

Glycemic Variability and Acute Complications in Type 1 Diabetes: A Non-Randomized Comparative Cross-Sectional Study of Basaglar and Non-Basaglar Use in a Tanzanian Tertiary Hospital

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Abstract

Background and Aims: Type 1 Diabetes Mellitus (T1DM) requires lifelong insulin therapy, and glycemic variability provides clinically useful information beyond HbA1c by describing short-term glucose fluctuations. This study compared CGM-derived glycemic variability and acute glucose excursions among Basaglar and non-Basaglar users attending a tertiary diabetes clinic in Tanzania. **Methods:** This prospective, non-randomized comparative cross-sectional study included 200 patients aged 6 - 26 years with T1DM attending the diabetic clinic at Kilimanjaro Christian Medical Centre (KCMC) during 2023-2024. Participants were classified according to the basal insulin regimen they were already receiving: Basaglar (insulin glargine; n = 105) or NPH/Insulatard (n = 95); treatment was not assigned by the investigators. CGM was performed for 14 days using the FreeStyle Libre Pro iQ system. All analyzed records were reported as 100% sensor-active over the monitoring period. Glycemic variability was defined by coefficient of variation (CV), calculated from glucose standard deviation (SD) and mean glucose, and categorized as acceptable (CV ≤ 36%) or unacceptable (CV > 36%). CGM ranges were defined as TIR 70 - 180 mg/dL, TAR > 180 mg/dL, and TBR < 70 mg/dL. Aggregate numeric mean glucose, SD, TIR, TAR, and TBR values were not available in the retained source summary and were therefore not reconstructed or imputed. **Results:** Among Basaglar

users, 84/105 (80.0%) had acceptable glycemic variability and 21/105 (20.0%) had unacceptable variability. Among non-Basaglar users, 14/95 (14.7%) had acceptable glycemic variability and 81/95 (85.3%) had unacceptable variability. In unadjusted analysis, Basaglar use was associated with lower odds of unacceptable glycemic variability than NPH/Insulatard use (cOR 0.043, 95% CI 0.021 - 0.091; $P < 0.001$). This association remained after adjustment for age, sex, and duration of diabetes (aOR 0.043, 95% CI 0.020 - 0.090; $P < 0.001$). During the 14-day CGM period, hypoglycemic and hyperglycemic excursions occurred in both treatment groups.

Keywords

Glycemic Variability, Continuous Glucose Monitoring, Insulin Glargine, NPH Insulin, Type 1 Diabetes Mellitus, Tanzania

1. Background

Type 1 Diabetes Mellitus (T1DM) is a chronic autoimmune disease characterized by destruction of pancreatic β -cells and absolute insulin deficiency, requiring life-long exogenous insulin therapy [1] [2]. Genetic susceptibility and environmental exposures contribute to disease development, although the precise mechanisms vary between individuals [1]-[3]. In children and young adults, achieving stable glycemia is challenging because insulin requirements are influenced by growth, puberty, diet, physical activity, adherence, and other clinical factors [4] [5]. Glycemic variability describes fluctuations in glucose over time and provides information that complements HbA1c, which primarily reflects average glycemia over the preceding 2 - 3 months [6]-[8].

In children, T1DM symptoms include frequent urination, excessive thirst, increased hunger, weight loss, fatigue, blurred vision, and recurrent infections. High blood sugar can lead to dehydration, weight loss, and fatigue from ineffective glucose utilization. T1DM may also present with diabetic ketoacidosis (DKA), marked by nausea, vomiting, rapid breathing, and altered mental status. Diagnosis is confirmed through specific glucose levels: random plasma glucose ≥ 11.1 mmol/L, fasting plasma glucose ≥ 7.0 mmol/L, 2-hour OGTT ≥ 11.1 mmol/L, or HbA1c $\geq 6.5\%$ [1] [2] [4]. Managing Type 1 Diabetes Mellitus (T1DM) in children involves life-long insulin therapy, either through multiple daily injections (MDI) or continuous insulin infusion via a pump. Regular blood glucose monitoring is essential, with continuous glucose monitoring (CGM) systems offering real-time data for optimal glucose control [9].

Diabetes is a major global noncommunicable disease. The World Health Organization reported that 422 million adults were living with diabetes in 2014 and that diabetes directly caused approximately 1.5 million deaths in 2012 [10]. Diabetes can lead to serious complications affecting the cardiovascular system, eyes, kidneys, nerves, and lower limbs. T1DM differs from type 2 diabetes in its patho-

physiology and requires insulin replacement from diagnosis [1] [2].

