ORIGINAL RESEARCH

Good Glycemic Control in Type 2 Diabetes Mellitus: An Inquiry-based on Clinic Records in Six Cities of Maharashtra state of India

Shaym Ashtekar

Abstract

Background: Type 2 Diabetes mellitus (T2DM) is a global epidemic, with about 7.3% prevalence in the Indian adult population, 10.3% pre-diabetes, also has a 47% undiagnosed caseload. This study is about Good Glycemic Control (GGC) in T2DM management.

Objectives: To estimate the proportion of GGC attainment among T2DM patients, and associated factors.

Methods: The records (m:202, f: 142) of the first visit of patients attending a private clinic and six lifestyle-modification-diabetes-reversal-clinics in Maharashtra were studied. The sampling was based on convenience. Independent variables like age, gender, energy intake, height, weight, waist, hip, weekly aerobic time, parental history of T2DM, and HbA1c as an outcome variable (by HPLC method), along with antidiabetic medication (ADM) generic count were studied from available records. Data was available in Excel and analyzed with JAMOVI 4.8.6 software.

Results: The study population was mainly sedentary (48%), upper class (54%), and college-educated (72%) with a higher male proportion (59%). Diet type was both vegetarian (45%) and mixed (48%) subjects as compared general population. Findings include Mean and (SD) values: age 53.5(8.89) years, T2DM duration years 5.54 (4.75), Waist in cms F 102(8.86), M 102(11.8), energy intakes in Kcal f 896(324), m 1211(493), HbA1C in gm%: 7.73(2.29), use of ADM 38.1%, missing ADM information 58.4%, ADM free 3.5%, patients having GGC 54.7%. Linear regression for GGC outcome for independent variables age, energy intake, aerobic time, and diabetes duration showed no statistically significant association at p=0.05.

Conclusion: We found that 54.7% of patients had GGC. Sizeable missing data was a constraint.

Keywords: Type 2 diabetes mellitus, HbA1C, BMI, Waist size, Good Glycemic Control

Journal of Research in Medical & Interpathy Sciences. 1(2);2023

Introduction

Type 2 diabetes (T2D) is a rising public health issue as suggested by several studies in India and the National Program for NCDs.[1] India has a T2DM prevalence of 7.3% of the adult population and 10.3% pre-diabetes, and also has a 47% undiagnosed caseload.[2] The much talked about 'rule of halves' states that nearly half of the diagnosed patients are taking any treatment and only half of them are well-treated. In India Kalra et al have stated a 'two-thirds rule' as follows: "Two-thirds of people with diabetes have concomitant hypertension or dyslipidemia; two-thirds do not get their HbA1c assessed; and two-thirds of those who do, do not achieve target values.[3]" The clinical aim of Good Glycemic Control (GGC) is a result of favorable host factors (age, waist size, BMI, energy restriction, and physical activity) as well as anti-diabetic medication (ADM). GGC is defined as HbA1C<7 gm%.[4] In the absence of HbA1C testing, blood glucose monitoring is an option, but this test is limited to current blood glucose level, in contrast to HbA1C which gives a 12-week weighted average. GGC is crucial to T2DM management so that microvascular damage and organ damage are prevented. GGC attainment is difficult even in developed countries with organized healthcare systems, and a Scottish study showed that only 53% of subjects could attain GGC at the end of two years.[5] In the absence of surveys to estimate GGC attainment, we must bank on clinic-based studies of compliance and GGC. There are two difficulties in this. First is poor record keeping and data availability of clinics managing T2D, and second lack of HbA1C testing due to its cost implications upwards of Rs 500 per test, whereas point-of-care technology is available to patients and clinicians for glucose estimation (BSL).[6] Most clinicians hence prefer to use BSL to HbA1C. This study from secondary data from private clinics and lifestyle-modification-diabetes reversal centres started by ADORE trust, popularly known as the Dixit movement, aims to (a) estimate the proportion of GGC,

Department of Community Medicine at SMBT Institute of Medical Science & Research Centre, Nashik, MS, India

Corresponding Author: Shaym Ashtekar, Professor at Department of Community Medicine at SMBT, IMSRC, Nashik, MS, India Email: ashtekar.shyam@gmail.com

OrcID: https://orcid.org/0000-0002-4034-1235

Conflict of Interest: The author has declared no conflict of interest.

