Ethiopian Orthodox Christian Fasting and Glycemic Outcomes in Type 2 Diabetes: A Facility-based Comparative Cohort Study

By: Brook Alemayehu (MD), Internist, Endocrinology & Metabolism Subspecialty Fellow

Advisor: - Dr. Tedla Kebede (Consultant Internist & Endocrinologist, Associate Professor of Medicine at Addis Ababa University)

A THESIS SUBMITTED TO ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCES, DEPARTMENT OF INTERNAL MEDICINE, ENDOCRINOLOGY & METABOLISM UNIT IN PARTIAL FULFILLMENT FOR THE REQUIREMENT OF SUBSPECIALITY CERTIFICATE IN ENDOCRINOLOGY & METABOLISM

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Declaration Form

I, Dr. Brook Alemayehu Tesfaye, certify that this research is my own work, and that I have acknowledged all material and sources used in its preparation, whether they be books, articles, reports, lecture notes, and any other kind of document, electronic or personal communication. I also certify that this research work has not previously been submitted for assessment in any other unit, except where specific permission has been granted from all unit coordinators involved, or at any other time in this unit, and that I have not copied.

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Student's Name: Dr. Brook Alemayehu Tesfaye .

Student's Signature: _____

Date of signing: _____

Final Approval Sheet

This thesis entitled Ethiopian Orthodox Christian Fasting and Glycemic Outcomes in Type 2 Diabetes: A Facility-based Comparative Cohort Study conducted by Dr. Brook Alemayehu Tesfaye has been submitted with my approval as advisor.

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Abbreviations and Acronyms

AAU ---------Addis Ababa University

ADA ---------American Diabetes Association

ASCVD ---------Atherosclerotic Cardiovascular Disease

ATPIII---------Adult Treatment Panel III

BG ---------Blood glucose

BMI ---------Body Mass Index

BP ---------Blood pressure

CAD ---------coronary artery disease

CHS ---------College of Health Sciences

CI ---------Confidence Interval

CKD-EPI---------Chronic Kidney Disease Epidemiology Collaboration

CVD ---------Cerebra vascular Disease

DBP ---------Diastolic Blood Pressure

DDP-IV---------Dipeptidyl peptidase-4

DKD ---------Diabetic Kidney Disease

DM ---------Diabetes Mellitus

DN ---------Diabetic Neuropathy

DR ---------Diabetic Retinopathy

eGFR ---------estimated glomerular filtration rate

EOTC ---------Ethiopian Orthodox Tewahedo Church

ETB ---------Ethiopian Birr

FBS ---------Fasting Blood Sugar

FFM ---------Free fat mass

FMoH ---------Federal Ministry of Health

HDL-C----------High Density Lipoprotein Cholesterol

HHS ---------Hyperosmolar Hyperglycemic State

hr ---------Hour

IDF ---------International Diabetes Federation

IF ---------Intermittent Fasting

ILI ---------Intensive Lifestyle Intervention

IRB ---------Institutional Review Board

kg ---------Kilo grams

LDL-C---------Low Density Lipoprotein Cholesterol

LED ---------Low Energy Diet

LMIC ---------Low-and-middle income countries

MENA---------Middle East and North Africa

mg/dl ---------Milligrams per deciliter

mm Hg---------Millimeter of mercury

NSAP ---------National Strategic Action Plan

OR ---------Odds ratio

PAD ---------Peripheral arterial disease

SBP ---------Systolic Blood Pressure

SD ---------Standard Deviation

SGLT2---------Sodium-glucose co-transporter 2

SMBG ---------Self-monitoring of blood glucose

SU ---------Sulfonylurea

T1DM ---------Type 1 Diabetes Mellitus

T2DM ---------Type 2 Diabetes Mellitus

TASH ---------Tikur Anbessa Specialized Hospital

TC ---------Total Cholesterol

TG ---------Triglyceride

UACR ---------urine albumin-to-creatinine ratio

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Abstract

Background:

Religious fasting is a common practice across many faith traditions, yet most research on fasting and diabetes has focused on Ramadan fast. Ethiopian Orthodox Christian (EOTC) fasting involves prolonged abstinence from animal products and day time food restriction, but its metabolic implications for patients with diabetes is not well studied

Objective:

To assess the impact of Ethiopian Orthodox Christian (EOTC) fasting on glycemic control, anthropometric and lipid parameters, and hypoglycemia risk among patients with type 2 diabetes.