The incidence of T1DM varies substantially by age, geography, genetic background, and environmental exposures [11]-[14]. T1DM commonly presents during childhood and adolescence but can occur at any age. The increasing recognition of T1DM in young people worldwide emphasizes the importance of early diagnosis, reliable access to insulin, structured diabetes education, and regular monitoring to reduce acute and chronic complications [5] [12].

In sub-Saharan Africa, T1DM care is affected by delayed diagnosis, limited access to insulin and glucose-monitoring technologies, health-system constraints, and socioeconomic barriers [15]-[18]. Tanzanian studies have documented challenges in achieving glycemic targets among children, adolescents, and young adults with T1DM [4] [9] [19] [20]. These challenges support the need to evaluate glucose patterns and insulin regimens in routine outpatient care using measures that extend beyond HbA1c.

Evidence from African settings indicates that the age at onset and sex distribution of T1DM vary across countries. In Tanzania, limitations in population-based surveillance and delayed or missed diagnosis have contributed to uncertainty in estimating disease incidence [16] [17]. Acute complications, including DKA and hypoglycemia, and long-term microvascular and macrovascular complications contribute to morbidity, mortality, reduced quality of life, and substantial costs for affected individuals, families, and health systems [18] [19].

Research on diabetes increasingly emphasizes strategies to improve prevention of complications and the quality of disease management. The WHO Technical Advisory Group on Diabetes has highlighted the need for research and innovation that address gaps in diabetes care, particularly in resource-limited settings [6] [21]. In T1DM, glycemic variability is clinically important because greater glucose fluctuation is associated with increased exposure to both hypo- and hyperglycemia [22].

Basal-bolus insulin therapy combines basal insulin to suppress hepatic glucose production between meals and overnight with prandial insulin to cover meal-related glucose excursions. NPH (Insulatard) is an intermediate-acting basal insulin with a pronounced peak and a shorter, more variable time-action profile; it often requires twice-daily administration. Insulin glargine U100 (Basaglar) has a flatter profile without a pronounced peak and a longer duration of action, allowing once-daily basal administration in many patients [23] [24]. Pharmacokinetic studies in T1DM have shown that glargine has a flatter and more prolonged action profile than NPH, although clinical outcomes depend on dose, prandial insulin, adherence, diet, and other patient-level factors [23] [24].

Glycemic variability (GV) describes fluctuations in glucose concentrations within and between days, including periods of hypoglycemia and postprandial hyperglycemia [25] [26]. For CGM-derived glucose data, the coefficient of variation (CV), calculated as standard deviation divided by mean glucose and expressed as a percentage, is a commonly used measure of GV. A $CV \leq 36\%$ is generally considered acceptable, whereas $CV > 36\%$ indicates higher or unacceptable glycemic variability.

ity [7]. GV complements measures of average glycemia by describing the magnitude of short-term glucose fluctuations [27].

In Tanzania, T1DM management involves clinical follow-up, access to insulin, diabetes education, and glucose monitoring. HbA1c reflects average glycemia over approximately the preceding 2 - 3 months, whereas CGM provides complementary information on glucose patterns, time in range, and glycemic variability [28]-[31]. Differences in the pharmacologic profiles of insulin glargine and NPH may be associated with different glucose patterns; however, in a non-randomized study such as the present one, observed differences cannot be interpreted as causal treatment effects [8] [32] [33]. Patient age, duration of diabetes, treatment characteristics, adherence, diet, physical activity, and other clinical or socioeconomic factors may also contribute to glycemic variability [28] [34].

Evidence comparing glycemic variability among young people using Basaglar and NPH insulin in routine care in sub-Saharan Africa remains limited. The present study therefore compared CGM-derived glycemic variability and acute glucose excursions among children, adolescents, and young adults with T1DM receiving Basaglar or NPH/Insulatard at KCMC. Because treatment was not randomized, the study was designed to describe associations rather than establish treatment effectiveness. Prospective studies with detailed characterization of basal and prandial insulin exposure are needed to determine whether observed associations persist after accounting for treatment selection and other confounders.