(b) explore current practices of T2D management, and (c) estimate some determinants of GGC attainment.

Material and Methods

Study settings: This is a records-based study conducted in 2019-20 from (a) weekly DRCs organized by ADORE Trust Pune from seven cities of Nasik, Pune, Kalyan, Thane, Hingloi, Aurangabad, Solapur (b) A private clinic in Latur, Maharashtra. From 925 records available in the Database, were omitted due to inclusion in other studies and for incompleteness of records, with 346 available for study. A waiver from IEC was obtained by email for study based on records. The records-data base was used only for initial first-visit entry features. Part of this data set was used for two follow-up studies, while this study looks at baseline features of the larger data set for a limited purpose of GGC attainment.[7,8]

Sample size: Using the Open Epi website for sample size calculation we arrived at a sample size of 329 with the following assumptions: "Population size (for finite population correction factor or FPC) (N): 100000. Hypothesized %frequency of outcome factor in the population (p): 31%+/-5. Confidence limits as % of 100 (absolute +/-) (d): 5%. Formula used is n = [DEFF*Np(1-p)]/ [(d2/Z21-α/2*(N-1) + p*(1-p)]" (ref-Open Epi).[9]

We have used the database of patients made available by ADORE Trust. From the original methodology manual made available by the ADORE team, the following details are available. Diabetes status was assumed if the patient had HbA1c ≥ 6.5 gm%, with or without ADM use. Weight was taken on digital weight machines of the same make at all seven centers, and stadiometers were used for height. Waist and hip were measured by tape measure at mid-point between ischial tuberosity, and at greater trochanters respectively in standing position. HbA1c was measured in local labs using HPLC technique, and Fasting insulin was done with CLIA/CMAI technique. Prescriptions were deciphered for generic ADM use using 1-mg website. Weekly aerobic time was estimated by enquiring about daily average walk-time and days in the week walking.

Database in excel was scrutinized for the availability of variables such as age and gender, and from 344 was selected. The data were cleaned by checking and replacing with average for erroneous outliers in case of anthropometric measurements of waist, hip, HbA1c, and energy intakes. The available list of brand name medications was deciphered into generics. GGC was taken as Hba1C ≤ 7.00 gm% (ref) and analyzed for the influence of variables such as gender, waist, BMI, ADM use, energy intake and weekly aerobic minutes from the records. The energy intakes were worked out from cereal intake calories from the NIN handbook and multiplied by a rounded factor of 2.2 to account for other food sources, based on studies.[10,11] For analysis, we used JAMOVI version 4.8.6.[12,13]

Results

The case records had the following city-wise contribution: (a) Marathwada and South Maharashtra (91), Thane and Kalyan (166), and Pune (86). The records had 41.3% women and 58.7% men. The socio-demographic attributes of the patients are shown in Table 1. Table 2 shows the age, anthropometric estimates, diabetes duration, and glycemic status of subjects. Table 3 shows the prevalence of recorded categorical risk factors. Table 4 shows the Linear regression model for HbA1c outcome using independent variables of age, energy intake, aerobic time, and hip size had a statistically significant association at p=0.05. Comorbidities reported in records show that 68 patients out of 344 (19.8%) had some comorbidity, including notably hypertension, heart disease, and thyroid disorder.

Table1: Socio-Demographic profile of the study subjects (n-344).