Method:

A prospective comparative cohort study was conducted at Tikur Anbessa Specialized Hospital (TASH) among adults with type 2 diabetes who either fasted or did not fast during the Great Lent fast of 2025. Baseline and post-fasting data were collected via a structured questionnaire. Anthropometric measurements and laboratory tests were taken at each time points. Paired and independent t-tests were done to detect within and between group differences, respectively. Regression model was used to identify predictors of hypoglycemia in the fasting group. ANCOVA was used to adjust for baseline imbalances.

Results:

A total of 128 participants were included in the study (64 each in each group). There was a significant HbA1c reduction in the fasting group (mean change in HbA1C of -0.4%, 95% CI: -0.7, -0.1) as well as in the non-fasting group (mean change in HbA1C of -0.6%, 95% CI: -0.8, -0.3). However, there was no difference between the two groups with estimated marginal mean (EMM) change 0.1%, 95% CI -0.2,0.5). Similar findings were noted in weight, BMI and waist circumference. A trend towards better lipid benefit was noted in the fasting group but did not attain statistical significance. Hypoglycemia rates were comparable between the two groups (26.6%in the fasting group and 23.4% in the non-fasting group). However, more frequent hypoglycemia (5 or more episodes per person) occurred in 7 (41.2%) patients in the fasting

group as compared to 3 (20.0%) in the non-fasting group. There were 3 episodes of level 3 hypoglycemia and all were in the fasting group. Presence of diabetic kidney disease was as an independent predictor of hypoglycemia in the fasting period (aOR=10.9, 95% CI 1.4 to 86.3).

Conclusion:

EOTC fasting may be safely practiced by many individuals with type 2 diabetes but individualized risk assessment, structured education, and treatment adjustment are essential.

Keywords: Fasting, Religious, Religious fasting, Diabetes, T2DM, Orthodox, Christian, EOTC, Ethiopia

1.Introduction

Religious fasting is a popular practice among people of various faiths (Christianity, Islam, Judaism etc.) around the world and is commonly used for spiritual cleansing, self-discipline, empathy, and growing closer to the divine. The time, particular practices, and reasons for fasting vary in each religion, although most entail refraining from certain foods or activities for spiritual reasons. Religious fasting, in addition to its spiritual benefits may have physical and metabolic health benefits.

The Ethiopian Orthodox Church (EOTC) has distinct fasting practices from other Christian and non-Christian fasting traditions in several key ways. In addition to the twice-per-week (Wednesday and Friday) fasts throughout the year, there are six designated fasting periods each year. These include the Great Lent (Abiyi Ts'om or Tsome Hudade, the 55-day fast leading up to Easter), Nativity Fast (pre-christmas fast, 45 days), Sene fast (Apostles fast, 10–40 days), Assumption or Dormiton fast (Tsome Felseta, 15 days), Nineveh fast (3 days), and Gehad fast (1 day). The level of fasting frequency and duration is significantly more extensive compared to the practices of other Christian denominations. It has around 180 mandatory fasting days per year for lay-people and up to 252 days for clergy. (1)

During fasts, the typical practice is to have only one meal (or often 2 meals) per day, either in the evening or after 3 PM. On Saturdays and Sundays during fasting periods, people may have breakfast around 9–9:30 AM after the morning church service and prayer is over. During the Holy Week (the final week of the Great Lent fast), the fast is even stricter, with complete avoidance of food and fluid consumption from Thursday evening until the Resurrection Liturgy on Saturday night/Sunday morning for the most devout Christians. EOTC fasting requires abstaining from all animal products, such as meat, dairy, and eggs. This creates a vegan diet during fasting periods. Alcohol consumption is also prohibited during fasts (2). Therefore, the EOTC fasting practices incorporate characteristics of energy restriction, time-restricted feeding, and a vegan eating pattern.

