Original article

Rationale and methodology for a population-based study of diabetes and common eye diseases in a rural area in Bangladesh: Bangladesh Population-based Diabetes and Eye Study (BPDES)

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Abstract:

Objectives: The purpose of this study were (i) to assess the knowledge, attitudes and practice (KAP) and impact of socioeconomic factors upon the prevalence of pre-diabetes and diabetes (ii) compute a diabetes risk score and (iii) estimate the undiagnosed prevalence of hypertension amongst a large adult population in rural Bangladesh. ***Methods/design***: A sample of 3104 adults aged ≥30 years were interviewed from a cluster sample of 18 villages in the Banshgram Union of the Narail District, Bangladesh. Each participant was interviewed using a semi-structured questionnaire that assessed participant knowledge, attitudes and practice (KAP) regarding diabetes, its risk factors, complications and management. Data on demographic details, education, socioeconomic status, medical history, dietary and lifestyle behavior was obtained. Fasting capillary glucose, blood pressure, presenting vision and anthropometric parameters were measured. Participants were stratified into those without diabetes, pre-diabetes, and diagnosed diabetes (known and newly diagnosed). The association of KAP components and other risk factors with diabetes status was assessed. Logistic regression analysis allowed for the development of a non-invasive risk-stratification tool to be developed and implemented for the rural Bangladeshi community. Multinomial logistic regression was applied to report the associations of risk factors with the severity of hypertension. ***Results and discussion***: In Banshgram, over 95% people had not undergone any previous diabetes screening. Baseline demographics estimated the prevalence of diabetes in the sample was 3.2% (n=99). 47% of participants had no formal education. Whilst there is literature on the prevalence of diabetes in urban and semi-urban Bangladesh there is a paucity of evidence examining the impact of KAP of diabetes amongst the general community. We believe that the BPDES has developed a methodology to provide new evidence to guide health policy and targeted population-based interventions in these rural areas.

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Background:

Diabetes mellitus (DM) is a significant contributor to the global burden of morbidity and mortality caused by non-communicable disease.[1] The World Health Organization (WHO) estimates that of the 347 million people worldwide diagnosed with diabetes 70%reside in low and low-middle income countries.[2] Bangladesh is one such low-income country confronted with a growing burden of diabetes and its complications. In 2011 the International Diabetes Federation (IDF) estimated the prevalence of diabetes in Bangladesh to be 9.6%, one of the highest estimates of diabetes in the Asia-pacific region, with up to 50% undiagnosed diabetes.[3]

The impact of diabetes is further compounded by the often indolent nature of the disease whereby people with diabetes remain asymptomatic until systemic complications develop. Globally, studies have shown that up to 50% of all people with type 2 diabetes are undiagnosed.[4] It is established that individuals at high risk of developing diabetes, particularly pre-diabetes (impaired fasting glucose and impaired glucose tolerance) are largely unaware of their risk status.[4] Knowledge of diabetes and its risk factors has been shown to facilitate earlier diagnosis and attenuate the incidence of complications.[5] Contributing factors to the emergence of diabetes in low-resource countries include limited education levels, access to health care services, urbanisation and changing lifestyle, and attitudes towards perceptions and prioritisation of health.[5-7]

Despite the growing number of studies of investigating the prevalence of diabetes in rural and urban areas of Bangladesh[8-10] there is a paucity of evidence regarding the Knowledge, Attitudes and Practices (KAP) and its impact on diabetes and diabetes risk in the general community. Studies of KAP are useful to address the needs of a community for any particular health issue and to develop specific targeted interventions. The only study of its kind was conducted in 2012 by Saleh et al amongst a sample of 508 patients with newly diagnosed type II diabetes attending outpatient departments of healthcare centres in urban Bangladesh.[11] The authors concluded that 84% of respondents had at best an "average" basic knowledge of diabetes (using the University of Michigan Diabetes Knowledge Test); and 90% of respondents did not test their blood glucose regularly.[11] Whilst the study provided useful insight into the KAP of diagnosed patients, only one-third of the sample resided in a rural area, and it did not include people with pre-diabetes. Thus studies of KAP regarding diabetes and risk factors for related NCDs are a powerful method to improve awareness and management of diabetes in the community.