	Level	Count	Proportion% of R total
Gender	Female	142	41.3
	Male	202	58.7
Group Number	Aurangabad, Latur, Solapur & Hingoli	91	26.5
	Kalyan+Thane	166	58.4
	Pune	86	25.1
Reported Activity type	Heavy	1	0.3
	Moderate	115	33.4
	Missing	62	18
	Sedentary	166	48.3
Occupation	Business	36	10.5
	Domestic work	85	24.7
	Farming	17	4.9
	Not mentioned	16	4.7
	Other	77	22.4
	Service-job	113	32.8
Ration-card color	Missing	159	46.2
	Orange	86	25
	White	85	24.7
	Yellow	14	4.1
Social class	General	185	53.8
	Missing	75	21.8
	OBC+other	63	18.3
	Reserved	21	6.1
Education	College	248	72.1
	MISSING	22	6.4
	Non-Lit	3	0.9
	Schooling	71	20.6
Diet type	Mixed	165	48
	Vegetarian	156	45.3
	No mention	23	6.7

Table 2: Gender-wise descriptives of variables of the study population.

	Gender	Age (yrs)	Kcal intake	T2DM duration (yrs)	Current weight (kg)	Waist (cms)	Hip Cir (cms)	HbA1C (gm%)	Fasting Insulin (mIU/mL)	Aerobic time/ week (min)
N	Female	142	126	75	90	108	118	142	90	142
	Male	202	178	107	147	148	169	202	132	202
Missing	Female	0	16	67	52	34	24	0	52	0
	Male	0	24	95	55	54	33	0	70	0
Mean	Female	53.3	896	6.17	87.3	102	120	7.73	14.5	119
	Male	53.7	1211	5.1	89.8	100	117	7.72	13.4	131
95% CI mean lower bound	Female	51.8	839	4.9	83.8	100	116	7.36	9.45	93.5
	Male	52.5	1138	4.32	87	98.1	114	7.4	11.1	110
95% CI mean upper bound	Female	54.7	953	7.44	90.8	103	123	8.1	19.6	144
	Male	55	1284	5.89	92.5	102	120	8.05	15.6	152
Median	Female	53	792	5	89	101	117	7	9.69	0
	Male	54	1210	4	91	99.5	115	6.9	10	90
Standard deviation	Female	8.55	324	5.52	16.6	8.86	20.8	2.25	24.2	151
	Male	9.14	493	4.1	16.8	11.8	20.8	2.32	13	152
Minimum	Female	25	440	1	49.1	83	90	4.8	2.1	0
	Male	27	440	1	50.8	77	80	4.8	2.63	0
Maximum	Female	74	2024	27	126	130	184	16.9	206	630
	Male	75	2904	30	135	145	170	15.8	98	840
Shapiro-Wilk W	Female	0.987	0.932	0.794	0.97	0.968	0.945	0.801	0.336	0.783
	Male	0.988	0.956	0.798	0.98	0.963	0.952	0.84	0.611	0.816
Shapiro-Wilk p	Female	0.208	< .001	< .001	0.037	0.011	< .001	< .001	< .001	< .001
	Male	0.096	< .001	< .001	0.032	< .001	< .001	< .001	< .001	< .001

Table 1 shows in brief, that the study population was mainly sedentary (48%), upper class (54%), and college-educated (72%) with a higher male proportion (59%). The diet type was both vegetarian (45%) and mixed (48%). Table 2 shows continuous variables with mean and (SD) values: age 53.5 years (8.89), T2DM duration years 5.54 (4.75), Waist in *cms* F 102(8.86), M 102(11.8), energy intakes in Kcal f 896(324), m 1211(493). HbA1C in gm% was 7.73(2.29). From Figure 1, 38.1% of subjects used ADM, while 58.4% of records had no information, and 3.5% were ADM-free. Table 3 shows that 54.7% of patients showed GGC. Except age, all continuous variables were non-normal as shown by Shapiro-wilk test in Table 2. We tested the correlation of waist size and HbA1c (256 records) and found a weak Pearson's correlation (0.0215, df 254, p=0.807).

Figure 1 shows the use of ADM by patients, while Figure 2 shows GGC by gender. Figure 3 shows meal frequency practiced before joining the lifestyle clinic, with a median of six meals/day. Figure 4 shows violin plots of HbA1C in women and men. Figure 5 shows histograms of age, energy intake, weekly aerobic time, and hip size.

We separately analysed records of the Latur clinic, which was a non-lifestyle change subgroup, and had a mean HbA1C 7.65 (1.88) gm%, and the GGC attainment proportion was 44.6%. The independent t-test showed no significant difference (t=-0.268, df 342, p=0.789).