2. Materials and Methods

This was a prospective, non-randomized comparative cross-sectional study involving patients with Type 1 Diabetes Mellitus aged 6 - 26 years attending the diabetic clinic at Kilimanjaro Christian Medical Centre (KCMC) during 2023-2024. Participants were recruited from the KCMC diabetic clinic. Eligible patients were identified from diabetic clinic records using a recruitment checklist and were enrolled consecutively from eligible clinic attendees during the study period. Patients were eligible if they had T1DM, were aged 6 - 26 years, had been receiving insulin therapy for more than 6 months before enrolment, provided written informed consent and/or assent as appropriate, and remained on the same type of insulin therapy during the study period. Pregnant patients and debilitated patients unable to adequately participate in consent or questionnaire procedures were excluded. Participants were compared according to the basal insulin regimen they were already receiving; treatment allocation was not randomized or assigned by the investigators.

2.1. Data Collection Methods

Data collection involved a structured questionnaire, clinical information, patient records, laboratory testing, and continuous glucose monitoring. Treatment exposure was defined by the basal insulin regimen used at enrolment. Basaglar users received insulin glargine once daily, whereas non-Basaglar users received NPH insulin (Insulatard) twice daily. All eligible participants had been receiving insulin

therapy for more than 6 months and remained on the same insulin type during the study period. The questionnaire recorded insulin type (including Actrapid, Insulatard, Mixtard, and Basaglar), injection timing, and total daily insulin dose. Total daily insulin dose was expressed in IU/kg/day and categorized as <0.8 , $0.8 - 1.2$, or >1.2 IU/kg/day. The source study did not capture sufficient information to report the duration on the current basal insulin, basal-only dose, participant-level reason for selection of Basaglar versus NPH, or a group-specific concurrent prandial insulin regimen. These requested exposure characteristics therefore cannot be reported without unsupported assumptions. Basal treatment was part of routine clinical care and was not assigned by the investigators.

HbA1c was measured separately from CGM using the LumiraDx platform and represented average glycemia over approximately the preceding 2 - 3 months. CGM was performed for 14 days using the FreeStyle Libre Pro iQ system. For CGM analyses, hypoglycemia was operationally defined as sensor glucose < 70 mg/dL (<3.9 mmol/L), hyperglycemia as sensor glucose > 180 mg/dL (>10.0 mmol/L), and time in range as $70 - 180$ mg/dL ($3.9 - 10.0$ mmol/L), consistent with standardized CGM metrics [35]. Glycemic variability was assessed using coefficient of variation (CV), with $CV \leq 36\%$ categorized as acceptable and $CV > 36\%$ as unacceptable. A prespecified minimum CGM completeness threshold was not stated in the original protocol; however, all participants included in the analysis had 14-day CGM records reported as 100% sensor-active and sufficient for calculation of CV. Current consensus recommends at least 70% active CGM data over 14 days for pattern assessment [35].

Acute glucose excursions were derived from the 14-day CGM monitoring period rather than from a retrospective questionnaire window. Participants were categorized as having hypoglycemia only, hyperglycemia only, or separate episodes of both hypoglycemia and hyperglycemia during monitoring. “Both” therefore indicates distinct low- and high-glucose episodes occurring at different times, not simultaneous events. DKA was collected as part of the broader clinical history but was not an outcome summarized in the comparative acute-event analysis and is therefore not included as a CGM-defined acute outcome.

2.2. Data Analysis and Interpretation

Data were analyzed using SPSS version 25 for the original study, and the primary regression analysis was re-estimated from the individual-level study dataset for this revision. Continuous variables were summarized using mean (SD) or median (interquartile range), as appropriate, and categorical variables using frequencies and percentages. Glycemic variability was dichotomized as acceptable ($CV \leq 36\%$) or unacceptable ($CV > 36\%$), with unacceptable glycemic variability coded as the binary outcome. The primary exposure was basal insulin regimen (Basaglar versus NPH/Insulatard). Crude associations were estimated using binary logistic regression. A parsimonious multivariable logistic regression model was specified a priori and included age, sex, and duration of diabetes as potential confounders be-

cause these factors may be associated with both treatment selection and glycemic outcomes. Duration of diabetes was calculated from the recorded date of diagnosis to the date of CGM activation. Crude odds ratios (cORs) and adjusted odds ratios (aORs) with 95% confidence intervals (CIs) and two-sided P values were reported. Statistical significance was defined as $P < 0.05$. The adjusted model included all 200 participants and converged successfully. Because treatment allocation was non-randomized, adjusted estimates are interpreted as associations and not causal treatment effects. No unsupported variables were added to the model solely for statistical significance, in keeping with transparent observational reporting principles consistent with STROBE.

