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Feasibility of Oral Glucose Tolerance Test as a Diagnostic Tool for Diabetes Prevalence Study in a Rural Community

Jayaprakash Appajigol[1*], Manjunath Somannavar[2], Ramesh Araganji[3]

[1]*Department of General Medicine, KLE University's Jawaharlal Nehru Medical College,Nehru nagar, Belgaum-590 010, Karnataka, India*
[2]*Department of Biochemistry, KLE University's Jawaharlal Nehru Medical College, Nehru nagar, Belgaum-590 010, Karnataka, India.*
[3]*Department of Physiology, Bangalore Medical College, Bangalore, Karnataka, India*

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*Corresponding Author

Tel : +919790196151

Email: jayaprakashappajigol@gmail.com

Abstract

Introduction

Diabetes population is relentlessly increasing. This rise is substantially contributed by increasing prevalence in rural communities. We need to have prevalence studies in different communities to know the nature of the disease. For conducting diabetes prevalence studies, best test to rely upon is OGTT. This study was aimed to examine the feasibility of conducting OGTT in a rural community as a diagnostic tool in diabetes prevalence study.

Methods

Meeting village leaders, arranging community gatherings and involving village representatives in health awareness program were the preparatory methods used in the study. Study team was trained to carry out various procedures involved. Every alternate person according to the electoral list was identified and reminded about his turn by repeated community announcements and meeting personally. Brief history, anthropometries were taken and OGTT was performed with 75 gram glucose load.

Results

Out of 341 participants invited, 326 consented and 318 completed the study. Eight participants did not turn up for second blood test but under went all other procedures. We conducted ten screening visits to complete the entire study procedures. The response rate for consenting and entering the study was 95.6% and that for completing the study was 93.2%. Out of 318 participants completed the study, 182 (57.2%) were females and 136 (42.7%) males. So total time spent for 10 screening visits was 70 hours. Total cost of the screening the village was 20,520 Indian rupees.

Conclusion

The present study suggests that collecting OGTTs in rural communities is feasible. Committed research team, proper heath education, active involvement of the community members and long term association before starting the screening procedures results in better response rates.

Key Words: Diabetes, Feasibility, Oral Glucose Tolerance Test, Rural Community

Introduction

India is currently the epicenter of the diabetes epidemic with a prevalence of 41 million in 2006 that will increase to 70 million by the year 2025.[1] The increased disease burden in rural areas is a significant contributor to the epidemic. Traditionally type 2 diabetes mellitus (T2DM) had a low prevalence in rural (1.3%) compared to urban (3%) communities because of active life-styles.[2] However, economic growth, better agricultural equipment, urbanization of villages and changing dietary patterns have had effect on the prevalence of diabetes in rural communities also.[3] However, as India is a country with diverse cultures and life styles, so the burden of disease also varies in different populations[4, 5, 6]. Diabetes prevalence studies are required in different population groups across the country to determine the exact nature of disease. Results from such studies is extremely important to the government of India which has recently launched the National Program for control of Diabetes, Cardiovascular Disease and Stroke.[7] However, a reliable and feasible screening method to conduct the diabetes prevalence studies that can provide this data is not yet available to researchers.

Need for the OGTT

Urine glucose testing was used in studies conducted in the 1930s[8], but has been more discounted because of low sensitivity.[9,10] Fasting plasma glucose (FPG) tests are problematic as the sole diagnostic test because of low sensitivity, that is, one out of three cases of diabetes will be missed. FPG also cannot identify participants with impaired glucose tolerance (IGT)[11]. It has been documented that many

Asians with diabetes are known to have isolated hyperglycemia 2 hr post glucose loading with normal fasting values, hence only FPG is not reliable.[12] HbA1c would be useful when used as part of a stepwise process, for example combined with FPG[13] but is not feasible in India because of poor standardization and the high cost associated with it. Random blood glucose is usually not used because of its variability and poor sensitivity.[14] Given, these limitations, the oral glucose tolerance test (OGTT) appears to be the best available test to detect the prevalence of T2DM in countries like India.

