# Glycemic control and its determinants among patients with diabetes mellitus in the Teaching Hospital, Batticaloa, Sri Lanka

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## Abstract

This study aimed to identify the determinants of good glycemic control among patients with Diabetes Mellitus (DM) in Batticaloa District, Sri Lanka. A case control study was conducted among 339 patients with DM in medical clinics, Teaching Hospital, Batticaloa. Cases (n=113) were patients with DM who had fasting blood glucose equal or less than 110 mg/dl in and controls (n=226) were patients with DM who had fasting blood sugar more than 110 mg/dl in at least last 3 consecutive occasions during last 6 months. The validated and pre-tested interviewer administered questionnaire was used to collect data. Data collection was carried by the trained data collector in order to avoid interviewer bias. DM duration less than 7 years (OR 0.30, 95% CI=0.14-0.64), rural residence (OR=2.08, 95% CI=1.04-4.15), regular exercise (OR 5.96, 95% CI=3.08-11.51), fixed time for consumption of medication (OR 4.22, 95% CI=1.59-11.24), regular clinic follow-up (OR 4.61, 95% CI=1.22-17.34) and normal body weight (BMI < 23 Kg/m$^2$) (OR 0.15, 95% CI=0.07-0.31) were found to be the factors associated with good glycemic control in the multivariate logistic regression model. Patients with DM should be advised on regular exercise, maintain the ideal body weight, regular clinic follow-up and drug compliance for the better glycemic control.

**Keywords:** glycemic control, diabetes mellitus, determinants, regular exercise, Sri Lanka

## 1. Introduction

The prevalence of Diabetes Mellitus (DM) has become more widespread in the developing counties[1]. In Sri Lanka, around 1.5 million adults suffer from DM and the numbers are expected to rise up to 2.1 million by the year 2030[2]. The standardized prevalence of DM for Sri Lankans was 10.3%, and the prevalence of DM in urban and rural population was 16.4% and 8.7% respectively[3].

Adequate blood glucose control is associated with the reduction of microvascular and macrovascular complications of DM[4,5]. Poor and inadequate glycemic control among patients with DM creates a major public health problem[6], which is associated with high cost for the patients as well as the government[7].

Glycemic control remains as major therapeutic aim for prevention of target organ damage and other complications arising from DM[6]. Recognizing the factors of good glycemic control contributes to a clearer understanding of modifiable factors, which would help to achieve improved glycemic control and improved patient function and outcomes[8].

Although glycemic control is known to reduce complications of DM, it is a challenge for many patients to achieve it[9]. Both patient and health care provider factors may contribute to poor glycemic control[10]. Indeed, therapeutic control of DM generally involves rigorous and permanent lifestyle changes including dietary inter-ventions, physical activity along with strict medical régime[11,12].

A number of studies have addressed the determinants of glycemic control. A study found that glycemic control is significantly associated with age, ethnicity, duration of DM, type and number of medications taken, obesity,

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psychological variables and family support[13]. Further, Body Mass Index (BMI), adhered to diabetic diet, self-monitoring of glucose, gender, access to nurse educator and ethnic background were found to be significant determinants of good glycemic control[14,15].

Fasting blood sugar (FBS) of 110 mg/dl or less is considered as target for better control of hyperglycaemia among patients with DM[16]. Further, American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) Consensus Statement in 2017 recommended that FBS has to be maintained < 110 mg/dl as a target for the better outcome for the patients with DM[17].

The recommended target glycemic control is very difficult to achieve among patients with DM in clinical practice unless the associated factors with good glycemic control are known. Therefore, the aim of this study was to identify the determinants for good glycemic control of DM among patients at Teaching Hospital, Batticaloa District, Sri Lanka.

## 2. Methodology

### 2.1 Study design

An unmatched (1:2) case control study was conducted among patients with DM at the medical clinics of Teaching Hospital in Batticaloa district, Sri Lanka. A case was defined as a patient with DM who had fasting blood sugar less than or equal to 110 mg/dl in at least last 3 consecutive occasions during last 6 months and control was defined as a patient with DM who had fasting blood sugar more than 110 mg/dl in at least last 3 consecutive occasions during last 6 months.