We conducted a population-based study of the KAP of diabetes in combination with conventional anthropometric and blood glucose measurements in an adult population in a rural area of the Narail district in Bangladesh. The study is novel as it offers a unique opportunity to identify the impact of KAP and socioeconomic factors on the risk of pre-diabetes and diabetes. The purposive analysis will offer evidence to guide targeted intervention approaches in this understudied demographic.

The specific aims of the BPDES were:

1. To assess the knowledge, attitudes and practices (KAP) regarding diabetes, its management, risk factors and its complications in an adult population in a rural district of Bangladesh.
2. To estimate the prevalence of diabetes, pre-diabetes (impaired fasting glucose and impaired glucose tolerance), hypertension, and self-reported disability in a rural Bangladeshi community.
3. To document the association of KAP and socio-demographic factors with the prevalence of diabetes and pre-diabetes.
4. To compute a diabetes risk assessment tool for rural Bangladesh

Setting and Population

Bangladesh is a country of 148 million people divided into 64 districts. Each district is divided into sub-districts named Upazilas (493 in total), and each Upazila further divided into a number of Unions. Each Union consists of villages that are divided into Para or localities that are comprised of several households.

Participants were recruited from Banshgram Union of the Narail District (Figure 1). Banshgram is located approximately 200 km southwest of the capital city Dhaka and has an eligible population of approximately 5,500.[12] The study location was selected as it was considered to be representative of a typical rural demographic in Bangladesh. The Narail District, with an estimated population density of 746 per km^2, compares more to the national population density of 964 per km^2 than other districts such as Gazipur (1852 per km^2).[13] It is not at the extremity of remote locations such as Rangamati (83 inhabitants per km^2), nor is it a catchment of a metropolis such as Dhaka (8,111 inhabitants per km^2).

Additionally, the study aimed to capture socio-economic risk factors for diabetes in a rural area that is distinct from semi-urban settings. Narail

has a population literacy rate of 48.6%, which is comparable to the national literacy rate of 51.8%, but is far below the estimated 56.4% in the Gazipur District.[13] This would clearly have an influence on health literacy in such areas of the country. However, to date there has been no published research on the KAP of the general population (diagnosed and undiagnosed diabetes) residing in rural Bangladesh regarding diabetes.

Sample size and Power, and Recruitment Strategies

The required sample size was based on the estimated prevalence of diabetes in adults in Bangladesh of 9.4% in 2011 according to the International Diabetes Federation's (IDF) Diabetes Atlas.[3] We assumed at 2.5% margin of error to estimate the true prevalence of diabetes in this rural area provided a required sample size of 2389 participants to be recruited with a significance level of 0.05 and a statistical power of above 80%. Allowing another 20% non-response rate a sample size of 2867 was decided to recruit for the estimate of diabetes prevalence. The distribution of selected participants in regards to gender and age groups in each village was similar to their distribution in the source population. The sample size was also deemed adequate to estimate the prevalence of hypertension in a rural community assuming a prevalence of hypertension amongst adults of 14%, and accepting 2.5% margin of error.[14]

The recruitment strategy involved identifying and inviting each participant aged ≥ 30 years from each of the 18 villages of the Banshgram Union. This age range was selected as previous studies have demonstrated that this is an acceptable threshold of age above which the prevalence of diabetes and hypertension increase.[7,15] Exclusion criteria were those aged ≤30 years, pregnant women, those who were acutely unwell. The community was made aware of the study through public announcements at mosques, print media, and advertisements on community notice-boards.

Cluster random sampling method was adopted where each village was considered a cluster. Within each cluster the age and gender distribution was proportionate, and homogenous between clusters. Furthermore, at least 50% of the eligible population from each of the 18 villages were sampled. The team members interviewed participants on day one and informed participants where to attend the nearest community centre or school on the next morning (day two) for clinical examination and the measurement of fasting capillary glucose. Across all 18 villages that were sampled less than 10% of participants interviewed on day one failed to present for day two assessment.

Data Collection:

1. General Questionnaire

All participants were interviewed using a semi-structured questionnaire using a door-to-door recruitment strategy. There were four teams of trained data collectors with 4-5 in each team. The team members interviewed participants during the day and informed them to attend the nearest community centre or school next day morning to undertake clinical examination and the collection of fasting blood samples. There were 22 assessments centres in total chosen based on the facilities available for assessment and the closest proximity of the participants.

