blood pressure values will be collected using standard manometers and the average of those values will be considered the final blood pressure value.

Lipid profile, blood glucose, and full blood count: A venous blood sample of 10-12 ml will be collected from each participant after an overnight fast using 5cc and 3cc syringes and vacutainers. Serum glucose concentration, total cholesterol, triglycerides, and HDL-cholesterol will be determined using a Cobas c501 auto analyzer using an electro chemiluminescent immunoassay (ECLIA, Roche Diagnostics). LDL cholesterol will be determined using the Friedewald formula. A full blood count will be tested using the Sysmex XN-10 analyzer (Sysmex, Kobe, Japan). HbA1c will be evaluated by ion-exchange high-performance liquid chromatography. The investigations are to be carried out at an accredited laboratory.

Dietary measurements

A culturally validated Food Frequency Questionnaire (FFQ) will be used to obtain habitual intake of calories, macronutrients, and micronutrients [29].

Physical activity

Physical activity will be evaluated by using the International Physical Activity Questionnaire (IPAQ) long version.

Sleep quality

The validated Sinhala version of the Pittsburgh Sleep Quality Index (PSQI) for Sri Lankans [53] will be self-administered to participants to assess their sleep quality during the previous month.

Other information

In addition to the above parameters, participants' demographic, lifestyle characteristics, family history, occupational, and medical history will also be evaluated as potential confounding variables

Statistical analysis

The data will be entered by a minimum number of dedicated staff and saved in a computer with password protection and will be analyzed using SPSS (version 23.0; SPSS, Inc., Chicago, IL, USA). Shift work and day work participants will be compared with each other with regards to their demographic, occupational characteristics, and health-associated behaviours using the independent sample t-test, Chi-square, and Fisher's exact tests, as appropriate. Distributions of continuous variables will be tested for normality using the Kolmogorov-Smirnov test. The non-parametric Mann-Whitney U test will be used for asymmetrical continuous variables. Furthermore, logistic regression analysis is proposed to be performed to determine the effect of shift work on the odds of MetS following adjustments for the effects of potential confounders.

Data management and monitoring

Any data collected as part of this research project will be stored securely as per the Queensland University of Technology (QUT) management of research data policy. Data and documents will be locked and secured for 5 years, under the supervision of the principal investigator. Simultaneously, softcopies will be kept password protected for the above-prescribed period. Following the completion of the due period, the documents will be shredded and the softcopies will be permanently deleted. All samples are to be used up for the mentioned laboratory assessments and the remainder will be discarded under standard protocol while maintaining safety standards.

Dissemination of study findings

The results of the above study will be published in local and international, peer-reviewed journals and presented at international conferences and clinical meetings.

Ethical considerations

The study has been approved by the Ethics Review Committee of the Faculty of Medicine, University of Colombo, Sri Lanka (EC-20-066) and the Queensland University of Technology (QUT) Human Research Ethics Committee (UHREC Ref. no: 2000000831). Any change in the study protocol will be notified to the relevant regulatory authorities and study participants, with re-consent being taken from participants if required.

Discussion

Night-shift work is known to cause major disturbances in a worker's circadian rhythm, which is associated with the onset of several health problems and diseases including MetS [30]. This article presents a comparative cross-sectional study design to investigate the association between shift working behaviour and MetS. Although similar studies have been carried out in developed countries regarding different shift systems and their effect on employee health, no prior research has been carried out in developing countries to identify the impact under local working conditions. Therefore, to the best of our knowledge, this is one of the first cross-sectional studies evaluating the association between shift working and the risk of MetS among Sri Lankan workers.

This cross-sectional study design and comprehensive approach will help to address the current research gap regarding the relationship between night-shift work and MetS among shift workers and regular day workers. Based on the findings of the current study, different strategies to overcome the negative health effects of night-shift work could be developed. In fact, if the findings indicate that

shift work significantly increases the risk of developing the MetS, necessary adjustments to their work schedules could be made by reducing the frequency or duration of night work. Subsequently, additional lifestyle interventions could be imposed to improve their health [31]. In addition, these work schedule modifications would eventually lead to a reduction of the burden of health care costs and minimize the negative impacts on productivity.

According to prior studies increased age, lifestyle, physical inactivity, specific job role, and shift work all have an influence on MetS [32]. Several studies have investigated the association between MetS and physical activity. Some studies have indicated little or no difference in physical activity levels between day and night workers [33], whereas others have discovered that night workers exercise more than day workers [34]. Moderate to vigorous physical activity has been proven to minimize the incidence of MetS in a study of a European population [35]. Since the physical activity levels and other lifestyle variables are known confounders between shift work and MetS, these variables will be measured using questionnaires during this study. Later the confounding variables are to be included in the analysis to interpret the results accordingly.

The present study will also provide the required foundation for future, large-scale, multi-centered studies to investigate the risk of other chronic diseases and the health status of workers engaged in different shift schedules. Furthermore, the study results could be a starting point for the development of interventions that prevent negative health effects caused by night-shift work. In addition, the findings of the study might be useful in designing shift schedules and also in developing occupational health policies.

Trial status

Enrolment for the trial has not yet started (scheduled date – 1st July 2021).

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None.

Ethics clearance

The study has been approved by the Ethics Review Committee of the Faculty of Medicine, University of Colombo, Sri Lanka (EC-20-066) and the Queensland University of Technology (QUT) Human Research Ethics Committee (UHREC Ref. no: 2000000831).

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