Discussion

Major Study findings: In this group with a mean age of around 53.5 (8.89) years, and mean diabetes duration of about 5.54 (4.75) years, and 38% using ADM, we observed a GGC attainment level of 54.7%**.** Use of ADM and hence compliance with medical treatment, was reportedly only 38% but information on ADM use was missing from many records (58%). The energy intakes were modest for women (mean 945 Kcal) and men (1245 Kcal), while the mean aerobic

Table3: Some categorical risk factors in study population.

	Level	Count	Proportion in % of category
Tobacco	0	301	87.5
	1	22	6.4
	2	2	0.6
	No Response	19	5.5
Smoking	None	315	91.6
	Yes	10	2.9
	No Response	19	5.5
Gutkha	None	320	93
	Yes	5	1.5
	No Response	19	5.5
Alcohol (weekly)	None	297	86.3
	Yes	21	7.1
	No Response	26	7.6
DM in G parents	T2DM in Grandparent	25	7.3
	NA & Missing	319	92.7
DM in Parents	NA & Missing	246	71.5
	Present	98	28.5
DM in siblings	NA&Missing	279	81.1
	Present	65	18.9
ADM use	ADM free	12	3.5
	No info of ADM	201	58.4
	On ADM use	131	38.1
Good Glycemic Control	0 (No)	156	45.3
	1 (Yes)	188	54.7

exercise duration per week was 116 and 146 minutes for women and hence below the mandatory minimum of 150 minutes. The reported meal frequency before lifestyle change acceptance was about 6 meals. The diet patterns of vegetarian and mixed types are balanced. Habitual use of tobacco chewing, smoking, and alcohol consumption are low though most subjects may have declined to offer any information on these matters. Hence although the sampling is of convenience type, the study can give a fair idea of the bulk of T2DM management in the state. However, ADM use at 38% is an underreporting problem, or simply missing data since the study subjects are mostly educated and urban.

The independent variables, as shown in figure 5 histograms are mostly non-normal, except for age. The HbA1C violin diagrams suggest that the bulk of HbA1C values are closely around the mean, with some outliers as shown. Given the non-normal distribution of most of the independent variables, linear regression analysis is unreliable.

The study involves an adequate sample size but weakly represents the T2DM patient population, and except the study center at Latur, all patients were already seeking lifestyle change at the time of joining the free clinics. The sample is more male, urban, educated, sedentary, and higher income groups (shown by white ration card). The locations are spread across the state, namely Marathwada, Mumbai, western Maharashtra, Konkan, and South Maharashtra. A subgroup of Latur clinic with 56 cases had a mean HbA1C 7.65 (1.88) gm%, and the GGC attainment proportion was 44.6%. t test shows no difference between HbA1C values of Latur and other centers. Thus, GGC attainment is low even in the non-lifestyle-change clinic data part of our records.

The estimates of energy (Kcal) intakes and aerobic activity time in this study are largely recall-based and objective estimation is difficult. The energy intake is based on staple-cereal intakes from records and then extrapolated using an adjustment factor of 2.2X cereal intakes, based on a report

Table 4: HbA1C by risk factors: Linear Regression

Model Fit Measures						
Model	R	R^2				
1	0.156	0.0244				
Model Coefficients - HbA1C						
Predictor			**Estimate**	**SE**	**t**	**P**
Intercept			8.12527	1.91991	4.232	< .001
Hip Circumference			0.00189	0.01114	0.17	0.866
Age			-0.00461	0.02544	-0.181	0.856
Est Cal intake			-3.14e−4	4.22E-04	-0.743	0.459
Meals/day			-0.03035	0.11677	-0.26	0.795
Aerobic min/week			0.00143	0.00167	0.852	0.396
Diabetes duration (yrs)			-0.03014	0.04035	-0.747	0.457

