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Miscellaneous

Community Medicine Section

Life Course Socioeconomic Transition and its Association with Early Onset Type 2 Diabetes: Protocol for a Sequential Exploratory Mixed Method Study

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ABSTRACT

Introduction: The prevalence of early onset type 2 diabetes (Diabetes below the age of 45 years) is increasing worldwide. Transition in socio-economic position–i.e. Life Course Socio-Economic Transition (LSET) - may contribute to the development of early onset T2D through complex processes involving economic and occupational opportunities as well as individual life style choices.

Aim: To develop and validate the life course socioeconomic transition questionnaire and to know the association between life courses socioeconomic transition and early onset type 2 diabetes.

Materials and Methods: This study follows sequential exploratory mixed method study design. It consists of one qualitative strand followed by two quantitative strands. Qualitative strand consist of in- depth interview among the community dwellers to develop a tool for measuring LSET. Two quantitative strands consist of the validation of the questionnaire by conducting cross-sectional survey among 200 randomly selected community dwellers and a hospital based case control study using the same questionnaire.

Results: Those who have a history of lower SEP during his childhood period and enjoying higher SEP during his adulthood period have an increased risk for developing type 2 diabetes at their younger age (18-45 years).

Conclusion: This study will help to develop a validated life course socioeconomic transition questionnaire and application of that tool in an epidemiological study.

Keywords: Case-control, Questionnaire, Socioeconomic position, Validation

INTRODUCTION

Early onset Type 2 Diabetes (T2D) (onset of type 2 diabetes before the age of 45 years) can create a big impact on the population's health. To search for the determinants of T2D we may have to look beyond traditional risk factors, e.g., sedentary behaviour, obesity and unhealthy diet [1,2]. Transitions in Socioeconomic Position (SEP) of an individual may be an example of such a determinant. SEP is a powerful determinant of the likelihood of health damaging exposures and of the possession of particular health enhancing resources [3]. An individual's SEP is dynamic from his/her birth to death, i.e., it may change. The dynamic nature of an individual's SEP can be measured by using a life course approach [4]. We can divide the life epochs of an individual broadly into childhood and adulthood. A number of life course studies have used a single indicator of SEP in each life epoch. India has complex social system and the existence of informal economy demands the use of multiple SEP indicators at each life epoch [5-7].

Various theoretical models have looked at the effect of SEP on health. All these models try to explain the effect of the cumulative nature of SEP or SEP at specific life epochs on health. Social mobility model, which talks about the progress of an individual's social position through his/her lifetime, is an exception; this may be more relevant to the study of health in developing countries [8-10]. Migration of the family member to either other states or abroad will result in sudden changes in the socioeconomic background of a household/ individual. Most of the lifestyle choices are decided by the SEP of an individual; so the change in SEP can lead to change in life choices, which may result in lifestyle diseases [11]. There are a number of studies on the prospective association between SEP and T2D; however, the link between changes in SEP- which we can call SEP transition- and T2D remains comparatively unexplored.

Relevance of study setting

Kerala state in India has a high Human Development Index (HDI), close to many more developed countries [12]. Rural Kerala has undergone a drastic change in living standards and lifestyles in the span of 20-25years on account of influx of money in recent years from people working abroad, mainly in Gulf countries [13]. The newly aroused affluent community may have high risk for developing lifestyle diseases like type 2 diabetes. The impact of sudden affluence on different social classes and its associated risk of developing life style diseases are largely remaining unexplored. Pandalam in Alapuzha district is a best example for this scenario. The younger adults from this rural area are migrating to either Middle East countries or European countries for employment. This has brought in drastic changes in the socioeconomic background of the household and lifestyle of the family members at home over a short span of time [14]. The prevalence of early onset T2D in this area was 4% in a cross-sectional survey conducted in 1996 [15].

Rationale for the study design

In order to link life course socio-economic transition to the onset of T2D, we need qualitative research to elaborate the concept of 'life course socioeconomic transition'. We should then strive to identify the markers of socioeconomic transition of an individual, through developing and validating a tool (questionnaire). This tool is then to be applied in a quantitative study to measure socio-economic transition in individuals and link it to health outcomes.

1. Define the life course socioeconomic transition of an individual.
2. Develop a questionnaire to measure the life course socioeconomic transition.

3. Validate LSET questionnaire among the healthy individuals between the age strata of 18-45 year.
4. Explore the association between life course socioeconomic transition and early onset type 2 diabetes.