Fasting blood glucose of 110 mg/dl or less is indicated the better glycaemic control among patients with DM[16]. Further, American College of Endocrinology guideline emphasized that fasting blood glucose should be targeted <110 mg/dl[17] and the levels >110 mg/dl are associated with substantial cardiovascular risk.

The sample size was calculated for unequal case control ratio using following equation[18].

$$n = \frac{nCp_1'q_1'(Z\alpha + Z\beta)^2}{(P_1 - P_0)^2}$$

$P_0$ = Expose rate among controls was considered as 50%, R = Odds Ratio = 2, $Z_\alpha$ = value of standard normal distribution corresponding to a significant level of alpha (1.96 at 0.05 level), $Z_\beta$ = value of the standard normal distribution corresponding to the desired level of power (0.84 for power of 80%). The calculated sample size for case was 113 and control was 226.

### 2.2 Participants

The participants included in this study were patients with DM who have lived at least for 2 years in the Batticaloa district, diagnosed at least 2 years ago, with any treatment modality (oral hypoglycemic agents or insulin or both or diet alone) and age of above 30 years. Patients who were pregnant (GDM) and patients having any physical discomfort or pain due to surgery or ulcers when attending the medical clinic were excluded from the study.

### 2.3 Study instrument

The interviewer administered questionnaire (IAQ) was used to collect the data. First IAQ was prepared in English and then translated into Tamil language as Tamil language is mainly used by the Batticaloa population. Tamil translation was done by two independent language experts, retaining the original structure and content as much as possible. The translated questionnaire was compared by other two bilingual English – Tamil experts. The principal investigator (PI) discussed the variations with the two experts and consensual alterations were made. The agreed Tamil version of the IAQ was translated back to English by two bilingual English – Tamil experts. The translated version was rechecked with the original version by the PI for consistency and accuracy of the information. Corrections were done after discussing with the expert translators.

#### 2.3.1 Validation of study instrument

Judgmental validity was achieved by the assessment of the questionnaire by two Consultant Physicians and a Nutritionist with experience of treating patients with DM. Suggested corrections on the wording of the questions were attended by the PI.

#### 2.3.2 Pre-testing and piloting

Questionnaire was pre-tested among 10 DM patients in another hospital in Batticaloa district for acceptability, comprehension, clarity and suitability of the wordings used. Necessary modifications were done. Pilot testing was conducted in the same hospital to identify the potential problems in carrying out the study and to assess the time needed to carry out the study proper.

### 2.4 Data collection

IAQ was completed by trained data collector to avoid interviewer bias. Data collection was carried out by interviewing the patient and using medical records. The data collection was done on clinic day from Monday through Friday. Initially, the clinic's In-charge Nurse

recruited the case and control patients from the clinic according to the inclusion criteria and then these patients were sent to data collector for the interview. The data collector was unaware of the fact whether the patient is a case or control until the end of interview where fasting blood sugar level was assessed.

The nature of the study was explained by using information sheet and a written informed consent was obtained. None of the patients refused an interview. The information was obtained from the selected patients during their clinic waiting hours to enhance the compliance. Each interview lasted for about 30 minutes. Questions were asked in a neutral manner without any facial expressions or stressing on words.

Anthropometric measurements were also taken. Weight was measured with the participant wearing no shoes in kilogram (Kg) up to the nearest 100g[19] using Seca beam scale. Height was recorded in centimeter (cm) to nearest 1cm, with participant standing barefoot, feet together, with head, shoulders, buttocks and heels touching the back of the stadiometer. Head kept looking straight parallel to the floor[20]. BMI was calculated as BMI = weight in Kg/ height in metres$^2$ (Kg/m$^2$)[19].

### 2.5 Statistical analysis

Data were analyzed using Statistical Package for Social Science (SPSS) version 20. Odds ratio with 95% confidence interval was used to test the significance of the differences observed[21]. A probability of <0.05 was considered as statistically significant. Binary logistic regression analysis was used to control the independent and intervening variables upon another.