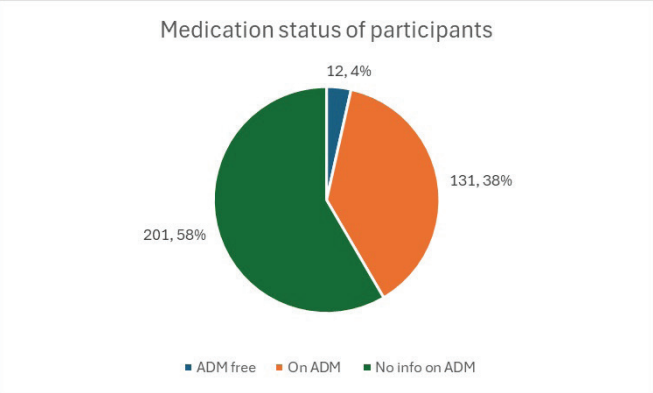

Figure 1: Medicaltion status of participants

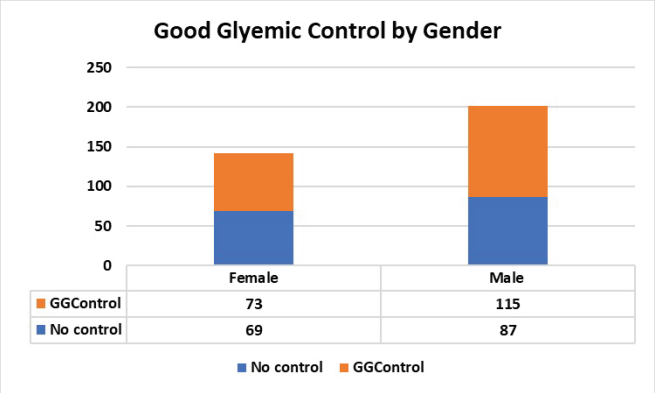

Figure 2: Gender-wise distribution of GGC.

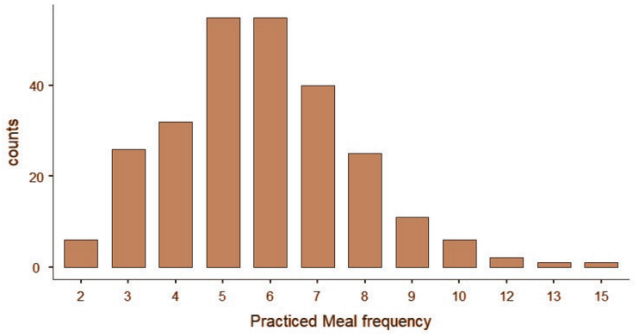

Figure 3: Initial daily meal frequency of participants.

'What India Eats' by Hemlatha. (ref) This gives only a ballpark estimate. The energy intake and physical activity estimates are therefore of limited value. The proxy indicators for these lifestyle factors need to be the outcome indicators of corpulence like BMI, waist size, and hip size. The weak correlation between waist size and energy intake (r=0.705, df =223, p=0.215) does not support such a relation in this study. Also, the weak correlation (r=0.0215) of waist size with HbA1c with a p-value of 0.807 in this study (255 records) is also unsupportive of corpulence and glycemic status.

Explaining GGC Levels

In India, the use of HbA1c for glycemic status is very limited and we observed that most diabetes experts

Our findings of GGC attainment levels concur with a larger Indian study of 2014(ref). The lack of Hb testing is reflected in missing information for 32% of patients. Due to this constraint, and that the majority of patients take treatment at private clinics, GGC levels are difficult to estimate in India. Now with POC machines for HbA1c, there could be more HbA1c testing in clinics. In this study, the DRCs insisted on the HbA1c report before attending clinic, hence we have some data on the HbA1c study here.

One Indian study using either Fasting blood sugar or HbA1c showed nearly 50% GGC levels, while another from India with a higher mean age group (57 years) suggests a 78% level of poor GGC attainment.[5,13] Goyal et al in a tertiary care hospital-based study from Western UP reported a failure to attain GGC in 65% of patients.[14] Thus, GGC attainment in this study at 54% compares well with other Indian studies having somewhat higher age groups.