An interviewer-administered semi-structured questionnaire was developed to collect relevant socio-demographic data and assess participant knowledge, attitudes and practice regarding diabetes, its risk factors and management. We also included questions regarding self-reported disability as this has previously not been assessed in this population, yet is an important determinant for the management of chronic diseases such as diabetes.[16] The presence of self-reported disability (present most or all of the time during the last 6 months for the categories of physical, mental disability, vision and hearing impairment) was used as this is a simple method of subjectively estimating disability in the community.[17] Additionally, details about medical history, and dietary and lifestyle behaviors were recorded. The medical history included the presence of known diabetes, hypertension, and current medications for diabetes and hypertension, and family history of diabetes (first degree relatives). Diet and lifestyle components assessed were tobacco consumption, dietary habits (frequency of consumption of fruits, vegetables, and rice), time spent on weekly exercise (including physical labour). Socio-demographic details including the highest level of education attained, occupation, and economic status of the household were collected.

2. Knowledge, Attitude and Practice Questionnaire

Given the relative paucity of validated diabetes-related KAP data that is available, the specific items included in the final questionnaire were derived from the following well validated instruments:

- AusDiab Health Knowledge, Attitudes and Practices Questionnaire[18]

- Diabetes Knowledge Test (developed by the University of Michigan)[19]
- Diabetes Risk Assessment Tool (developed by the Baker IDI, Australia)[20]
- Knowledge and Awareness of Diabetes Questionnaire developed for the Chennai Urban Rural Epidemiology Study.[21]
- KAP construction guides[22].

The questionnaire assessed knowledge of diabetes using 10 questions relating to definitions, symptoms, methods to diagnose, modifiable risk factors, and complications related to vision. Attitude was assessed with 3 questions relating to management of diabetes and approach to follow-up. For people with known diabetes practices were assessed with 5 questions on regarding self-testing, compliance with medication, and follow-up of eye care. KAP questions were recorded as dichotomous categorical responses (Yes=1, No=0). For the remainder of the sample, current practices regarding modifiable NCD risk factors: blood pressure, smoking, dietary habit, and exercise were asked. These risk factors were recorded as categorical responses (Yes=1, No=0, Do not know=9). For specific questions regarding consumption of fruit and vegetables, rice, and exercise were scored based on categories of frequency of activity (See questionnaire in Appendix).

3. Questionnaire research rigour and quality control

To ensure scientific rigour several processes were adopted in the methodology for the questionnaire. These were:

1. Face validity: Items in the questionnaire were evaluated for appropriateness of themes and content through two stages of peer review for face validity. Experts were endocrinologists, ophthalmologists and public health researchers in Bangladesh and Australia.
2. Pre-testing: A pre-test of the questions in the final questionnaire was conducted by interviewing clinicians (not involved in the face validity phase) and lay people.
3. Translation: The questionnaire was developed in English and then translated into Bengali by professional bilingual translators with experience in medical terminology. Bengali speaking clinicians and field-workers who were selected to conduct the interviews then checked the questionnaire in Bengali. It was further translated back into English and checked by the study authors.
4. Piloting: Five women and men who were independent of the study team were interviewed using the questionnaire and were asked to assess comprehension, wording, and appropriateness.
5. Data were collected through door to door survey

4. Clinical Examination Procedures

Anthropometric measurements (height, weight and waist circumference) were collected. Blood pressure was measured in the right arm with the person sitting upright, and a further measurement was taken following a period of at least 5 minutes rest. The two readings were averaged for systolic and diastolic blood pressure. The participant was considered to have hypertension if (a) they report to be taking blood pressure lowering medication, (b) recorded a systolic blood pressure >140mmHg and/or diastolic blood pressure >90mmHg (Table 1). Each individual underwent a distance presenting visual acuity (VA) using a 4-meter Snellen chart, assessed by trained staff.