3. Results

The study involved 200 patients with Type 1 Diabetes Mellitus at KCMC Hospital, including 105 Basaglar users (Insulin Glargine) and 95 non-Basaglar users (Insulatard/Insulin Isophane). The mean age was 15.4 years (SD 5.9), with most patients aged 13 to 19 years (34.5%). Males comprised 51% of the cohort, and 52.5% had a secondary education. Most patients lived in rural areas (60.5%), with 41.5% of parents married and 39.5% employed. The median guardian income was 80,000 Tanzanian shillings (IQR 25,000 - 200,000), and the median household size was 5 (IQR 3 - 6). Most patients (54.0%) were primarily cared for by their parents, while 11.0% were self-caring (**Table 1**).

Table 1. Demographic characteristics of the study participants (N = 200).

Characteristics	Frequency (n)	Percentage (%)
Patient age (years), mean (SD)	15.4 (5.9)	
≤12	68	34.0
13 - 19	69	34.5
>19	63	31.5
Patient sex		
Male	102	51.0
Female	98	49.0
Patient education		
Primary	57	28.5
Secondary	105	52.5
Tertiary	38	19
Residence		
Urban	79	39.5
Rural	121	60.5
Guardian education		
Primary	64	32

Continued

Secondary	77	38.5
Tertiary	59	29.5
Parents take care most of the time		
No	92	46.0
Yes	108	54.0
Self-care most of the time		
No	178	89.0
Yes	22	11.0
Parents marital status		
Married	83	41.5
Not married	117	58.5
Parent employment status		
Employed	79	39.5
Self-employed	44	22.0
Unemployed	34	17.0
Peasant	43	21.5
Monthly income (IQR)	80,000 (25,000 - 200,000)	
Monthly income (TZS)		
≤100,000	140	70.0
100,001 - 500,000	52	26.0
>500,000	8	4.0
Number of people in household (IQR)	5 (3 - 6)	
Number of people in household		
≤3	60	30.0
4 - 6	122	61.0
>6	18	9.0

Note: IQR: Interquartile Range; SD: Standard Deviation.

3.1. Clinical Characteristics of the Study Participants

The study comprised 105 Basaglar users (insulin glargine) and 95 non-Basaglar users (NPH insulin/Insulatard). Most participants had a normal body mass index (47.0%), 37.5% had a family history of diabetes, and 87.0% reported physical exercise. High carbohydrate, fat, and protein intake were reported in 81.0%, 62.0%, and 66.0%, respectively. Half of the participants (50.5%) had diabetes for less than 6 years, and 51.5% had average glucose within the study-defined range of 3.9 - 10.0 mmol/L. The overall HbA1c counts were reconciled from the treatment-specific source tables: 92 participants (46.0%) had HbA1c < 10% and 108 (54.0%) had HbA1c ≥ 10%. Total daily insulin dose was <0.8 IU/kg/day in 48.5% of partici-

pants, and 52.5% had high medication adherence (**Table 2**).

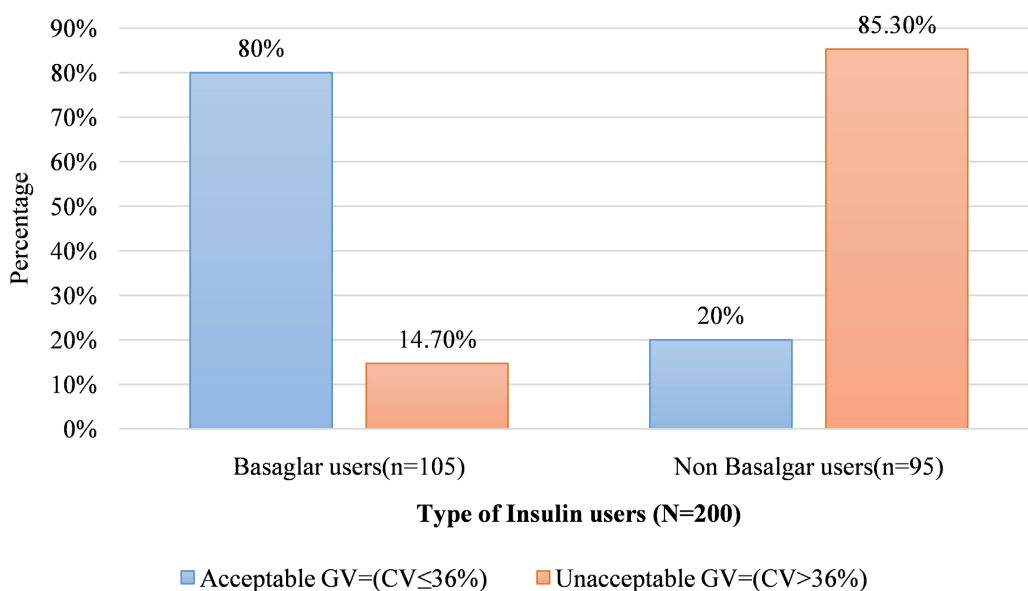
Table 2. Clinical characteristics of the study participants (N = 200).

