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The Prevalence of Obesity among Subjects with Chronic Kidney Disease – Cross Sectional Study of Sri Lanka Population

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Abstract

Background: The burden of chronic kidney disease (CKD) is growing rapidly around the world, particularly in Asia. Over the last two decades Sri Lanka has experienced an epidemic of CKD, especially in the "Mahaweli" river basin in North Central region of the island that was not attributable to conventional risk factors - hence widely termed "CKD-unknown". Similarly, obesity in the region also noted to increase but no formal study explored the obesity burden or its association with increasing CKD in the region.

Method: We will conduct an area wide cross sectional survey among all adult residents of the "Mahaweli" development project area C (Girandurukotte), in the North Central Province of Sri Lanka. We will collect relevant demographic and socio-economic data, medical history, anthropometric measurements, blood and urine for haematological and biochemical analysis. We will calculate prevalence of chronic kidney disease (overall and by CKD stage) and obesity using total number of participants as the denominator. The association of obesity and CKD will be assessed with regression models and adjusted for potential confounding factors and stratified by potential effect modifiers where appropriate.

Results: This study will provide accurate information on the prevalence of obesity and CKD in the region. Furthermore, this will explore the association between obesity and CKD, although causation may not be confirmed.

Conclusion: Obesity and CKD are increasingly recognised as major public health problems in Sri Lanka. Our study will provide vital information enabling the government to plan a coordinated response to tackle both obesity and CKD in the region.

Keywords: BMI; Chronic Kidney Disease; Obesity; Sri Lanka

Background

The chronic kidney disease (CKD) is common and increasing worldwide [1,2]. This has become an important health problem in the developing world, particularly in Asia [3]. Over the last two decades Sri Lanka has experienced an epidemic of CKD with ever growing number of patients pursuing medical care due to CKD as well as CKD related deaths, especially in the "Mahaweli" river basin in North Central region of the island nation [4-6].

This was apparently a new form of CKD which was not attributable to conventional risk factors such as diabetes mellitus, hypertension or infection and widely termed as "CKD-unknown" or "CKDu". In the past decade a number of small scale studies were conducted to determine the aetiology, prevalence and complications of CKDu in North Central region [5,7-11]. These hospital-based studies did not provide an accurate estimate of the problem as merely 10% or less of the people with CKD are aware of their diagnosis even in developed countries with better access to medical care [12]. A population based cross sectional survey conducted in 2010-2011 reported a point prevalence of CKDu to be 2-3% in this region [5]. A later survey in the same endemic region by Jayathilaka and colleagues reported an age standardised prevalence of CKDu of 12.9% for men and 16.9% for women [13]. Nonetheless, a well-designed population based cross sectional survey identifying the prevalence of CKD from all causes, not just due to CKDu, has not been conducted to date.

Multiple aetiological factors have been postulated for CKDu including chronic exposure to Cadmium, Lead, Arsenic and Ochratoxin-A through food chain [8, 9,13-16]. However, increasing CKDu may be multifactorial and obesity may also be a contributing factor - that has not been systematically studied to date [17].

CKD is detrimental, may be progressive and can lead to end-stage kidney disease (ESKD) requiring dialysis or a renal transplantation for survival. Individuals with CKD have a reduced life expectancy, and those who progress to ESKD have 20-fold higher mortality rates compared with age- and sex-matched individuals with normal kidney function [18,19]. However, if detected early and managed properly, then the otherwise inevitable deterioration in kidney function can be reduced by as much as 50% and may even be reversed, and lead to cost savings [20-22]. Therefore, it is important to recognise the magnitude of the public health problem, its aetiology, and available resources and plan appropriate response.

Aims of the Project

1. Describe the prevalence of CKD overall and by stage in "Mahaweli" development project area C (Girandurukotte), in the North Central Province (NCP) of Sri Lanka

2. Document the prevalence of renal replacement therapy (RRT) overall and by modality in "Mahaweli" development project "Area C (Girandurukotte)", in the NCP of Sri Lanka

3. Describe prevalence of obesity in the same area and assess the association between CKD and obesity

Significance of the Project

CKD and ESKD are increasingly recognised as major public health problems in the NCP of Sri Lanka. Number of premature deaths in ESKD patients due to lack of access to RRT are also on the rise in this region. Clearly, documenting the magnitude of the problem as well as the availability of its treatment in the region is the essential first step in developing appropriate response to the threat. Our study will provide this vital information enabling the government to plan a coordinated response. The innovative models of delivering preventive care can be organised, especially in rural areas where access to physicians is low. If obesity remains a substantial problem in the region, effective population based approaches to prevention and treatment of obesity may be implemented as part of the wider CKD prevention programmes. Government can be made aware of the number of preventable deaths and must be lobbied to increase access to dialysis for affected individuals where this is affordable in the context of the broader health needs of the population.