Recently, interest has increased to study the interaction between diabetes and religious fasting (3). While initial studies indicated that fasting did not worsen glycemic parameters, (4,5) subsequent studies were able to show benefits in terms of reduction in blood pressure, blood glucose, HbA1C, and BMI (6,7). However, hypoglycemia was shown to be the most common serious complication often faced during fasting periods (8,9). Studies on effects of Christian fasting on diabetes are limited both in Ethiopia and globally. In this study, we investigated the impact of EOTC fasting on glycemic control, anthropometric and lipid parameters, and hypoglycemia risk among patients with type 2 diabetes. We believe research like the present study will help develop culturally and religiously-sensitive diabetes education and management strategies to improve outcomes for patients who fast for religious reasons. To our knowledge, this study is the first to assess the impact of EOTC Christian fasting on diabetes related parameters in Ethiopia.

2.Objectives

2.1 General Objective

to assess the impact of the EOTC Great Lent Fast on metabolic and anthropometric parameters among patients with type 2 diabetes attending follow-up at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia.

2.2 Specific objectives

- To examine the effect of the EOTC Great Lent Fast on glycemic parameters (HbA1c, fasting blood glucose)
- To evaluate the effect of the EOTC Great Lent Fast on relevant clinical and anthropometric parameters.
- To identify possible safety of the EOTC Great Lent Fast

3.Research Design and Methods

3.1 Study area

The study was conducted at Tikur Anbessa Specialized Hospital (TASH), a university hospital and one of the largest tertiary hospitals in the country. It is the largest Endocrinology center in the country and the only higher institution with fellowship program in Endocrinology and Metabolism. The diabetic clinic serves around 800 to 1000 diabetic outpatients every month with average patient flow of 102 to 120 per day (10,11).

3.2. Study design and protocol

This was a facility based prospective comparative cohort study where participants were enrolled into two wings (fasting and non-fasting wings) with fasting participants matched 1:1 with non-fasting participants based on key variables known to influence glycemic and metabolic outcomes: age (±5 years), baseline HbA1C (±0.5-1%), educational status, insulin use, SGLT2-inhibitor use, presence of comorbidities and diabetes related complications. While sex and duration of diabetes were also considered during matching, perfect balance could not be achieved due to the availability of eligible participants at the time of recruitment. Data collection was conducted at two contact points: in the two weeks before the start of- and within 1 week of the end of the Great-Lent fast of 2025. There was no visit during the fasting period, but patients were encouraged to monitor their blood glucose and to bring the records at the post-fasting interview time.

3.3 Study Subjects and Eligibility criteria

Inclusion criteria were adults with type 2 diabetes who are 18 years of age and older, and are able to give informed consent. Patients with type 1 diabetes mellitus, advanced liver, cardiac or renal conditions, patients with history of recurrent hypoglycemia (2 or more hypoglycemic episodes over the preceding 3 months), those with diabetic emergencies over the preceding 1 month [diabetic ketoacidosis (DKA) or hyperosmolar hyperglycemic state (HHS) or severe hypoglycemia], patients with major physical, neuro-cognitive, psychiatric conditions interfering with diabetes self-care, pregnant women, and patients on glucocorticoid therapy were excluded.

Patients who came routine follow-up visits in the 2 weeks prior to the Great Lent fast of 2025 (2017 Ethiopian Calendar) were invited to participate.

3.4 Fasting

The Great-Lent fast of 2025 was observed between February 24, 2025 and April 19, 2025. Participants in the fasting group were those who observed the Great-Lent fast of 2025 in accordance with EOTC fasting traditions. This entails avoidance of food and fluid for at least 15 hours from the last day's supper as well as abstinence from any animal products, such as meat, dairy, and eggs for the whole duration of the fasting period.