Characteristics	Frequency (n)	Percentage (%)
Body mass index (kg/m²)		
Underweight	43	21.5
Normal	94	47.0
Overweight	45	22.5
Obese	18	9.0
Family history of DM		
No	125	62.5
Yes	75	37.5
Physical exercise		
No	26	13.0
Yes	174	87.0
Macronutrients per week: Carbohydrate intake		
Low	2	1.0
Moderate	36	18.0
High	162	81.0
Fat source use		
Low	8	4.0
Moderate	68	34.0
High	124	62.0
Protein		
Low	3	1.5
Moderate	65	32.5
High	132	66.0
Vegetables use		
Low	2	1.0
Moderate	49	24.5
High	149	74.5
Duration of diabetes mellitus (years)		
<6	101	50.5
6 - 10	66	33.0
>10	33	16.5
Average glucose (mmol/l)		
Normal (3.9 - 10.0)	103	51.5
Hyperglycemia (>10.0)	97	48.5

Continued

HbA1c (%)		
<10	92	46.0
≥10	108	54.0
Insulin dosage (IU/Kg/day)		
<0.8	97	48.5
0.8 - 1.2	76	38.0
>1.2	27	13.5
Medication adherence		
High	105	52.5
Moderate	60	30.0
Low	35	17.5

Among the 105 Basaglar users, 84 (80.0%) exhibited acceptable glycemic variability, and 21 (20.0%) exhibited unacceptable variability. Among the 95 non-Basaglar users, 14 (14.7%) had acceptable glycemic variability and 81 (85.3%) had unacceptable variability (**Figure 1**).



Note: GV: Glycemic Variability; CV: Coefficient of Variation.

Figure 1. Glycemic variability classification among Basaglar and NPH/Insulatard users based on coefficient of variation.

Glycemic variability differed between the two treatment groups. Among Basaglar users, 84/105 (80.0%) had acceptable glycemic variability, and 21/105 (20.0%) had unacceptable variability; among non-Basaglar users, 14/95 (14.7%) had acceptable variability and 81/95 (85.3%) had unacceptable variability. Recalculation from these denominators gives a crude odds ratio of 0.043 for unacceptable glycemic

variability among Basaglar versus NPH/Insulatard users (95% CI 0.021 - 0.091; $P < 0.001$) (**Table 3**). The point estimate lies within the reported CI, and the P value is consistent with the interval excluding 1.00. This estimate represents an association in a non-randomized comparison and should not be interpreted as a causal treatment effect.

Table 3. Association of glycemic variability between Basaglar users and non-Basaglar users (N = 200).

Basal Insulin Group	Glycemic Variability		OR (95% CI)	P Value
	Acceptable n (%)	Unacceptable n (%)		
Total	98 (49.0)	102 (51.0)		
NPH/Insulatard	14 (14.7)	81 (85.3)		
Basaglar (Insulin Glargine)	84 (80.0)	21 (20.0)	0.043 (0.021 - 0.091)	<0.001

Note: Acceptable GV = coefficient of variation (CV) $\leq 36\%$.

3.2. The Acute Complications between Basaglar Users and Non-Basaglar Users

Among the 105 Basaglar users, 30 (28.6%) had recorded hypoglycemic events, 41 (39.0%) had recorded hyperglycemic events, and 34 (32.4%) had records of both event types during separate episodes. Among the 95 non-Basaglar users, 40 (42.1%) had hypoglycemic events, 29 (30.5%) had hyperglycemic events, and 26 (27.4%) had both event types during separate episodes. Hypoglycemia and hyperglycemia were therefore not interpreted as simultaneous events (**Figure 2**).