MATERIALS AND METHODS

This study is sequential exploratory mixed method study with three strands [Table/Fig-1]. The first strand involves developing a questionnaire to measure the life course socioeconomic transition of individuals between the age group of 18-45 years. For this, we propose to start with in-depth interview among the residents of Kerala and the experts in social epidemiology, to define the construct of 'life course socio-economic transition' and develop a tool to measure it.

Strand 1 Development phase of the questionnaire	Strand 2 Validation phase	Strand 3 Hospital based case control study
• Indepth interview among the commuity residents and experts • Developing themes • Creation of an intempol	• Translational validity • Construct validity	• Administering the questionnaire to cases and controls • Check any associate on between life course SEP and early onset type 2 diabetes

[Table/Fig-1]: Outline of the study.

I Qualitative strand (Phase 1)

The approach used for sampling in this phase will be purposeful sampling procedure. The researcher will invite the individuals between the age group of 18-45 years among the community dwellers of Kerala. Researcher will include maximum individuals to get the maximum representation from the various districts of Kerala. After giving participant information sheet and getting the consent from the participant, researcher will fix the time and location of the interviews. The number of participants will be decided by data saturation. Define the construct LSET based on the available literature and in-depth interview among the experts in social epidemiology and community dwellers. Community dwellers will be the residents of Kerala from the birth itself and belongs to the age group of 18-45 years. This step is due to the absence of a well-accepted single definition of the construct in Indian context. Initial item pool will be created by the process of literature review and in-depth interview among the community dwellers. The in-depth interviews among community dwellers (residents of Kerala) will help to identify the possible markers of LSET and converting them to items which can then become part of the questionnaire.

Ia) Data analysis

Qualitative data will be analyzed using theme development procedure and data management conducted using the software of WEFT. We will record all interviews and audio files of the interview will be transcribed. Then the researcher will examine the content and extract the face and latent themes. Each transcribed words will be considered as a unit of analysis. The codes also help in the formation of themes. As the interviews progress and the relationships among the themes emerge it will help to identify the markers of LSET. Findings of this strand will help to define the construct 'life course socioeconomic position' and identify the markers of LSET. Initial item pool for the questionnaire will be used for the second phase or quantitative strand 2.

II Quantitative strand I (Phase 2)

Initial item pool will be given to 10 experts (experts from public health, social epidemiology, sociology and economics) for selecting the most appropriate items on the basis of priority. Based on the scores obtained for each item, we will prioritize, and the highest ranked items will be selected for further step. We will use a 5-point Likert-type format for further part. Translation in to the local language Malayalam will be done, after which it will back translated into English by a second person, and the 2 English versions will be checked for consistency. Conflicts will be resolved by repeating this cycle. Each item in the translated and back-translated questionnaires will undergo strict verification and necessary corrections will be done until both versions became agreeably consistent.

II. a) Reliability measures

We will examine the LSET-Q to assess its reliability. We will use two estimators of reliability (internal consistency reliability and test-retest reliability) in this study. Internal consistency will be measured by Cronbach's alpha correlation coefficient. Cronbach's alpha is equivalent to the average of possible split-half estimates.

Test-retest Reliability

Test-retest reliability is estimated by administering the same tool to the same sample on two different occasions on the assumption there will be no substantial change in the construct under study between the two sampling time points. A high correlation between the scores at the two time points indicates the instrument is stable over time. We will do the test-retest reliability of the LSET-Q by administrating the questionnaire to randomly selected 25 adults (between the age group of 18-45 years), from a diabetes outpatient clinic of Medical Trust Diabetes care hospital, Kulanada, Pathanamthitta. They will complete the LSET-Q on two different occasions; at baseline and eight weeks later.

II b) Translational validity

II b 1) Content validity

Content validity indicates the content reflects a complete range of the attributes under study and is usually undertaken by seven or more experts. We will ask eight purposely chosen experts in the areas of social epidemiology, economics, epidemiology and Sociology to review the draft of LSET-Q to estimate its content validity. Each reviewer will independently rate the necessity and relevance of each item on the LSET-Q by using a 3 point rating scale (1=not necessary, 2= useful, but not essential, 3=essential) and a 4-point Likert scale (1=not relevant, 2=somewhat relevant, 3=relevant, 4=very relevant). We will use the Content Validity Index (CVI) to estimate the validity of the items.