Importance of GGC for clinical management in India:

GGC is a crucial way of damage control in T2DM.[15] Indian patients remain largely undiagnosed, without adequate treatment and lifestyle management, and falter in treatment compliance. Further, the HbA1c testing, which reports the glycemic status of the last 12 weeks, is essential for measuring the treatment effectivity of T2DM. This study of a large group of patients from several parts of Maharashtra, responding to a lifestyle change campaign, offered to take the HbA1c test at their own cost and hence we could get sizeable data on GGC status. The study shows that of those who took the HbA1c test, 35% had attained GGC. Of the GGC attainers, 32% were using ADM.

The energy intakes are modest and not in the very low-calorie category, while the mean duration of aerobic activity is also low at <150 min/week for both sexes.

In the GGC attainers, users and non-users had a comparable share (47% and 53%).

The important learning from this study is that GGC, which is crucial in the clinical management of T2DM, is a weak factor and we need to rethink the medicalized approach to T2DM management. The reported aerobic time per week (mean <150 min) is also a tell-tale weakness. We also saw adverse corpulence parameters, as mean waist size 102 cm (F) and 100 cm (M), while healthy parameters for Indians are below 80 and 90 cms suggested by an ICMR study.[16] Hence there is a challenge in both diagnosing GGC and lifestyle modification.

In the absence of HbA1c, self-monitored blood glucose (SMBG) is a recommended practice in India by RSSDI.[17] Finally, in brief, our study underlines 'a rule of halves' as regards GGC levels, which calls for comprehensive approaches in T2DM management for better outcomes. One possible direction is a two-meal-a-day and exercise approach along with ADM use. This approach has shown favorable results for glycemic control and reduction of ADM.[7,8]