5. Capillary Blood Glucose Testing

All participants, irrespective of their known diabetes status, were requested to attend the following morning for a fasting blood glucose test. They were advised to fast for 8 hours before the test. Participants with self reported diabetes (defined as a previous diagnosis of diabetes by a medical doctor, or on current oral hypoglycaemic medication or insulin) were also required to have a fasting capillary glucose measurement. Capillary fasting blood glucose was collected and processed using Accu-Check Inform II (Roche Diagnostics, Australia). If a participant failed to comply with the requested fasting protocol, they were requested to fast overnight and attend the next morning for the blood test. Since capillary blood glucose was used for diagnosis, whole blood sample was collected from 11 females and 9 males to check accuracy of the measurements.

Definition of Diabetes Mellitus and Hypertension

We used the World Health Organization (WHO) diagnostic criteria for diabetes and hypertension in this study (Table 1).

Quality assurance

All team members participated in an intensive two day training program in Narail before the commencement of the survey. The purpose was to outline the rational of the study, all procedures and potential pitfalls of data collection. A single-day pilot study preceded the main study to familiarize the team with all study procedures and allow for an optimal flow of participants through the study.

Data were collected on paper first, and then entered into an electronic database. Five per cent of the entire data was entered twice by independent data

Table 1. Diagnostic criteria for diabetes and hypertension used in the BPDES

Diabetes Mellitus[23]	Hypertension[24]
• Diabetes Mellitus: Fasting capillary glucose≥6.1 mmol/L • Impaired Fasting Glucose (IFG): Fasting capillary glucose≥5.6 - <6.1 mmol/L	• Normal blood pressure: Systolic BP < 120 mmHg Diastolic BP <80mmgHg • Grade 1 Hypertension Systolic BP 140-159 mmHg OR Diastolic BP 90-99 mmHg • Grade 2 Hypertension Systolic BP 160-179 mmHg OR Diastolic BP100-109 mmHg • Grade 3 Hypertension Systolic BP≥180 mmHg OR Diastolic BP>110 mmHg

entry operators to assure accuracy. Similarly, the study coordinator randomly checked a total of 10% of all participants entered to check the quality of data entry. Frequency and range checks were conducted to identify outliers and those were re-checked at the field level to do correction if needed.

Statistical Methods for Analysis

The prevalence of pre-diabetes or diabetes was compared in associations with each of the socio-demographic characteristics. Chi-square tests and binary logistic regression models were used to estimate the odds ratio (OR) and 95% confidence intervals (CI) for diabetes and other disease outcomes in associations of socio-demographic and anthropometric measurements adjusted for covariates. Rasch analysis, a form of item response theory (IRT) that transforms ordinal or binary scores into interval-level estimates[25,26] was performed to compute the person measures based on the knowledge items relevant to diabetes and its risk factors in a logarithmic scale and the estimated mean scores for categorical exposures were computed using Generalized Linear Model for diabetes status after multivariable adjustment. The risk score for identifying people with high risk of diabetes was computed based on the significant associated risk factors and the predictive capacity of the risk assessment tools were verified using receiver operating curve (ROC) analysis to report the sensitivity and specificity. Neural Network algorithm was also applied to identify risk factors which were able to classify diabetes and normal with different assigned probability.

Ethics Approval

The research protocol has been approved by Human Research Ethics Committee for the Bangladesh Medical Research Council (Reference: BMRC/NREC/2010-2013/68). The study adheres to the tenets of the Declaration of Helsinki. Written consent was obtained from the participants who were able to sign and verbal consent was obtained from those who were unable (47%) prior to inclusion. In the case of verbal consent, the data collector signed the

Table 2. Timeline of Research Phases

	Sep-Dec 2012	Dec 2012- June 2013	June 2013-
Questionnaire and question guide development	√		
Training of field workers	√		
Household surveys		√	
Anthropometric measurement		√	
Data entering and transcription		√	
Data analysis			√
Manuscript preparation and submission			√

Table 3: Socio-Demographic Characteristics of the Study participants (N=3104)

	Number	%
Age (in years), <35	240	8
35-45	876	28
45-55	942	30
55-65	590	19
>65	456	15
Gender, Female	2032	65
Religion, Muslim	2599	84
Level of Education		
No education	1462	47
1-5 primary	921	30
6-10 High school	495	16
SSC or above	226	7
Socio-economic condition		
Insufficient funds all or most the time	423	14
Insufficient funds some of the time	1077	35
Balance (neither deficit or surplus)	1320	43
Sufficient funds most of the time	268	9
Participants with known diabetes	99	3.2
Participants with known hypertension	228	7.4

consent form for the participants with their approval. Participants were informed of their rights to withdraw from the study at any stage or to restrict their data from the analysis.