II b.2) Face validity

It evaluates the appearance of the questionnaire in terms of feasibility, readability, consistency of style and formatting, and the clarity of the language used. We will develop an evaluation form, which will help respondents assess each question in terms of Clarity of the wording, Likelihood the target audience would be able to answer the questions and layout and style. We will randomly select 10 young adults from the outpatient clinics of Medical Trust diabetes care hospital and will complete the face validity form on a Likert scale of 1-4 (strongly disagree= 1, disagree= 2, agree= 3, and strongly agree= 4).

II c) Construct validity

It refers to the degree to which the intended independent variable (construct) relates to the proxy independent variable (indicator). Factor analysis will be used to do the construct validity. The sampling population for factor analysis is (n =100) young adults (18-45 years) from the rural population of Kerala. We will recruit the samples using snowball sampling technique. We will use exploratory factor analysis (Direct oblimn method) for the factor analysis of LSET- Q.

III Quantitative strand II (Phase 3)

The second quantitative strand is a hospital based matched case control study.

Study hypothesis

The hypothesis of the second quantitative strand of the study is 'in comparison with individuals who remain free of early onset type 2 diabetes, those who develop this disease will have a low childhood SEP and high adult SEP (SEP transitions towards affluence in their life course socioeconomic position)'.

Study site

Medical trust Diabetes Care hospital (a rural diabetes care hospital situated near Pandalam), situated in the Central Kerala, which serves more than 3,00,000 population with a catchment area extending to Northern Kerala. The average number of diabetic patients approaching the outpatient department of the hospital is 200/day.

Study population

The source of cases for the case control study will be the type 2 diabetes patients, in the age group 18-45 years, who report to the hospital. We hope to recruit 210 cases between April 2015 and December 2015. We will recruit population based age, sex and frequency matched controls from a randomly selected Panchayath (rural (Hospital catchment area =15 kilometeres physical distance from the hospital by Phibbs & Robbinson's method 1993) [16]. We will recruit one age and sex matched control for each incident case within 15 days of recruitment of the case, thus following an incident case control design. The sample size results in a power of 80% to detect an odds ratio (OR) of 2.0, assuming exposure prevalence of 25% among controls (National Sample Survey Organisation survey – 2014) [17]. We assume incomplete and missing information in 5% of sample pair. We explained the inclusion and exclusion criteria for the cases in [Table/Fig-2].

Recruitment and selection of population based controls

ASHA worker will approach the first eligible person in the electoral roll and rule out the history of intake of Oral Hypoglycaemic Agents (OHA) or any previous diagnosis of type 2 diabetes. After getting the consent of the potential control, ASHA worker will do the finger prick test for capillary blood glucose monitoring (CBG monitoring) for confirming their non diabetic status on the next convenient day of the participant. We explained the inclusion and exclusion criteria for the controls in the [Table/Fig-3].

Overview of statistical plan of analysis

Life course socioeconomic transition is the exposure variable.

1. SEP=low (childhood) and SEP =low (adulthood)
2. SEP = high (childhood) and SEP = high (adulthood)
3. SEP = low (childhood) and SEP= high (adulthood)
4. SEP = High (childhood) and SEP = low (adulthood)

We will club the first 2 categories: they have a stable SEP. Third and fourth categories clubbed together will form the group with the changed SEP. We will estimate the unadjusted and adjusted odds ratios for developing early-onset T2D and their 95% confidence intervals using conditional logistic regression to evaluate associations between individual exposures and the risk of T2D. Other attributes like diet, physical activity, tobacco use, alcohol consumption and body mass index will be considered in the analysis to identify confounding, interaction, or mediation effects. We will use SPSS (SPSS 20.0 for Windows, SPSS Inc., Chicago, Illinois, USA) for statistical analysis.

Ethical consideration

Ethical approval has been obtained from the ethics committee of the Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST-IEC registration no:ECR/189/Inst/KL/2013). Informed consent will be obtained from the participants prior to the study for both controls and cases.

Cases: We will provide a participant information sheet and informed consent to those who are selected for the study. We will conduct the interview during the waiting time for physician's visit so that they will not be biased by the physician's advice.