3.5. Sample size and sampling technique

Using the standard sample size calculation formula for comparing two independent groups (12), a two-sided significance level of 5% and a power of 80%, the sample size was computed to detect a difference of -0.81% between the two groups (13). This yielded a minimum sample size of 25 participants per group.

3.6 Outcome measures

The primary outcome measure was the change in HbA1c levels from baseline to post-fasting. Secondary outcomes included changes in FBS, BP, changes in anthropometric parameters (weight, BMI, waist circumference), changes in lipid parameters, and adverse events (such as hypoglycemic events, hyperglycemic complications, breaking of fast and need for medication adjustments or discontinuations).

3.7 Data collection

Data was collected digitally (KoboCollect v2024.2.4) using a structured questionnaire developed for this study (supplementary material 2). It included direct patient interview, laboratory testing and abstracting of necessary information from the patients' charts at each contact point. A standardized digital BP apparatus was used for blood pressure assessment at all time points. Body weight was measured by calibrated digital weight scales. Standing height was taken in a standardized manner and the result rounded to the nearest 0.5 cm. Laboratory tests were conducted at EPHI (Ethiopian Public Health Institute), the national referral laboratory, which has ISO 15189:2012 and NGSP certification.

3.8 Ethical and related issues

The study was conducted after receiving clearance from the Institutional Review Board (IRB) of the Department of Internal Medicine, College of Health Sciences (CHS), Addis Ababa University (Protocol No. 07/24). Additionally, patient interviews, sample collection and chart review was conducted after the patients' written informed consent. Each respondent were ensured of the confidentiality of the information they provide.

3.9 Operational definition

Fasting: in the current study, means fasting in accordance with EOTC fasting traditions. This entailed avoidance of food and fluid intake from the last day's supper for at least 15 hours as well as abstinence from any animal products, such as meat, dairy, and eggs for the whole duration of the fasting period.

Fasting period: in the current study, means the Great Lent fast of 2025 (2017 E.C.) which was between February 24, 2025 and April 19, 2025 (Yekatit 17 to Miazya 12/2017 E.C.).

Pre-fasting diabetes education: any sort of consultation, counselling or education that a person receives from health care worker concerning diabetes self-care during the fasting period.

Fasting Blood Sugar (FBS): In this study, FBS an arithmetic mean (average) of at least 3 capillary or venous fasting blood glucose records measured on separate days with in the preceding 1week to data collection. This applies to both the pre-fasting and post-fasting FBS data.

Change in FBS: the difference, in mg/dL, between the post-fasting FBS and pre-fasting FBS data for each study subject.

Hypoglycemia: in the current study, was either symptoms consistent with hypoglycemia (if blood glucose was not measured) or low recorded blood sugar (below 70 mg/dL).

Level 1 Hypoglycemia: low blood glucose levels between 70 mg/dL and 54 mg/dL which is often self-treatable.

Level 2 Hypoglycemia: serious drop in blood glucose levels to below 54mg/dL but not requiring assistance from a third party.

Level 3 (severe) hypoglycemia: a severe drop in blood glucose where the individual experiences altered mental and/or physical functioning, requiring assistance from a third party for recovery, regardless of the specific blood glucose level at the time.

Assistance from a third party: help provided by another person, typically a family member, friend, or bystander, to manage the emergency situation. This can include administering glucose or glucagon, monitoring, support, contacting emergency medical support, bringing the patient to the health institution

Hypoglycemia or hyperglycemia requiring hospital visits: means severe instances of low or high blood sugar that necessitate medical intervention, such as emergency department visits or hospital admissions regardless of the specific blood glucose level at the time.

Recurrent hypoglycemia: 2 or more hypoglycemic episodes within 3 months prior to enrollment to the study

Minimum number of hours fasted: is the shortest duration of time that the person fasted in a day (from the previous night supper till the first meal of the following day)

Total number of days fasted: is the total number of days the person was able to fast for the minimum of number of hours deemed eligible for the current study. i.e. 15 hours of fasting from the previous night supper till the first meal of the following day.

Glycemic Control: the management of blood glucose levels within a target range and is often assessed using metrics such as fasting blood glucose levels and HbA1c (glycated hemoglobin) (13).