Detailed Research Plan

Study population

The location: "*Mahaweli*" *development project area C* (*Girandurukotte*), *in the North Central Province of Sri Lanka*

"Mahaweli" river basin development project in 1969-80 was the largest multi-purpose development project conducted in Sri Lanka to date with a view to establish a controlled irrigation system and increase the area of paddy cultivation, manage flood waters, hydro-electricity generation and develop new townships for farmers.

The area C (Girandurukotte) is a purpose built planned township in the river basin and it's relatively isolated, hence this area has a stable population which is ethnically homogeneous. The houses were built alongside 6 roads, each extending from the town centre to periphery, close to each other leading to relatively higher population density in the area. Area C (Girandurukotte) has a health centre, a public school, a Buddhist temple, a local government agent's office and a playground as public facilities. According to the national census in 2012, 2214 adults (51.2% females) were living in 723 households in area C (Girandurukotte) (http://www.statistics.gov.lk/). Both health centre and local government agent's office have a proper record keeping system and have kept up-to-date information about the residents from the inception of this township, making it easier to conduct a reliable study. These records showed that the number of residents diagnosed with CKD was gradually rising over last two decades with the highest increase over last five years; however the actual CKD prevalence in the region remains unknown.

We selected "Mahaweli" development project area C (Girandurukotte) since this population is equally affected by CKD as rest of "Mahaweli' river basin. Moreover, the area C (Girandurukotte) has a small land size, easily accessible dense stable population and reliable demographic data.

Target population: We will include all non-institutionalised subjects (18 years or older on 01/01/2017) permanently living in "Mahaweli" development project area C (Giradurukotte). The permanent residency status will be confirmed against the records at the government agent's office and the electoral records. Any person younger than 18 years, visiting or temporary residing in the area at the time of survey will be excluded.

Study design

We will conduct an area wide population based cross sectional survey. Allowing for non-compliance with request to participate, we expect to survey about 2000 participants in 650-700 households from 01st to 31st of January 2017.

Outcome definitions

We will define CKD as reduced estimated glomerular filtration rate (eGFR) and/or presence of proteinuria. CKD will be classified according to National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) guidelines [23]. Renal replacement therapy will be defined as receiving any form of maintenance dialysis or with a functioning renal transplant. Obesity will be defined and classified based on body mass index (BMI) according to World Health Organization classification [24].

The following definitions will be used where applicable:

Proteinuria – albumin/creatinine ratio >2.5mg/mmol (male) and >3.5mg/mmol (females)

Haematuria – presence of >10 red blood cells per high power field

Anaemia – serum haemoglobin <100 g/l or on Erythropoietin stimulating agents

Hypocalcaemia – serum total calcium of < 2.2 mmol/l

Hyperphosphatemia – serum phosphate >1.5 mmol/l

Body mass index – body weight/height^2 kg/m^2

Conduct of survey

We will recruit and train 30 data collectors at Hector Kobbekaduwa Agrarian Research and Training Institute, Colombo, Sri Lanka. A data collector will visit each household to record the number of eligible adults, inform residents about the survey and request them to participate (contacting through telephone is not reliable as this facility is not widely available). We will provide with information leaflets and contact details of the data collector if further information is required. If subjects tentatively consent to participate, an appointment will be made in one of the clinic days convenient to them but the formal consent will not be made at this point. We will encourage them to come along with all adults (18 years or older) in the household to the clinic. Repeated visits will be made to contact if not contacted during initial visit (up to a maximum of 3 attempts). On failing to contact after 3 visits alternate methods will be used (ie. through the temple, neighbours or health centre etc.).

Data collection and management: We will organise 10 full day clinics over January 2017 at the health centre in area C (Girandurukotte) to review and collect pathology samples from participants.

At the clinic each participant will be consented formally and sign a formal consent form. A trained data collector will conduct the clinical interview using an interviewer administered questioner. Study investigators will take turns to monitor data collection process to ensure uniformity and highest standard.