Inclusion criteria for cases	Rationale	Exclusion criteria for cases	Rationale
T2D patients between the age of 18 -45 (including) years.	We defined early onset type 2 diabetic patients as those who are diagnosed as type 2 diabetes by a modern medical practioner within the age group of 18-45 (both completed) years and who are taking oral hypo glycaemic agents. According to WHO and ADA clinical practice guidelines 2013, the usual age for diagnosing T2D is after the age of 45 years.	Patients of type 1 diabetes.	There is a possibility of T1D occurring in this age group of 18-45 years. Since the cases are selected from the outpatient clinic of a major diabetic hospital, plasma C-Peptide is checked in patients diagnosed as T2D within the age group of 18-45 years. This will help to exclude the T1D in this age group. C –peptide is the marker of diagnosing T2D among the individuals with high glycaemic status.
Duration of T2D does not exceed 1 year. This will be ensured by checking either the date of first oral hypoglycaemic agent /first hospital admission for type 2 diabetes. That will be selected as index date.	To get an incident case. Age at diagnosis of T2D is the approximate (more closer) age for incidence of T2D.	Patients will be excluded in case of ever use of insulin before the age of 18 years.	This is to exclude the potential cases of type 1 diabetes.
Diagnosed as T2D by a physician using the following criteria FPG >=126mg/dl or /and PPG >= 200mg/dl.	It is the universal criteria to ensure the uniformity in diagnosing T2D.	Those who have no oral hypoglycaemic medications and under diet control.	It avoids selection of subjects who have a transient hypoglycaemic status. They have a high chance to reverse the glycaemic status to normal by choosing diet control.

[Table/Fig-2]: Inclusion and exclusion criteria for the cases [18].

Inclusion criteria	Rationale	Exclusion criteria for cases	Rationale
Who will be free from T2D FPG < = 100mg%.	To ensure the non diabetic status of the controls and excluding the potential controls with impaired fasting glucose.	FPG > 100 mg/dl.	Excluded Impaired fasting Glucose (IFG) and type 2 diabetic cases. They are high risk for developing type 2 diabetes within a short time.
Randomly selected one population based Control matched for age and sex. Controls should be in ± 5 years of age for each case.	Hospital based controls cannot guarantee both the cases and controls are coming from the same study base Age and sex can act as the confounders between LSEP and T2D.	History of Gestational Diabetes Mellitus (GDM).	GDM patients have a high chance to become type 2 diabetic patients within a short span of time.
Selecting the population based controls from the randomly selected panchayaths of catchment area of the Medical Trust Diabetes care hospital, Kulanada, Pathanamthitta.	To get the representation of the study base Availability of a hospital based non diabetic control is very limited in a diabetic care hospital.	History of polycystic ovarian syndrome (PCOS).	Metformin is the treatment of choice for PCOS. Metformin is one of the oral hypoglycemic agent and it will affect the plasma glycemic status.

[Table/Fig-3]: Inclusion and exclusion criteria for the controls [19].

Controls: Either the ASHA worker or principal investigator will provide the participant information sheet to the selected individuals in the community prior to the capillary blood glucose test. Data collector will visit the house in the next day and will ask about their willingness. We will collect the blood sample in the next convenient day of the potential controls.

Excluded potential controls: Excluded potential controls (who have no h/o diagnosis of type 2 diabetes, but their FBG > 100 mg/dl) will get individual counseling on life style modification to control their blood glucose level.

Data management: Only the principal investigator will have access to the data. Research proposal has been approved by Medical Trust Diabetes Care Hospital. We will maintain the confidentiality of the data in every step of the study.

RESULTS

Data collection tools

1. Questionnaire

We will use developed and validated LSEP- questionnaire (strand 1&2) to measure the life course socioeconomic transition of both cases and controls. We will use the medical records to collect the data on sex, age, Fasting Blood Sugar (FBS) and PostPrandial Blood Sugar (PPBS) of the cases

2. Blood samples

2(a) Blood glucose monitoring for the potential controls

ASHA worker will ask for the h/o oral hypoglycaemic agents intake or diagnosis of T2D to the potential controls. Capillary Blood Glucose (CBG) monitoring is used as a screening tool to identify individual's normoglycaemia state. We will use Accu-Check Aviva, Roche Diagnostics, for the blood glucose monitoring. Device has a capacity of 200 readings/device. We will purchase all devices and strips from local regular distribution sources (pharmacies, 25 strip lots per device). We will do fasting blood glucose test by using finger prick test of blood glucose monitoring. Blood samples will be obtained after a minimum fasting time of 8 hours. They will wash their hands prior to performing the measurements. We will take precautions to avoid capillary milking. Devices and test strips were examined by trained technician. Equipment calibrated based on the manufactures recommendations. We will strictly follow the calibration and quality control measures as recommended by the supplier of the equipment.

2 b) Rationale for doing CBG monitoring

CBG monitoring is less expensive and a good performing screening tool in population based interventions. Venous and capillary samples will give the same result in the fasting state. But in the non-fasting state capillary will give higher results than venous samples. The current generation of meters and strips are quick to use and require a very small volume of blood. The CBG determinations as screening tool and Venous plasma glucose (VPG) as reference with a cut-off point of 7 mmol/L (126 mg/dl), resulted in a sensitivity of 81.4% and specificity of 97.8% [20].