Breaking a fast: in this study, is a condition where the person is forced to eat and/or drink during the fasting period or completely terminate the fasting process due to diabetes related complications.

Hypertension: in this study, is a persistently elevated blood pressure [SBP>=130 mm Hg and DBP>= 80 mm Hg] on at least 2 occasions 24 hours apart or a patient already diagnosed with hypertension (to be retrieved from the patient clinical records) or already on anti-hypertensives (13).

Dyslipidemia: for this study, is either according to the ATPIII definition (14) [I.e. the presence of one or more of the following lipid abnormalities: Total cholesterol level ≥ 200 mg/dl, Triglyceride level ≥ 150 mg/dl, LDL-c levels ≥ 100 mg/dl, or HDL-c levels < 40 mg/dl or < 50 mg/dl in males and females, respectively], or already on lipid lowering agents. For the current study, the presence of dyslipidemia was retrieved from patients' clinical records.

Atherosclerotic Cardiovascular Disease (ASCVD): a group of conditions that arise from narrowing of arteries due to the buildup of plaque, leading to restricted blood flow to vital organs. ASCVD includes coronary artery disease (CAD), peripheral artery disease (PAD), and cerebrovascular diseases like ischemic stroke (14). For the current study, the presence of ASCVD was retrieved from patients' clinical records.

Diabetic Kidney Disease (DKD)- is defined as the presence of persistent albuminuria [based on 2 or more measurements of either 24 hours urinary protein excretion or urine albumin-to-creatinine ratio (UACR)] and reduced estimated glomerular filtration rate [eGFR, assessed by CKD-EPI calculator based on creatinine measurement) in the absence of signs and symptoms of other primary causes of kidney damage (13). For the current study, the presence of DKD was retrieved from patients' clinical records.

Diabetic neuropathy (DN): is a heterogeneous group of neuronal disorders due to diabetes (13) and include Distal Symmetric polyneuropathy (DSPN), Mononeuropathy, Mononeuritis multiplexa, Polyradiculopathy and Autonomic Neuropathy. For the current study, the presence of DN was retrieved from patients' clinical records.

Diabetic retinopathy (DR): a specific vascular complication of diabetes characterized by damage to the retinal blood vessels and nerves due to prolonged periods of high blood sugar levels (13). For the current study, the presence of DN was retrieved from patients' clinical records.

3.10 Statistical analysis

SPSS 25 (IBM, Chicago, IL, USA) was used for the statistical analysis. Paired t-test was used to assess the within group pre- post- differences in HbA1C and other anthropometric and metabolic parameters. Independent (unpaired) t-test was used to assess between group differences. Analysis of Covariance (ANCOVA) was used to adjust for the observed baseline differences in sex distribution and duration of diabetes. Chi-square test and/or Fisher's exact tests were used to

assess association between categorical variables. Bivariate logistic regression was used to see crude associations between various variables and hypoglycemia. For multivariate logistic regression, variables were selected based on clinical relevance, statistical significance ($p<0.1$) and absence of multicollinearity. Statistical significance was considered when $p < 0.05$. Given the number of secondary end points assessed, we recognize the potential for type 1 error. Secondary end points were interpreted as exploratory, and p-values were not adjusted for multiple comparisons. The findings should therefore be interpreted with caution and considered hypothesis generating.

4. Results

4.1 Participants

A total of 170 participants were recruited for the study. 23 patients did not meet the inclusion criteria. A total of 157 participants were enrolled into the study after getting informed consent and assigned into the fasting or non-fasting group based on their personal interest. In the post-fasting follow up period, further 29 patients were lost to follow-up. 128 participants (64 in fasting wing and 64 in the non-fasting wing) completed the study according to protocol (Figure 1).