However, challenges faced in conducting prevalence studies with the OGTT are due to complexity of the procedures, such as multiple timed blood samplings and consumption of 75 gram glucose drink, resulting in low response rates. This is especially true in rural communities where people go to fields early in the morning hours and come back only in the late evening. Economic and survival concerns predominate except when illness becomes symptomatic. Although implementation may be challenging, the results provide a precise estimate of glycemic states.

We have limited data explaining the methods employed, challenges faced and strategies implemented to get good response rate in conducting OGTT in rural community. So pilot testing will help to analyze the difficulties and in developing strategies to overcome.

This study was aimed to examine the feasibility of conducting OGTT in a rural community as a diagnostic tool in diabetes prevalence study.

Materials and methods

This was a cross sectional study to evaluate the feasibility of conducting OGTT in rural community as a tool for diabetes prevalence study.

Population

The village Jakanaykana koppa, 22 Km away from our Medical College was selected due to the feasibility and minimal influence of urbanization on the village. The population of the village was around 950. Electoral list had 682 people in it.

We planned to screen every alternative person according to the list and if the person denies to consent or not eligible for the study based on inclusion/exclusion criteria, the very next person was included. Ethics committee of Jawaharlal Nehru Medical College Belgaum approved the protocol.

Analysis

Considering prevalence of T2DM (p) as 10% and absolute error of 2.5%, sample size estimated to be 580. Revising sample size for finite population, we got the sample size of 315.

Data collected was entered on a excel sheet and response rate was calculated for every 100 participants by simple counting.

Procedures

Meeting the village leaders: We went to the door step of village leaders and explained about increasing burden of non-communicable diseases in rural communities. They responded positively by citing the example of recent observation of rise in death due to heart attack in their village, which was the first victory we got in establishing a good rapport in the village. Based on this we explained the possible causes and risk factors for rise in rate of heart attacks and how the science is advancing to prevent these deaths. Leaders got excited by knowing the facts. Then we explained about our study and advantages and disadvantages of participation. We also explained them clearly that the participation in the study is going to be strictly on voluntary bases.

Arranging community gathering: A community gathering was planned on a specific day along with village leaders to disseminate knowledge about non-communicable diseases and T2DM. The request to attend the gathering was disseminated by the way of person to person spreading the news, distributing flyers, repeated announcements through the community announcement speakers and street to street announcement by a villager who is a designated person in the village.

Involving villagers in health awareness programs: With the help of above mentioned methods about 100 villagers gathered at the specified place. Village leaders spoke about the rising burden of non-communicable diseases in rural communities and importance of early detection and timely treatment of T2DM to prevent its complications. Research team members introduced the study to the community. We explained about the methods of each component of our study including history taking, anthropometry, blood pressure recording, the procedure of OGTT and informing the results and further plan of treatment. Involving villagers to speak to their own people was critical, as it became an important motivation to participate in the study.

Training the study team: We trained study staff for filling up of the data forms, taking anthropometric measurements, collection of blood samples and administration of 75 grams of glucose. We developed a standard operating procedure (SOP) for the various steps to be followed by the study team once participant enters the site as follows.

Every screening visit was planned on Sundays. At each screening visit 40 participants were invited to participate. Each participant was informed about the date of screening a week prior personally meeting by a village volunteer. Every day reminders were sent on last three days before the day of screening by village announcement methods.

Once participant came to the study site the standard steps as described were followed.

Step 1 Informed consent was taken and participant enrolled according to inclusion and exclusion criteria.

Step 2 Demographic data namely, name, age, sex, occupation, years of residence the village, Medical history consisting of history of concomitant medications, history of pregnancy in case of females, history of T2DM, hypertension, ischemic heart disease, habits of tobacco and alcohol consumption.

Step 3 Anthropometric measures, including, Weight measurement in Kg, Height in meters, BMI=Wt(Kg)/(Ht)^2 (m), waist measurement in centimeters. Blood pressure measurements 3 times at least 5 minutes apart in sitting posture by using mercury sphygmomanometer.

Step 4 Biochemical tests-Fasting blood sample was collected after overnight fasting for 8-10 hours. Participants were asked to drink 75 gram glucose in water in 5 minutes and

second blood sample was collected after 2 hours. (Those who were known diabetes patients were not given oral glucose, instead asked to have light breakfast 2 hours before the second blood drawing). Blood glucose testing was done by glucose oxidase-peroxidase (GOD-POD) method. Any participant who had not maintained fasting or postprandial state satisfactorily was screened in the next visit.