Results and Discussion:

The study started in September 2012. The time frame of research is shown in Table 2. The socio-demographic characteristics of participants are shown in Table 3. Eight precent participants were below 35 years of age, 65% were female, 84% Muslim and the rest were Hindu, 47% did not have any education compared to 7% had School Secondary or above education level, 14% had insufficient funds most or all of the time for at least one year before data collection, 99 (3.2%) knew that they had diabetes.

Our study endeavored to explore the contribution of differential risk factors for diabetes and pre-diabetes in rural Bangladesh. We consider KAP an important societal risk factor given that contemporary studies from India and Cambodia have highlighted almost half the population had never heard of the term diabetes, and far fewer had heard of important complications such as diabetic retinopathy.[5,27]

The only KAP study of diabetes in Bangladesh was performed on patients with diagnosed adults attending outpatient clinics at health centres.[11] Till date, no studies in Bangladesh have explored the level of knowledge in the general population. This is of particular concern given consistent findings across population based studies of diabetes in rural populations that patients belonging to higher socio-economic strata with higher family income had greater knowledge of diabetes[5], yet also higher prevalence of diabetes compared to those with lower income.[28] Data from Bangladesh suggests that when comparing urban with urbanising 'rural' areas this paradox cannot be explained by differences in body mass index obesity, waist to hip ratio or hypertension.[9] This justifies the argument to further explore population health literacy, particular in remote and low-income regions as this will likely impact on true effect of future health interventions in these areas before they are confronted by urbanisation.[27]

In summary, all of these studies interviewed participants and recorded socio-economic and demographic details. However, they fell short of reporting undiagnosed diabetes, and asking about the baseline knowledge of diabetes within the community. Therefore, there was a clear deficiency in estimates of diabetes and the societal factors that contribute to the disease understanding within a true rural community.

The BPDES aimed to provide a population-based estimate of the prevalence and risk factors, and KAP for people at risk of diabetes and those with known diabetes in a rural area in Bangladesh. Importantly, the research will report the estimated prevalence of undiagnosed diabetes from a rural area. The validated questionnaire offers the scope to explore the impact of socio-demographic aspects and their impact on diabetes and its risk factors. The study also presents a unique opportunity to estimate knowledge and attitudes towards common eye diseases for the first time in this population.

The BPDES presents a unique opportunity to assess the gaps in public awareness of diabetes in an area of rural Bangladesh. The philosophy of the project was to assess beyond academic purpose alone and work with the scope of a local non-government organisation (the Organisation for Rural Community Development) to capture information that would be practically beneficial to health policy planners in the Banshgram Union, local health authorities, and ultimately the population. Studies of KAP