### 2.6 Ethical issues

The ethical approval was obtained from Ethic Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura, Sri Lanka (ERC No: 627/12).

## 3. Results

A total of 339 DM patients were included (113 good glycemic control and 226 poor glycemic controls) in this study. Respondent rate was 100%. Participants were 98 (29.9%) men and 241 (71.1%) women, aged between 31 and 81 years, with mean age of 57.98 years (SD ± 9.50) and median of 58.00 years (IQR = 13).

Among good glycemic controls, around 36% (n=41) of males had good glycemic control and they were nearly 2 times more likely to have good glycemic control than the female patients (OR 1.69, 95% CI=1.04 - 2.75). Among all good glycemic controls, about 25% (n=28) of them had physically active employment and they were nearly 2 times more likely to have good glycemic control than patients with unemployment or with physically inactive employment (95% CI=1.01 - 2.76). Patients living in rural areas were nearly 3 times more likely to have good glycemic control than those who living in an urban area (OR 2.76, 95% CI=1.73 - 4.39). The summary of the sociodemographic factors is shown in Table 1.

**Table 1. Glycemic control by sociodemographic factors**

| *Socio-demographic Characteristics* | *Good glycemic control (n=113) n (%)* | *Poor glycemic control (n=226) n (%)* | *Unadjusted odds ratio (95% CI)* | *Adjusted odds ratio (95% CI)* |
|---|---|---|---|---|
| Gender | | | | |
| Male | 41 (36.3) | 57 (25.2) | **1.69 (1.04-2.75)** | 1.50 (0.72-3.11) |
| Female | 72 (63.7) | 169 (74.8) | | |
| *Age (years) | | | | |
| < 60 | 60 (53.1) | 126 (55.8) | 0.89 (0.57-1.41) | - |
| ≥ 60 | 53 (46.9) | 100 (44.2) | - | |
| *Level of education # | | | | |
| Primary | 29 (25.7) | 67 (29.6) | 0.82 (0.49-1.36) | - |
| Others | 84 (74.3) | 159 (70.4) | | |
| *Monthly income (Rs) | | | | |
| Low (<10,000) | 75 (66.4) | 168 (74.3) | 0.68 (0.42-1.11) | - |
| Middle & high (≥ 10,000) | 38 (33.6) | 58 (25.7) | | |

*Continued*

| *Socio-demographic Characteristics* | *Good glycemic control (n=113) n (%)* | *Poor glycemic control (n=226) n (%)* | *Unadjusted odds ratio (95% CI)* | *Adjusted odds ratio (95% CI)* |
|---|---|---|---|---|
| *Marital status[$] | | | | |
| Married | 75 (66.4) | 169 (74.8) | 0.67 (0.41-1.09) | - |
| Other | 38 (33.6) | 57 (25.2) | | |
| Employment | | | | |
| Physically active | 28 (24.8) | 36 (15.9) | **1.74 (1.00-3.03)** | 0.70 (0.32-1.50) |
| Physically inactive | 85 (75.2) | 190 (84.1) | | |
| Place of residence | | | | |
| Rural | 68 (60.2) | 80 (35.4) | **2.76 (1.73-4.39)** | **2.08 (1.04-4.15)** |
| Urban | 45 (39.8) | 146 (64.6) | | |

[#] – Educational level was self-reported. Primary education was defined as who had attended school up-to grade 5 or less. "Other" educational level included more than Grade 5.

[$] – Marital status of the patient was self-reported. "Other" marital status included unmarried (17 patients), Living together (1 patient), separated (6 patients), divorced (2 patients) and widowed (69 patients).