2 c) Validation of CBG monitoring [20]

CBG monitoring is less expensive and a good performing screening tool in population based interventions. Venous and capillary samples will give the same result in the fasting state. We will perform Venous Plasma Glucose (VPG) test for the purpose of validation of Capillary Blood Glucose (CBG) monitoring in 10% of the total controls. We will follow standard laboratory procedures for all blood tests in the field.

DISCUSSION

Measuring socioeconomic transition

According to literature, this is the first attempt to develop a tool for measuring the socioeconomic transition in public health research in Kerala. There is significant change in the socioeconomic status of people living in Kerala over the past 25-30 years. This transition is more relevant in rural areas of Kerala state. This socioeconomic transition is a result of migration of people from Kerala to other countries and states for jobs and also. Land revolution and the increased literacy rate acted as catalyst for both migration and socioeconomic transition. Most of the rural Keralites are following so-called 'periurbanized' way of living and practicing conspicuous consumption. This in turn has resulted in a drastic change of life style among the rural population of Kerala. This should reflect in the incidence and prevalence of the non-communicable diseases in Kerala [13,14,21].

Socioeconomic position (SEP) vs Socio-economic Status (SES)

Most of the research studies use 'Socio-Economic Status' (SES) to represent the socioeconomic background of an individual. Change in the socioeconomic position from the childhood to adulthood (or later) is defined as socioeconomic transition. The dynamic nature of the socioeconomic conditions of an individual's life course is well accepted in the definition of socioeconomic position. Krieger et al., defined 'socioeconomic position as the social and economic factors that influence what positions individuals or groups hold within the structure of society' [22]. This definition is accepting the multidimensional and dynamic nature of the individual's socioeconomic condition. SEP is a period estimate of a socioeconomic condition of an individual. Socioeconomic status is representing the static nature of the socioeconomic condition of an individual. The static nature of socioeconomic condition is observed in either more economically deprived or super rich category. It is a point estimate of a socioeconomic condition of an individual. Most of Indian socioeconomic scales/indexes are considering SES as an assessment tool. Modified Kuppuswami scale is one of the tools to assess the socioeconomic status of individuals [23]. It might be relevant in research studies conducted in other Indian states. But it is less relevant in a state like Kerala with high HDI and GDP based on the NRI money influx. This study is accepting rapidly changing nature of socioeconomic condition of Kerala society and trying to develop a culturally relevant tool to measure the socioeconomic position of the individual. The variables in this tool may be adequate only for the particular population and time period. But still, some of the parameters to measure the socioeconomic position of the individual childhood and adulthood period will be helpful for making a platform for other tool development studies in future.

Life course studies are very important in non-communicable disease epidemiology. Most of the research studies have proved the effect of adverse life course events on the incidence of noncommunicable diseases. They are using the theoretical models like the critical period model, accumulation model of life course epidemiology. Social mobility model is more relevant in studies related to recently affluent community [5,6,24]. Social mobility frame work is being in this life course socioeconomic transition study. It is very important to conduct the life course studies in a state like Kerala with diabetes prevalence of 22% [25]. In our knowledge, this is the first attempt to make a tool for measuring the life course socioeconomic transition and check its association with early onset type 2 diabetes by using a social mobility framework.

The next step will involve the application of this tool in a hospital based case-control study to know the association between life course socioeconomic transition and early onset type 2 diabetes. The study uses the social mobility theoretical framework. Previous studies in this broad area have focused on static indicators such as socio-economic status or position to explain lifestyle factors which lead to diabetes. In a rapidly changing society such as Kerala, a dynamic indicator like the life-course socio-economic transition is

a more appropriate and sensitive indicator to capture the markers of high risk. It is expected that this in turn, will generate insights into possible preventive strategies.

LIMITATION

Small sample size for the validation survey is one of the limitations of this study. The validated questionnaire is going to be applied in a hospital based setting. The length of the questionnaire and the questions which are not related to their disease condition may cause lack of interest in diabetic patients.

CONCLUSION

The study will provide a substantial evidence for the association between life course socioeconomic transition and early onset type 2 diabetes and identifying a high-risk group among Keralites. It will help in developing effective interventions to reduce the incidence of early onset type 2 diabetes among the high-risk group. Application of this tool in other non-communicable diseases research is also a further scope of this research study.

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