At each visits we collected field notes and journals to document the daily flow and challenges that occurred in implementing this study. Then we analyzed them at the end of each visit and strategies were developed to overcome the same in subsequent visits.

Protection of Human Subjects

The approval of institutional ethics committee was taken before the start of the study. All participants signed the informed consent form before the study. All the patient information kept confidential.

Results

Out of 341 participants we invited 326 consented and 318 completed the study. Eight participants did not turn up for second blood test but under went all other procedures. We conducted ten screening visits to complete the entire study procedures.

Response rate

The response rate for consenting and entering the study was 95.6% and that for completing the study was 93.2%. Out of 318 participants completed the study, 182 (57.2%) were females and 136 (42.7%) males.

The following table shows number of participants screened at each screening visit.

Table-1: Number of participants screened at each screening visit

Screening Visit	Number of participants screened
Visit 1	38
Visit 2	43
Visit 3	21
Visit 4	34
Visit 5	27
Visit 6	36
Visit 7	28
Visit 8	32
Visit 9	36
Visit 10	31

Time required

Each screening visit screened an average of 33 participants and lasted for 5 hours i.e. from 6:00 AM to 11:00 AM. Travel time required for each screening visit was 2 hour. So total time spent for 10 screening visits was 70 hours.

Cost of the screening program

Each blood test cost was 25 Indian rupees and total cost for blood test of 326 participants was 16100 rupees. Travel expenses included, expenses for ten village visits for screening and 5 pre-screening visits to village. It accounted for 3420 rupees. The cost of data forms, consent forms and flyers was 1000 rupees. Workers in study team and community members worked on voluntary basis. So total cost of the screening the village was 20520 Indian rupees (461 US dollars approximately).

Challenges faced and the strategies developed to overcome

Field notes documenting the challenges encountered while implementing the screening was analyzed and following strategy were developed.

Reluctance for blood testing: Many villagers never wanted to know about a disease which is asymptomatic and not hampering their work. Discussing the importance of early detection and possibility of prevention of T2DM made them to participate.

False propaganda: During our third screening visit we came to know that there was a false propaganda in the village that we utilize the villagers' blood for our hospital purpose. It was reflected by very low turnout for screening i.e. 21during that screening visit. Village leaders came to our rescue and with their help we could convince the truth and subsequent screening visits response was good.

Discussion

Previous prevalence studies using different methodologies have reported different response rates as below. Prevalence study by Ramachandra et al[15] in rural Chennai in 2004 had response rate of 75.4% where OGTT with venous blood testing was used as a diagnostic tool. The non-responders in the study refused to undergo any medical screening or were not available at the time that tests were conducted. It appears that developing good rapport with the community and proper health education made many participants to undergo screening. And we started screening early in the morning i.e. at 6:00 AM, so that the availability of villagers was taken care.

Another study by Sadikot et al[5] in 2004 got a response rate of 91.2 in rural arm of the study but OGTT was conducted using capillary blood. In this study we used OGTT with venous blood sampling which is according to the WHO guidelines.

Vijaykumar et al[16], in prevalence study in rural Kerala with only fasting plasma glucose got a response rate of 82.7% and they further concluded that carrying out OGTT requires greater resource in terms of money and time. In our study, we could get a better response rate with minimal resources.

Motivation of rural community to participate in diabetes prevalence studies is a difficult task due the commitment they have in the fields. By following an organized and structured method we achieved good response rate of 93.2%.

Strengths and limitations

This was a small study yet had the advantage of being a population based in a rural community which had minimal influence of urbanization and majority of participants never knew about the T2DM. We used OGTT with venous blood sampling which is more authenticated method for diagnosing T2DM. It demonstrated that the involvement of community members played an important role for the success of the study. This study effectively utilized village communication media like loud speaker announcements and street announcements which are cost effective and reach everyone in villages.

Conclusions

The present study suggests that collecting OGTTs in rural communities is feasible. Committed research team, proper heath education, active involvement of the community members and long term association before starting the screening procedures results in better response rates.

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