* – Were not found to be the significant factors in univariate analysis. Therefore, not included in multivariate analysis

### 3.2 Health status of the patients

The mean duration of DM was 6.46 years (SD ± 5.45) with a median of 4.00 years (IQR = 7) among all patients. Mean duration of DM for good glycemic controls was 5.33 years (SD ± 4.35) with a median of 4.00 years (IQR = 3.25) while poor glycemic controls had the duration of 7.03 years (SD ± 5.86) with a median of 5.00 years (IQR =8). Among all good glycemic controls, about 81.0% (n=91) of patients had been having DM for 7 years or less and these patients were nearly 3 times more likely to have good glycemic control compared with participants who have DM for more than 7 years (95% CI=1.60- 4.68).

The mean Body Mass Index (BMI) among all patients was 25.13 Kg/m$^2$ (SD± 3.71) with a median of 24.84 Kg/m$^2$ (IQR = 4.68) and range from 17.70 - 41.80 Kg/m$^2$. The mean BMI among good glycemic controls was 22.84 Kg/m$^2$ (SD ± 2.71) with a median of 22.49 Kg/m$^2$ (IQR = 3.13) while 26.27 Kg/m$^2$ (SD ± 3.61) with a median of 26.04 Kg/m$^2$ (IQR = 4.18) was among poor glycemic controls. Majority of good glycemic control patients (85%, n=96) were within normal body weight (BMI is less than 23 Kg/m$^2$) and they were 9.5 times more likely to have good glycemic control than those who were with overweight (95% CI=5.33-17.08) (Table 2).

**Table 2. Glycemic control by health status of patients**

| *Factors* | *Good glycemic control (n=113) n (%)* | *Poor glycemic control (n=226) n (%)* | *Unadjusted odds ratio (95% CI)* | *Adjusted odds ratio (95% CI)* |
|---|---|---|---|---|
| Duration of DM (years) | | | | |
| ≤ 7 | 91 (80.5) | 136 (60.2) | **2.74 (1.60-4.68)** | **0.30 (0.14-0.64)** |
| >7 | 22 (19.5) | 90 (39.8) | | |
| Complication of DM | | | | |
| Known | 106 (93.8) | 194 (85.8) | **2.49 (1.07-5.85)** | 0.66 (0.21-2.10) |
| Unknown | 7 (6.2) | 32 (14.2) | | |
| Body Mass Index (BMI) | | | | |
| 18.5 - 22.99 Kg/m$^2$ (normal) | 96 (85.0) | 84 (37.2) | **9.55 (5.33-17.08)** | **0.15 (0.07-0.31)** |
| ≥23 Kg/m$^2$ (overweight) | 17 (15.0) | 142 (62.8) | | |

BMI was categorized based on WHO South East Asia BMI classification

### 3.3 Self-management behaviors of patients

Among those who had good glycemic control, around 74% (n=83) of patients followed the dietary recommendations given by health care provider at clinic and they were nearly 4 times more likely to have good glycemic control than those who do not follow the dietary recommendations (95% CI=2.33 - 6.25).

Among good glycemic controls, majority of them (76%, n=86) were doing regular exercise and these patients were nearly 7 times more likely to have good glycemic control than those who were not doing regular exercise (OR 6.72, 95% CI =3.31-13.64) (Table 3).

### 3.4 Clinical details of the patients

Among good glycemic controls, almost all patients consumed prescribed medication regularly (97%, n=109). Those who had regular medication were 3.5 times more likely to have good glycemic control than those who do not consume medication regularly (95% CI=1.21-10.41).

The percentage of patients who had fixed time for the consumption of medication every day was higher among good glycemic controls than poor glycemic controls (92.7% vs. 68.6%). These patients were nearly 6 times more likely to have good glycemic control than those who do not have the fix time for drug consumption every day (95% CI=2.70-12.64).

Almost all patients (97%, n=109) had regular monthly clinic follow-up among good glycemic controls. These patients were nearly 7 times more likely to have good glycemic control than those who are not regular for the monthly clinics (95% CI=2.44-19.88) (Table 4).

### 3.5 Multivariate analysis of factors associated with good glycemic control

Binary logistic regression was applied to control for confounding factors and to predict the variables associated with good glycemic control. Each 1 year increase in duration of DM and each 1 unit ($Kg/m^2$) increase in BMI was related to a 70% and 85% reduction in odds of achieving good glycemic control respectively.

