



ASSOCIATION OF ADIPOSITY INDICES AND SPIROMETRY PARAMETERS AMONG OVERWEIGHT AND OBESE ADULTS IN THE COMMUNITY: A CROSS-SECTIONAL COMMUNITY-BASED STUDY PROTOCOL

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Abstract

Background: The prevalence of adiposity among children and adults in India is a long standing epidemic. The adverse effects of excessive fat accumulation is extensively reported for many non-communicable diseases in India. Yet, the empirical evidence of pulmonary impairment among non-smoking overweight and/or obese adults is overseen.

Objectives: This study seeks to investigate the proportional relation-ship between the pulmonary function parameters and degree of adiposity indices among non-smoking community dwelling adults living in Chennai city. Further, the burden of pulmonary impairment, and gender difference will be established.

Methods: The research will be conducted in three phases: the initial phase will be conduction of scoping review to map the evidence of obesity distribution in South India, the second phase will be conducting a cross-sectional study to determine the burden of pulmonary impairment among obese adults and assess the relation-ship between the lung function parameters and degree of obesity, the final phase is to develop a home-based intervention strategy and delivery system to improve or restore the pulmonary function among obese adults with lung impairment. This protocol explains the proposed template to conduct a community-based cross-sectional study among the selected households from the selected division of the Chennai city. The adult participants with BMI > 25 kg/m² will be selected based on the systematic random sampling method from the selected households. Data collection tool consist of; socio-demographic data, physical measurements (BMI, AC, WHtR, and WHR,) and pulmonary parameters using spirometry.

Ethics and dissemination: This protocol was approved by the Institutional human ethics committee (DHR reg no: EC/New/INST/2021/2220), Meenakshi Medical College Hospital and Research Institute (MMCHRI), and approval for conduction was obtained (Ref no MMCH& RI IEC/Faculty/01June/2022) and prospectively registered in the Clinical Trial Registry of India (CTRI/2022/04/042313). The results will be presented in the Chennai regional, national, international conferences and the findings will be published in peer-reviewed journals.

Results: The findings will be described using mean, frequency distributions, SD, and percentages with 95% CI adjusted for age, the distributions of socio-demographic characteristics, anthropometric measures and cardio-metabolic of the study population by cross tabulation and independent t-test across gender. Pearson's chi-square will be used to evaluate the difference between a categorical variable and age-adjusted. One-way ANOVA will be used to compare continuous variables. Pearson's correlation test will be done to measure the association between anthropometric measures (BMI, WC, WHtR & WHR), age, and spirometry parameters (Fev1, FVC, Fev1/FVC, PEF). Age controlled bivariate analyses will be conducted with the dependent variables and independent variables then will be taken to multivariate analysis model based on assumptions. Statistical significance will be at a p-value of 0.05.

Discussion: This study will provide an insight into the overall relationship and discrete associations between the anthropometric indices and spirometry parameter among the non-smoking adults in Chennai.

Keywords: Obesity, Pulmonary function, Non-smokers, Spirometry

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1. Introduction

The undesirable effects of excessive body fat accumulation leading to chronic diseases particularly cardiovascular and metabolic diseases is known. Contemporary literature demonstrated that excessive bodily fat could have adverse effects on ventilatory functions leading to gradual pulmonary impairments. Some research work has utilized body mass index (BMI) and body weight as indicators of adiposity; a clear association between these indicators and ventilatory function exists only in individuals with a very high body weight or BMI (Jones and Nzekwu, 2006, Thyagarajan et al., 2008). Other studies (Cotes et al., 2001; Lazarus et al., 1997; Lazarus et al., 1998; OchsBalcom et al., 2006) estimated body fat using different anthropometric measures, the most common being waist circumference (WC) and waist-to-hip ratio (WHR), which are estimates of the accumulated fat in the abdominal region. Recent studies have reported that globally, more than 1.9 billion adults are overweight and 650 million are obese. Approximately 2.8 million deaths are reported as a result of being overweight or obese. Due to the consumption of energy dense food (i.e. unhealthy food habits), sedentary life style, lack of health care services and financial support, the developing countries are facing high risk of obesity and their adverse consequences (i.e. diabetes, ischemic heart disease, etc).