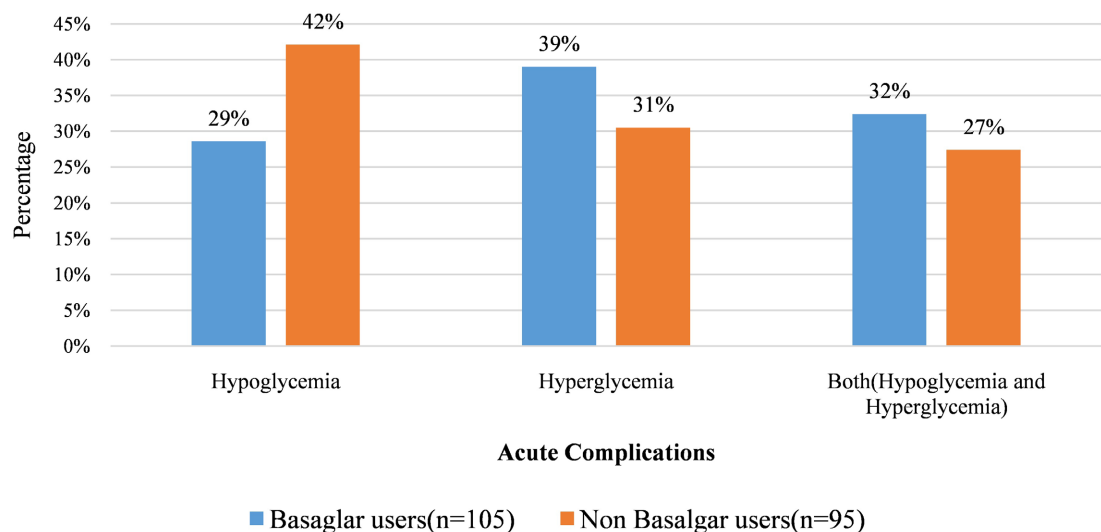


Figure 2. Acute complications between Basaglar users and non-Basaglar users (N = 200).

3.3. Association between Basal Insulin Regimen and Unacceptable Glycemic Variability

In the unadjusted logistic regression analysis, Basaglar users had lower odds of un-

acceptable glycemic variability than NPH/Insulatard users (cOR 0.043, 95% CI 0.021 - 0.091; $P < 0.001$). In the prespecified multivariable model adjusting for age, sex, and duration of diabetes, the association remained essentially unchanged (aOR 0.043, 95% CI 0.020 - 0.090; $P < 0.001$). Age, sex, and duration of diabetes were not independently associated with unacceptable glycemic variability in this model (**Table 4**). All reported point estimates fall within their respective 95% CIs, and the reported P values are directionally consistent with those intervals.

Table 4. Logistic regression model for unacceptable glycemic variability among participants with T1DM (N = 200).

Variable	cOR (95% CI)	P Value	aOR (95% CI)	P Value
Basaglar vs NPH/Insulatard	0.043 (0.021 - 0.091)	<0.001	0.043 (0.020 - 0.090)	<0.001
Age, per year	-	-	1.008 (0.936 - 1.087)	0.826
Female vs male	-	-	1.046 (0.499 - 2.192)	0.905
Duration of diabetes, per year	-	-	1.004 (0.909 - 1.108)	0.944

Note: Outcome = unacceptable glycemic variability (CV > 36%). Reference group for basal insulin = NPH/Insulatard; reference group for sex = male. cOR = crude odds ratio; aOR = adjusted odds ratio; CI = confidence interval. The adjusted model included basal insulin regimen, age, sex, and duration of diabetes.

4. Discussion

This study compared glycemic variability among patients with T1DM receiving insulin glargine (Basaglar) and NPH insulin (Insulatard) within routine outpatient care. Acceptable glycemic variability was observed in 84/105 (80.0%) Basaglar users and 14/95 (14.7%) non-Basaglar users. The observed difference indicates an association between basal insulin regimen and glycemic variability in this cohort; it does not demonstrate that Basaglar caused the difference because treatment was not randomized. Pharmacokinetic differences between insulin glargine and NPH may provide a biologically plausible explanation for different glucose patterns, but residual confounding related to clinical and treatment characteristics remains possible. CGM-based studies of basal insulin therapy similarly demonstrate that glycemic variability can differ across insulin regimens, supporting further prospective evaluation.