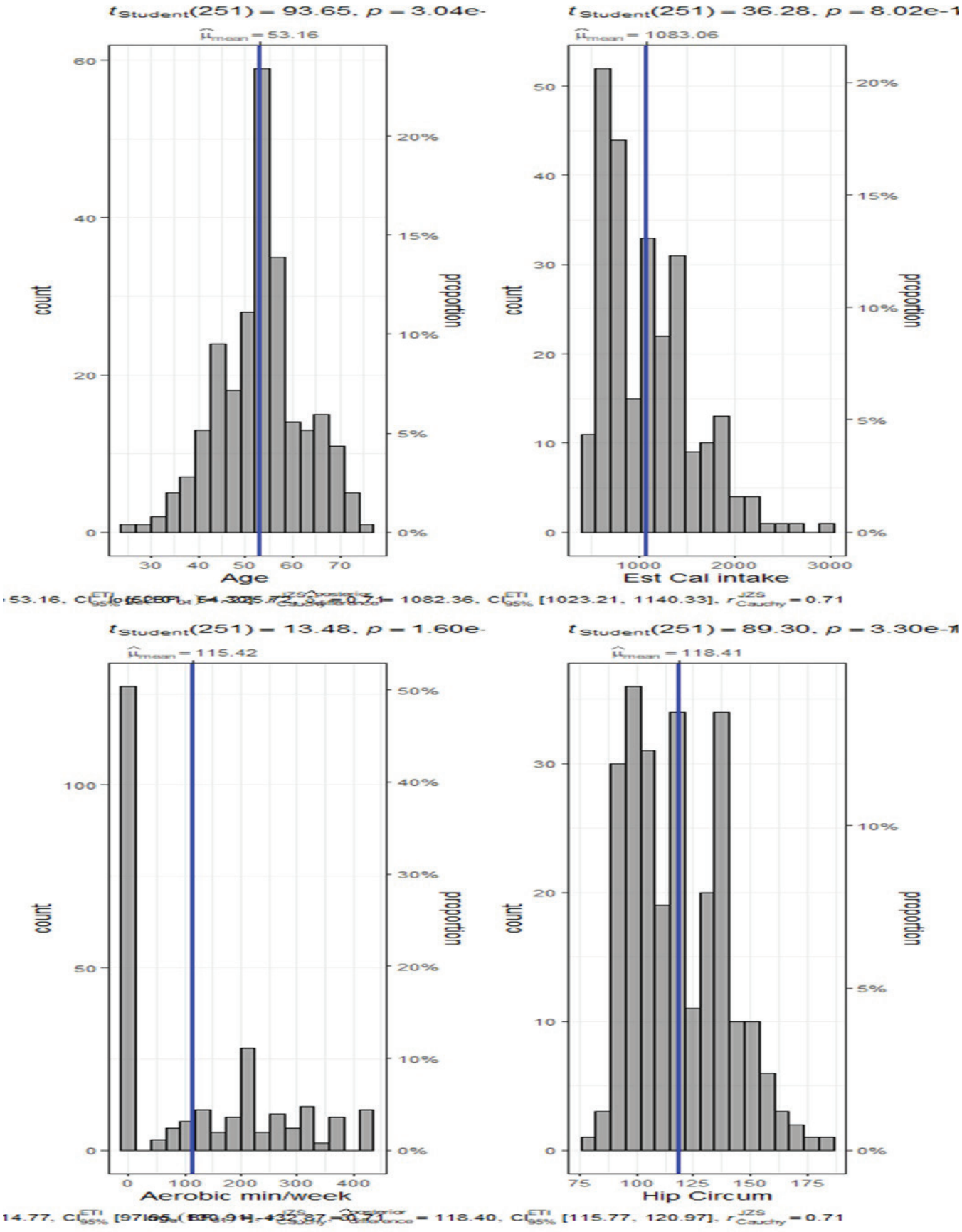

Figure 4: HbA1C distribution of participants.

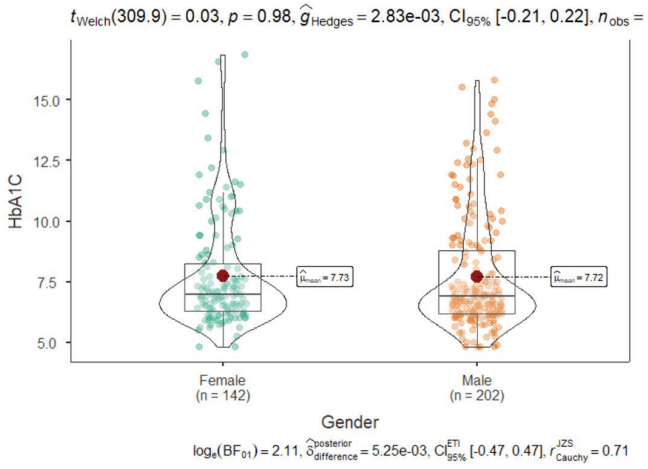

Figure 5: Distribution of age, estimated calorie intake, aerobic workout, and waist size.

Limitations

Record-based studies have several limitations including quality of data, errors, and poor information on the methodology used. It is not a population-based study but of records of patients who were attending clinic and DRCs. Missing data in important variables makes inferential analysis difficult and less tenable. Varying lab sources is another limitation of this study.

Recommendations

Studies of Public hospital-based records for GGC attainment are essential, and the factors leading to GGC. Focussed intervention studies for improving GGC attainment levels are critical to NCD control.

Acknowledgments

We are grateful to ADORE Trust for making an available database of patients in the campaign, including the private clinic records from Latur City.

Conflict of Interest

The author has no conflict of interest.