In India, more than 135 million individuals were affected by obesity. The prevalence of obesity in India varies due to age, gender, geographical environment, socio-economic status, etc. According to ICMR-INDIA-B study 2015, prevalence rate of obesity and central obesity are varies from 11.8% to 31.3% and 16.9%–36.3% respectively. In India, abdominal obesity is one of the major risk factors for cardiovascular disease (CVDs) [4]. According to the Global Burden of Diseases (GBD) WHO reporting poor health outcomes/all-cause mortality due to obesity and the authors reported that worldwide, at least 2.8 million people die each year as a result of being overweight or obese, and an estimated 35.8 million (2.3%) of global DALYs are caused by overweight or obesity. In 2015, 13.8% of men and 16.8% of women in the world were obese (with a BMI ≥ 30 kg/m²), compared with 4.8% for men and 7.9% for women in 1980. An estimated 205 million men and 297 million women over the age of 20 were obese in 2008 – a total of more than 500 million adults worldwide. In India, more than 135 million individuals were affected by obesity.

The prevalence of obesity in India varies due to age, gender, geographical environment, socio-economic status, etc. A systematic review of prevalence of obesity in India by Rajeev Ahirwar et al 2018, NCD risk factor surveillance reported that the obesity in South India were higher (i.e. 27.2%) followed by North India (i.e. 23.8%) and lowest in West India (i.e. 15%)

Though, the burden of obesity, risk, and factors in particular (CVDs and metabolic disorders) associated with fat accumulation is extensively reported. There is lack of methodological reliable empirical data related to the association and magnitude of relationship between the various measures of central adiposity and pulmonary impairments. Hence, this study aims to measure the central adiposity defined by waist circumference, waist-height ratio, waist-hip ratio, BMI, and pulmonary function defined by spirometry parameters and chest expansion measure, further identify the relationship between the measures.

Objective of the study:

The objective of this study is to establish the association of adiposity related anthropometric indices (WC, WHtR, WHC, and BMI) on the pulmonary function related parameters (measured by spirometry: Fev1, FVC) among the non-smoking overweight and obese adults in Chennai. The additional objective will be to determine the sex difference of the above stated relation-ship.

2. Methods

A cross-sectional design will be conducted to investigate the proposed objective and the proposal was presented to the Institutional human ethics committee (DHR reg no: EC/New/INST/2021/2220), Meenakshi Medical College Hospital and Research Institute (MMCHRI), and approval for conduction was obtained (Ref no MMCH& RI IEC/Faculty/01June/2022). The study protocol was prospectively registered in the Clinical Trial Registry of India (CTRI/2022/04/042313).

Inclusion and Exclusion criteria:

Adult participants who are permanent resident of the selected study area, aged > 18 years with no current or past smoking habit. Subject will be excluded in case of known or diagnosed COPD, asthma, facial paralysis, active respiratory infections, stroke, coronary artery diseases, congestive heart failures, and malignancy. Adults with diagnosed neuro-muscular disorders, known

thoracic deformity, nasal cleft, and those under weight loss program will be excluded. Pregnancy women and people undergoing dental interventions will be excluded. In addition, participants will be

excluded from spirometric testing if they answer positively to any of the spirometry safety exclusion questions mentioned below;

	Screening items for exclusion
1	Current painful ear infections
2	Eye surgery in the last 4 months
3	Chest/abdominal surgeries
4	Recent chest infection/Inclusive of TB/exposure
5	History of aneurysm/chest trauma/lung injuries
6	Stroke/TIA/chest pain in the past 3 months
7	History of cough/sputum/expectoration of blood from nose/mouth

Operational definition for overweight or obese is based on the International Diabetic Federation (IDF), WHO/International Society of Hypertension guidelines and American Diabetic Association (ADA). General obesity was defined as BMI ≥ 25 kg/m², central obesity was defined using Euroid values; waist circumference (WC) of ≥ 94 cm (men), ≥ 80 cm (women), waist-height ratio (WHtR) of ≥ 0.50 and waist-hip ratio (WHR) of ≥ 0.90 for men, ≥ 0.85 for women will be defined as overweight (low risk as per central obesity) or obese (moderate or high risk as per central obesity). Considering the prevalence of the recent pandemic and concern over sample availability, we intend to include participants with post-covid infection after 6 months of infection.