Glycemic control remains particularly important in children, adolescents, and young adults with T1DM. The higher proportion of acceptable glycemic variability observed among Basaglar users in this study should therefore be interpreted as an association rather than evidence of treatment effectiveness. Tanzanian literature has documented challenges in achieving glycemic targets among young people with T1DM, emphasizing the importance of access to insulin, adherence, caregiver support, education, and regular follow-up. CGM complements HbA1c by characterizing short-term glucose excursions and may help clinicians identify patterns of hypo- and hyperglycemia that are not captured by HbA1c alone.

The re-estimated multivariable analysis strengthened the primary comparative finding. After adjustment for age, sex, and duration of diabetes, Basaglar use remained strongly associated with lower odds of unacceptable glycemic variability

compared with NPH/Insulatard use. The adjusted estimate was very similar to the crude estimate, suggesting that these prespecified confounders did not materially explain the observed difference between treatment groups. Nevertheless, because treatment was not randomized, residual confounding from factors such as access to insulin, prescribing decisions, adherence, diet, socioeconomic circumstances, and other clinical characteristics remains possible; the adjusted association should therefore not be interpreted as a causal treatment effect.

5. Acute Complications among the Patients with Type 1 Diabetes

During the 14-day CGM monitoring period, the source results reported 30 (28.6%) Basaglar users with hypoglycemia only, 41 (39.0%) with hyperglycemia only, and 34 (32.4%) with both event types; corresponding counts among non-Basaglar users were 40 (42.1%), 29 (30.5%), and 26 (27.4%). The reported categories sum to the treatment-group denominators. Because the available source materials do not provide a separate “neither” category or additional event-level data, these findings are reported descriptively as presented in the source results. The “both” category denotes occurrence of low- and high-glucose episodes during the monitoring period rather than simultaneous hypo- and hyperglycemia. These differences should not be interpreted as causal treatment effects.

6. Study Limitations

This study was conducted at a single center, which may limit generalizability. Its cross-sectional, non-randomized design prevents causal inference. Although the primary regression model adjusted for age, sex, and duration of diabetes, residual confounding may remain from factors influencing access to or selection of Basaglar, adherence, diet, socioeconomic circumstances, prandial insulin use, and other clinical characteristics. The sample size may not fully represent the broader T1DM population. Although analyzed CGM records were reported as 100% sensor-active, CGM measurements remain subject to sensor measurement error. The retained source summary did not provide aggregate treatment-group mean glucose, SD, TIR, TAR, or TBR values, so these metrics could not be reported numerically without re-accessing the underlying CGM export. Some clinical and behavioral variables relied on participant or caregiver report and may therefore be affected by reporting bias. The 14-day CGM period characterizes short-term glucose patterns and may not represent longer-term variability.

In this prospective, non-randomized comparative cross-sectional study, Basaglar use was associated with a substantially higher proportion of acceptable glyce-mic variability than NPH/Insulatard use. In the re-estimated parsimonious lo-gistic regression model, Basaglar use remained associated with lower odds of un-acceptable glyce-mic variability after adjustment for age, sex, and duration of dia-betes. CGM-detected hypoglycemic and hyperglycemic excursions occurred in both treatment groups during the 14-day monitoring period. Because treatment

allocation was not randomized, these findings demonstrate association rather than causation. Larger prospective and randomized studies are needed to determine whether the observed differences are attributable to the basal insulin regimen itself.

Transparency Statement

The corresponding author, Asmaa Kimaro, affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Ethical Approval

Ethical approval was obtained from the Kilimanjaro Christian Medical Centre Research Ethics Committee. Written informed consent was obtained from adult participants and from parents or legal guardians of minors, with assent obtained from minors as appropriate. The ethics approval number was not available in the retained manuscript source and has therefore not been fabricated.

Availability of Data and Materials

The study data are not publicly available because they contain participant-level clinical information. Data-access inquiries may be directed to the corresponding author and are subject to applicable ethical and institutional requirements.

Author Contributions

A.K. conceptualized the study, collected data, and drafted the manuscript. K.K., K.R., and V.M. contributed to study conceptualization, data curation, analysis, and manuscript revision. R.F., E.M., L.M., and A.S. provided supervision and critically revised the manuscript. All authors reviewed and approved the final manuscript.

Conflicts of Interest

The authors declare that they have no competing interests.

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