Patients who live in rural area (OR=2.08, 95% CI=1.04 - 4.15), were doing regular exercise (OR= 6.72, 95% CI=3.31-13.64), having fixed time for consuming medication (OR=3.53, 95% CI=1.32-9.44) and following regular monthly follow-up (OR=5.04, 95% CI=1.28- 19.89) were found to be significant factors for achieving good glycemic control in the logistic regression model.

**Table 3. Glycemic control and self-management behaviors**

| *Attitude related factors* | *Good glycemic control (n=113) n (%)* | *Poor glycemic control (n=226) n (%)* | *Unadjusted odds ratio (95% CI)* | *Adjusted odds ratio (95% CI)* |
|---|---|---|---|---|
| Follow dietary recommendations of doctor/Nurse | | | | |
| Yes | 83 (73.5) | 95 (42.0) | **3.82 (2.33-6.25)** | 0.94 (0.47-1.90) |
| No | 30 (26.5) | 131 (58.0) | | |
| Doing regular exercise | | | | |
| Yes | 86 (76.1) | 57 (25.2) | **9.44 (5.58-15.99)** | **6.72 (3.31-13.64)** |
| No | 27 (23.9) | 169 (74.8) | | |
| *Frequency of exercise/week among regular exercises | | | | |
| ≥ 3 days | 84 (97.7) | 43 (75.4) | **13.67 (2.97- 62.93)** | - |
| < 3 days | 2 (2.3) | 14 (24.6) | | |
| *Duration of exercise /day among regular exercises | | | | |
| ≥ 30 minutes | 82 (95.3) | 45 (78.9) | **5.47 (1.66 - 17.94)** | - |
| < 30 minutes | 4 (4.7) | 12 (21.1) | | |

* Were not found to be the significant factors in multivariate logistic regression model

**Table 4. Glycemic control by medication and clinic follow-up related factors**

| *Clinical related factors* | *Good glycemic control (n=113) n (%)* | *Poor glycemic control (n=226) n (%)* | *Unadjusted odds ratio (95% CI)* | *Adjusted odds ratio (95% CI)* |
|---|---|---|---|---|
| Taking medication regularly | | | | |
| Yes | 109 (96.5) | 200 (88.5) | **3.54 (1.21-10.41)** | 7.38 (0.87-62.56) |
| No | 4 (3.5) | 26 (11.5) | | |
| Time of consumption of medication | | | | |
| There is a fixed time | 102 (92.7) | 155 (68.6) | **5.84 (2.70-12.64)** | **3.53 (1.32-9.44)** |
| There is no fixed time | 8 (7.3) | 71 (31.4) | | |
| Regular clinic follow-up | | | | |
| Every month | 109 (96.5) | 180 (79.6) | **6.69 (2.44-19.88)** | **5.04 (1.28-19.89)** |
| Not every month | 4 (3.5) | 46 (20.4) | | |
| *FBS testing/monthly | | | | |
| Yes | 21 (18.6) | 36 (15.9) | 1.20 (0.67-2.18) | - |
| No | 92 (81.4) | 190 (84.1) | | |

* Were not found to be the significant factors in univariate analysis. Therefore, were not included in multivariate

## 4. Discussion

This is a hospital-based study, reflecting the determinants of good glycemic control among patients with DM attending medical clinic in Sri Lankan context. In this study, it is imperative to ensure that the observed risk between the outcome and the exposure is not distorted by extraneous variables or confounders. The present study was an unmatched case control study and attempts were made in the analysis to assess the confounding factors by using binary logistic regression. Further, a form of selection bias occurs when the subject enrolled for the study differs from those who decline to participate. The selection of cases and controls from the clinic, the cooperation of medical officers and In-charge nursing officer as well as the assurance of confidentiality may have resulted in the high response rate in the present study.

Interviewer bias occurs in case control studies when the exposure status is ascertained by interviewer. In this study, many steps were incorporated in methodology to minimize the interviewer bias by training of an interviewer by the PI, recruitment of case and controls by In-charge nursing officer at clinic and the close supervision of all steps by the PI.