Reporting guidelines:

This study will be reported as per the (STROBE) Strengthening the Reporting of Observational Studies in Epidemiology guidelines for observational studies [5].

Study design, source population, study setting, and period

A community-based cross-sectional study will be conducted during the proposed study period from April to July 2022 in Chennai city. The city has the highest population in the state with a population density of 26553 person/sq.km. According to the administrative set-up census India 2011-2022 data Chennai city has 155 divisions in 10 zones. All the obese and overweight adult male and female aged 18 – 60 years, permanent residents in the households of zone IX (Zone selected purposively since the institution MAHER is located), division 128 (K.K nagar), Chennai will be considered as source population [6]. (https://censusindia.gov.in/2011census/dchb/3302_PART_B_DCHB_CHENNAI.pdf).

Sample size determination and sampling

A single population proportion formula will be used to estimate the power calculated sample. Since, there are no similar study in reported among this population in Chennai, 50% expected prevalence will be considered. The following assumptions for infinite population [7] will be used: 95% confidence interval, ($Z_{\alpha/2} = 1.96$), 50% P, and 5% margin of error. A design effect of 1.5 will be used. The derived sample size was 576. Adding 10% non-response rate, the final sample size was 636.

$$n = (1.96)^2 (0.5) (0.5) / 0.0025, n = 384$$

$$\text{Design effect} = \text{multiply by } 1.5 = 384 \times 1.5 = 576$$

Sampling procedure:

Among the 10 zones and 155 division in the Chennai city, division 136 of zone IX will be selected purposively. Based on the data secured from the Directorate of Census Operations, Tamil Nadu (dco-tam.rgi@censusindia.gov.in) division 155 will be stratified into ward (administrative block), among the randomly selected wards, in the streets of the selected wards a systematic random sampling (after deriving K^{th}) will be used to select the households, a lottery method will be used to decide the participants in case of more than one presence (Figure 01).

Data collection and procedure

Prior to data collection, the proposal will be officially presented to the MAHER ethical review board and approval will be secured. Written informed consent will be obtained from the participants before data collection. A structured questionnaire will be used to collect socio-demographic, behavioural, physical, and clinical characteristics of the participants. The digital weighing scale will be used to measure weight to the nearest 0.1 kg in light indoor clothing and bare feet or with socks. Height was measured using a portable Stadiometer to the nearest 0.1 cm with the

participants standing erect posture, without shoes. Waist circumference was measured by placing a non-elastic plastic tape to the nearest 0.1 cm, horizontally midway between the 12th rib and iliac crest on the mid-axillary line using a stretch-resistant tape. Hip circumference will be measured at the level of greater trochanter [8]. Chest circumference will be measured using a non-elastic tape at the nipple level, axilla level, and the xiphoid level using the standard measurement procedure recommended by the American Lung association. Blood pressure measurements will be measured using appropriate arm cuff fitted on the left arm of participants using Omron (Hem 7120) automated BP machine after rest of 10 min in a seated position. Measurements will be done in triplicates at three-minute intervals. The mean of three readings of the diastolic blood pressure (DBP), systolic blood pressure (SBP) and heart rate (HR) will be calculated. A pulmonary function (hand held SPIROMETRY) test will be performed. Prior to the testing, participants' age, weight and height were computed into the device. The participants will be made to sit in an upright position and rested for at least 5 min prior to test, a nose clip will be used and the test will be conducted as per device protocol. The parameters assessed by the device are; the forced expiratory volume in 1 s (FEV₁), forced vital capacity (FVC), the peak expiratory flow (PEF), forced expiratory volume 25–75% interquartile (FEV₂₅₋₇₅) and ratio of FEV₁ to FVC (FEV₁/FVC) calculated. After measurement, the best three acceptable readings will be recorded and the mean calculated. The device will be disinfected after every participant and the mouthpiece replaced. To obtain a successful completion of each spirometry, the recommended protocol of ATS/ERS will be followed [9]. Safety considerations, hygiene procedure recommended by American Lung Association, to conduct spirometry during covid pandemic will be followed

Recruitment procedure:

The selected household will be approached to look for eligible participant and in case more than one participant, a random lottery method will be used to select one. If there is no eligible participant in the selected household, the immediate next house will be approached until an eligible candidate found. From there the next Kth household will be approached.