References

1. Khan MAB, Hashim MJ, King JK, Govender RD, Mustafa H, Al Kaabi J. Epidemiology of type 2 diabetes - Global burden of disease and forecasted trends. J Epidemiol Glob Health 2020;10:107-11.
2. Anjana RM, Deepa M, Pradeepa R, Mahanta J, Narain K, Das HK, et al. Prevalence of diabetes and prediabetes in 15 states of India: Results from the ICMR-INDIAB population based cross-sectional study. Lancet Diabetes Endocrinol 2017;5:585-96.
3. Kalra S, Saboo B, Sahay R, Khandelwal D, Talwar V, Unnikrishnan AG. The rule of two-thirds in diabetes epidemiology. Indian J Endocrinol Metab. 2017 Jan-Feb;21(1):242-244. doi: 10.4103/2230-8210.196027. PMID: 28217526; PMCID: PMC5240070.
4. American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of medical care in diabetes-2019. Diabetes Care 2019;42(Suppl 1):S13-28. doi: 10.2337/dc19-S002.
5. Olickal JJ, Chinnakali P, Suryanarayana BS,Saya GK, Ganapathy k, Subrahmanyam DKS, Medication adherence and glycemic control status among people with diabetes seeking care from a tertiary care teaching hospital, south India, Clinical Epidemiology and Global Health, 2021;11:100742. doi: 10.1016/j.cegh.2021.100742.
6. https://www.openepi.com/SampleSize/SSPropor.htm
7. Ashtekar S, Deshmukh PP, Ghaisas N, Ashtekar C, Upasani S, Kirloskar M, et al. Effect of twoonlymeal frequency and exercise on HbA1C outcomes, weight, and antidiabetic medication in type 2 diabetes in a popular lifestyle change campaign in Maharashtra, compared to conventional clinical management: Aquasiexperimental multicenter study in Maharashtra. Indian J Community Med 2023;48:91-7.
8. Ashtekar SV, Ashtekar RS, Deshmukh PR, Powar JD. Effect of a two-only-meals-a-day and exercise lifestyle on HbA1c and anti-diabetic medication in a follow-up study of subjects with type 2 diabetes attending a free clinic in a north Maharashtra city. Journal of Family Medicine and Primary Care. 2024;13(2):542-548. DOI: 10.4103/jfmpc.jfmpc_795_23
9. T, Ananthan R, Bhaskarachary K, Venkaiah K: Indian Food Composition Tables; 2017. Available from: https:// drive.google.com/file/d/1eqQ578gHiPoIaHaVYjQa_3sFe_LzGhm1/view
10. R Hemlatha AL: What India Eats; 2020. https://www.nin.res.in/nutrition2020/what_india_eats.pdf.
11. The jamovi project (2023). *jamovi*. (Version 2.4) [Computer Software]. Retrieved from https://www.jamovi.org.
12. R Core Team (2022). *R: A Language and environment for statistical computing*. (Version 4.1) [Computer software]. Retrieved from https://cran.r-project.org. (R packages retrieved from CRAN snapshot 2023-04-07).
13. Haghighatpanah M, Nejad ASM, Haghighatpanah M, Thunga G, Mallayasamy S. Factors that Correlate with Poor Glycemic Control in Type 2 Diabetes Mellitus Patients with Complications. Osong Public Health Res Perspect. 2018 Aug;9(4):167-174. doi: 10.24171/j.phrp.2018.9.4.05. PMID: 30159222; PMCID: PMC6110332.
14. Goyal J, Kumar N, Sharma M et.al. Factors affecting glycemic control among patients with type 2 diabetes at a tertiary health care center of western UP region: a cross-sectional study. Int J Health Sci Res. 2019; 9(3):12-20.
15. Rodriguez-Gutierrez R, Gonzalez-Gonzalez J G, ZuÃ±iga-Hernandez J A, McCoy R G. Benefits and harms of intensive glycemic control in patients with type 2 diabetes BMJ 2019; 367:l5887 doi:10.1136/bmj.l5887

16. Pradeepa R, Anjana RM, Joshi SR, Bhansali A, Deepa M, Joshi PP, Dhandania VK, Madhu SV, Rao PV, Geetha L, Subashini R, Unnikrishnan R, Shukla DK, Kaur T, Mohan V, Das AK; ICMR-INDIAB Collaborative Study Group. Prevalence of generalized & abdominal obesity in urban & rural India--the ICMR-INDIAB Study (Phase-I) [ICMR- NDIAB-3]. Indian J Med Res. 2015 Aug;142(2):139-50. doi: 10.4103/0971-5916.164234. PMID: 26354211; PMCID: PMC4613435.
17. Rao PV, Makkar BM, Kumar, A. et al. RSSDI consensus on self-monitoring of blood glucose in types 1 and 2 diabetes mellitus in India. Int J Diabetes Dev Ctries. 2018;38(3):260–279.