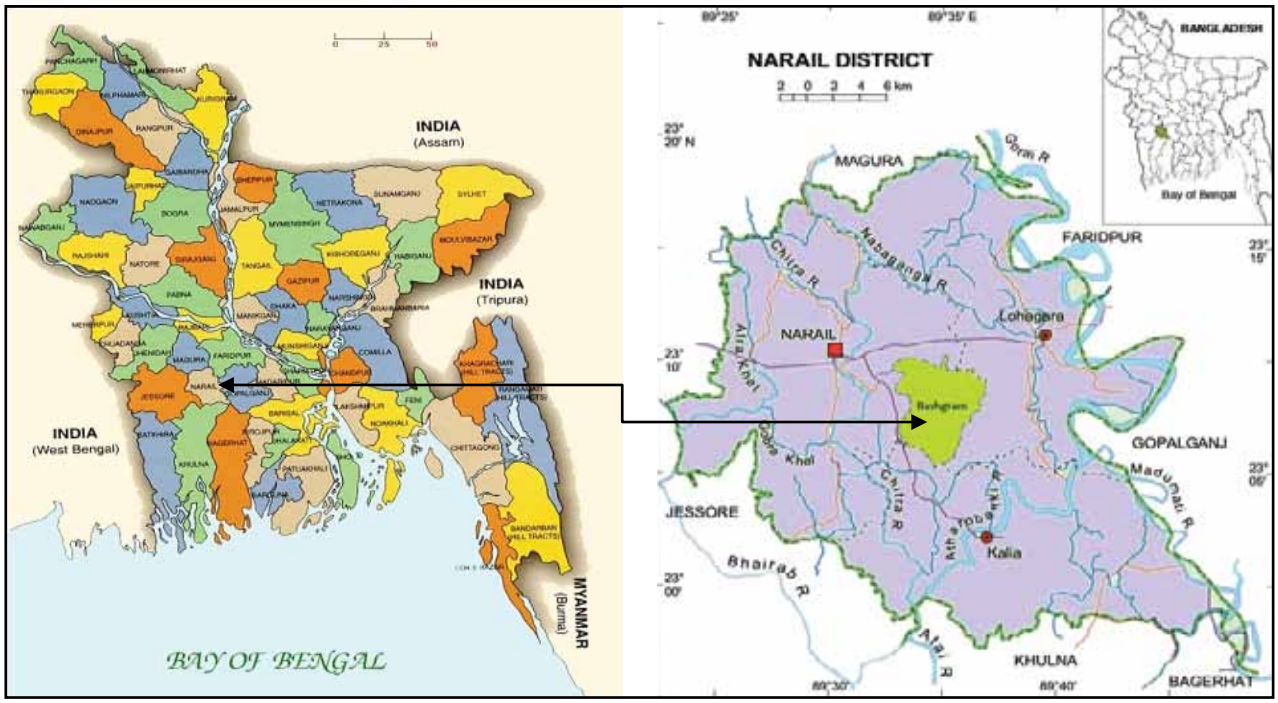

Figure 1. Map of Bangladesh showing the study area.

regarding eye health in rural Cambodia have shown that majority (85%) of the general population had heard of cataract, but only 8% had heard of diabetic eye disease.[29] With permission from the authors, we adopted similar questions in this study to assess KAP of common eye diseases. There have been no prior studies to document such information regarding community knowledge of eye health in Bangladesh.

There are limitations of our study methodology that are acknowledged. Firstly, we selected participants ≥30 years, where most other studies have included participants ≥20 years. The selection of this age range may exclude some participants with the disease outcome and at the same time a higher prevalence of disease outcome can be reported by excluding a potentially healthy sub-sample. Secondly, we used capillary glucose measurements only to confirm the diagnosis of diabetes. Ideally, undiagnosed patients would proceed to a formal oral glucose tolerance test with measurement of venous glucose levels. Accordingly, we used WHO capillary glucose cutoff values. Finally, it must be acknowledged the study was conducted in one area of rural Bangladesh. Whilst we have attempted to capture the situation in Banshgram, the study would obviously need to be repeated in a random sample of other remote areas in order for the results to be truly representative of a national perspective.

Conclusion:

Early identification and prevention are essential to the success of diabetes or any other diseases prevention and treatment programs. In addition, the importance of good self-management, and knowledge of diabetes at the community must be addressed and promoted. Screening is very essential to know the disease status of the general population in a community. Very few community based screening or population based studies of diabetes have been conducted in rural Bangladesh. Existing published studies were conducted mostly close to Dhaka, which limits extrapolation of the perspective in rural and remote areas. In Banshgram, over 95% people had not undergone any previous diabetes screening, and were unaware of their blood glucose level. Our study is the first to assess knowledge, attitudes and practices of the general community in Bangladesh regarding diabetes in a rural setting. It will also provide an update on the prevalence of diabetes and its risk factors. The study will also give an opportunity to develop a diabetes risk assessment tool to identify people with high risk of diabetes non-invasively. Prevalence and risk factors of hypertension have reported but this study will also estimate the undiagnosed hypertension and its risk factors. It is intended that these results will facilitate future education programs to increase awareness of diabetes, to improve diabetes control, and create a basis for follow-up to estimate the incidence of diabetes and its risk factors in Bangladesh with the potential to improve the management for persons with diabetes in rural areas.

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Figure Legends:

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