Data analysis

The data from questionnaire and the outcome measure metrics will be linked with identification numbers of the participants. Data will be entered into the Epi-info 7.0 version for windows (The Epi Info, Centres for Disease Control and Prevention, Division of Health informatics & surveillance (DHIS), The United States of America). Subsequently, the data will be exported to SPSS version 20.0 (IBM Statistical Package for Social Sciences) for windows. Access to the data will be limited to the investigators and no participant identifiers will be included in the database.

Overview of data analysis: The descriptive statistics will be used for frequency distribution, cross-tabulation tables, and graphs. Inferential statistics for the relationship/association between the proportion of pulmonary parameters and degree of obesity for all the anthropometric indices by means of the Pearson's and/or the Spearman's correlation based the normality test findings of the data distribution. Student-t test, Anova test, and Chi-square test (for categorical variables) for testing the hypothesis. A forward step-wise logistic regression model for the critical analysis of risk factors.

Expected outcome:

Based on our literature dissection of evidences, we strongly believe that the adiposity and interaction of other independent variables will have a detrimental influence on the spirometry parameters. Particularly FEV₁/FVC and PEF. Further, we also expect a meaningful difference in the relationship of anthropometric and spirometry measure between genders.

Declarations

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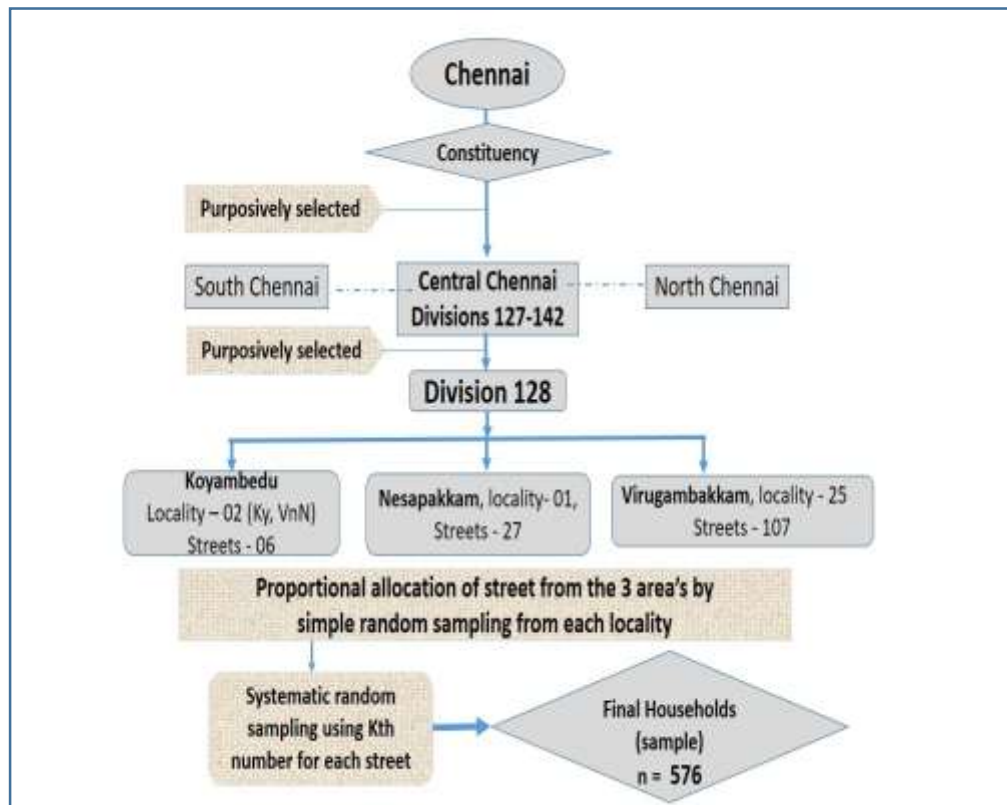
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Consent for publication: Not applicable
Legend 01

Figure 1. Proposed Schematic presentation of sampling procedur



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