For each participant following data will be collected:

- Demographic and clinical data (age, sex, weight, height, waist circumference, comorbidities, medications etc.)
- Socio- economic data (education, income, occupation, race etc.)
- Use of RRT and type (haemodialysis, peritoneal dialysis or renal transplant)
- Smoking status
- Clinic blood pressure (3 measurements 5-10 minutes apart)

For each participant following pathology samples will be collected:

- A mid-stream urine sample
- A trained nurse will draw a peripheral blood sample (about 10ml)

Validation procedures: All pathology samples will be analysed at a central laboratory. Samples will be stored under appropriate conditions in the field until transferred to the central laboratory at a leading Private Hospital in Colombo, Sri Lanka.

Serum creatinine, haemoglobin, calcium, phosphate, albumin and HbA1c will be reported for each blood sample. Analysing serum parathyroid hormone level is not feasible due to high cost. Serum creatinine will be measured using Integra 800 analyser by Roche Diagnostics, Mannheim, Germany and the GFR will be estimated using CKD-EPI formula [25]. The albumin/creatinine ratio and haematuria will be reported for each urine sample.

Confidentiality: All data collected for this study will be kept in a single secure database at Hector Kobbekaduwa Agrarian Research and Training Institute, Colombo, Sri Lanka. Individual data collectors will enter data from their questioners to the central database at the end of each clinic day. The completed questioners will be kept under the care of the principal investigator. Study investigators will receive pathology results and enter these to the central database. Excess blood and urine after analysis will be incinerated at the central laboratory. Only the study investigators, not the individual data collectors, will have full access to the database. The participants will be notified about their pathology results in person at the health centre.

Data analysis

The total eligible participants will be calculated using data recorded by data collectors at their initial home visits, electoral records and the records kept at the government agent's office. We expect a participation rate of up to 75-85% of all eligible participants. All continuous variables will be used in numerical form and non-continuous variables will be used in categorical form for analysis. The baseline characteristics will be described as mean and standard deviation for continuous variables (age, weight, BMI) and as percentage for categorical variables (diabetes, smoking, and obesity - BMI > 30 kg/m^2).

Primary analysis: We will calculate the prevalence of chronic kidney disease overall and by CKD stage using total number of participants as the denominator and report per 1000 population. If adequate number of individuals are identified, the prevalence of renal replacement therapy (overall and by modality) will also be calculated using total number of participants as the denominator.

We will also calculate the prevalence of obesity (BMI > 30 kg/m^2) using total number of participants as the denominator and report per 1000 population. The association of BMI and serum creatinine (as continuous variables) and, obesity and CKD (as categorical variables) will be assessed with regression models.

Secondary analysis: Prevalence of diabetes based on HbA1c criteria [26], proteinuria, haematuria, and complications of CKD such as anaemia, hypocalcaemia, and hyperphosphatemia will be calculated using total number of participants as the denominator and report per 1000 population. The association of BMI, HbA1C and serum creatinine will be tested with regression models.

Both primary and secondary analyses will be adjusted for potential confounding factors and stratified by potential effect modifiers where appropriate. All analyses will be performed with STATA, version 14 (Stata, College Station, Texas).

Study milestones

The study of milestones has been shown in a tabular form (Table 1).

Milestone	Date
First face to face meeting of key collaborators	November 2016
Data Collection	January 2017
Second face to face meeting	February 2017
Data analysis	February 2017
Drafting of manuscripts and report	March-April 2017
Third face to face meeting	April 2017
Manuscript submission	April-May 2017

Table 1: Proposed Study Milestones

Study reporting and publications

All reports from this project will be sent to all collaborating investigators for comments and approval. The results of the study will be disseminated by manuscripts in peer-reviewed publications in the fields of General Medicine, Obesity and Nephrology and by presentations at national and international meetings.

Ethical implications

Application will be made to ethical committee of the Ministry of Health, Government of Sri Lanka.

Participation in the study is voluntary, there will be no incentives provided for participation. Individual patient's valid informed written consent will be obtained prior to participation in the study. Individual patient identifiable information will not be released to any third party.

In addition to providing an accurate health assessment to individual participants, this study will deliver comprehensive up to date information on the magnitude of problem as well as the role of obesity as an aetiological factor in CKD. These benefits clearly outweigh the minimal risk involved with the study.

Appendix

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