In the present study, male patients had good glycemic control nearly 2 times more than the female patients. Similar observations have been recorded in other countries as well[21,22]. This could be explained that men usually take up exercises or employments outside their homes compared to female patients. Further, the estrogen related protective mechanisms might have been affected by DM in women[23] resulting adversely on lipid profile than in men[24]. Further, fat distribution might have greater role in distributing insulin action in women for their poor glycemic control[25]. However, a study carried out in United States has reported that men adults with DM had significantly poorer glycemic control compared to women[26].

The present study has observed that good glycemic control is associated with shorter duration of DM. This finding is consistent with several studies[27, 28, 29]. A recent study has stated that each one year increase in diabetes duration was related to 5% reduction in the odds of achieving good glycemic control[30]. But in contrast, a study by Nichols et al. (2000) highlighted that shorter duration of diagnosing DM was a highly significant predictor of poor glycemic control. Achieving or maintaining good blood glucose level is difficult in patients with a longer duration of DM[26]. Worsening of glycemic control over time could be explained by a reduction in pancreatic beta cell function and an increased fat mass, which would have led to greater insulin resistance during ageing process[21]. In addition, increased burden of comorbidities and drug resistance with longer duration of DM makes glycemic control more difficult. Therefore, it is essential to educate the patients on continuing to maintain good glycemic control.

The significant contribution of overweight to

glycemic control was also observed in this study population. Patients with normal body weight (BMI < 23 $Kg/m^2$) were 9.5 times more likely to have good glycemic control than those with overweight and obesity. Similar findings were shown in other studies as well[31,32]. Furthermore, it is found that obese patients were 2.4 times more likely to have poor glycemic control than overweight patients. Probably this could be explained by the fact that aggravation of insulin resistance as a result of increased fat mass and visceral adiposity, that affecting insulin sensitivity and causing insulin resistance[33]. But, this finding was different from studies, which have reported no association between obesity/overweight and glycemic control[34,35].

Further, this study showed that compliance to diet and lifestyle modifications resulted in better glycemic control. In addition, it is found that primary care physician is a strongest predictor for achieving good diabetic control as a result of effective communication and encouragement[36]. Therefore, it has been emphasized that intense education and ensuring appropriate changes in therapy would result in a significant short term and long term improvement of glycemic status enhancing diabetic care[37]. This would help in individualizing target HbA1c levels according to patient's preference, age, social, psychological status and other risk factors[21].

Physical activity intervention has been described as the paramount importance for blood glucose control and cardiovascular protection in patients with DM[38]. Findings of this study, also supports this fact. Physical activity has also been emphasized as an effective cost-saving tool in the care of DM[39]. Furthermore, a cohort prospective study had also highlighted that regular aerobic exercise predicted to lower long-term morbidity and mortality among patients with DM[40]. Therefore, an emphasis should be made over the importance of reinforcing physical activity especially walking. The continuous health education has to be promoted among patients with DM.

This study has highlighted that good glycemic control is achieved with adherence to regular medication. Similarly, several previous studies have found that good compliance with medication was associated with good glycemic control[41,42]. Health education needs to be provided to patients with poor drug compliance to improve compliance rather than changing medications or altering the dose to achieve targeted glycemic control.

**Limitation:** In this study, sample size of comparative study was calculated using 50% as the exposure rate among controls, in the Batticaloa district. Further, good glycemic control was determined by using FBS report rather than HbA1c level as HbA1c is not tested in the clinic, Teaching Hospital, Batticaloa.

## 5. Conclusions

Shorter duration of DM, living in a rural area, doing regular exercise, fixed time for consumption of medication, regular clinic follow-up and maintenance of normal body weight (BMI <23$Kg/m^2$) were found to be the factors for good glycemic control among patients with DM. Studies on determinants for good glycemic control is lacking among the population in Sri Lanka and thus, these determinants can be used by health professionals to provide targeted interventions to achieve good glycemic control and in patients at greatest risk of diabetic complications.

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## Conflict of interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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