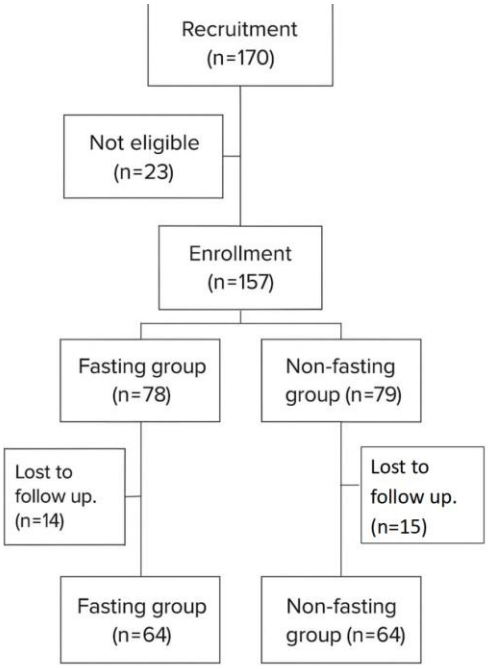

Figure 1: Study flow chart

Mean age of the total population 58.3 ± 9.1years and 68 (53.1%) of the total study participants were female. Mean duration of diabetes of the total study participants was 13.1± 8.8. More than half (58.6%) of the participants were on insulin-based therapy (Table 1, 2). Matching resulted in broadly comparable groups. However, the proportion of female participants was higher in the fasting group and the duration of diabetes was longer in the non-fasting group. These imbalances were accounted for in subsequent analysis to account for potential confounding. The median number of days fasted and median number of hours fasted per day in the fasting group were 55 days (IQR: 51-55) and 16 hours (IQR: 15-18), respectively.

Table 1: Baseline socio-demographic characteristics of the study population

Variable		**Total (n=128)**	**Fasting Group (n=64)**	**Non-fasting group (n=64)**	**p-value**
Sex	Male	60 (46.9%)	21 (32.8%)	39 (60.9%)	**p=0.001**
	Female	68 (53.1%)	43 (67.2%)	25 (39.1%)	
Age (in years)	Mean	58.3 ± 9.1	56.9±9.3	59.7±8.8	P=0.079
	Median	60	58.5	61.5	-
Educational status	No formal education	13 (10.1%)	7 (10.9%)	6 (9.4%)	p=0.313
	Primary school	14 (10.9%)	9 (14.1%)	5 (7.8%)	
	Secondary school	45 (35.2%)	25 (39.1%)	20 (31.3%)	
	College or above	56 (43.8%)	23 (35.9%)	33 (51.6%)	
Duration of Diabetes	Mean	13.1± 8.8	11.4±9.3	14.9±8.1	**p=0.027**
	Median	12.00	9	13.5	-

Table 2: Baseline clinical characteristics of the study population

Variable		Total (n=128)	Fasting Group (n=64)	Non-fasting group (n=64)	p-value
Insulin use	Yes	75 (58.6%)	33 (51.6%)	42 (65.6%)	p=0.106
	No	53 (41.4%)	31 (48.4%)	22 (34.4%)	
Glibenclamide	Yes	15 (11.7%)	5 (7.8%)	10 (15.6%)	p=0.169
	No	113 (88.3%)	59 (92.2%)	54 (84.4%)	
Other SU	Yes	6 (4.7%)	4 (6.3%)	2 (3.1%)	p=0.403
	No	122 (95.3%)	60 (93.8%)	62 (96.9%)	
Metformin	Yes	113 (88.3%)	60 (93.8%)	53 (82.8%)	p=0.054
	No	15 (11.7%)	4 (6.3%)	11 (17.2%)	
DPP4 inhibitors	Yes	10 (7.8%)	6 (9.4%)	4 (6.3%)	p=0.510
	No	118 (92.2%)	58 (90.6%)	60 (93.8%)	
SGLT2-inhibitors	Yes	28 (21.9%)	12 (18.8%)	16 (25.0%)	p=0.392
	No	100 (78.1%)	52 (81.3%)	48 (75.0%)	
Diabetic Retinopathy	Yes	25 (19.5%)	10 (15.6%)	15 (23.4%)	p=0.149
	No	88 (68.8%)	49 (76.6%)	39 (60.9%)	

	Unknown	15 (11.7%)	5 (7.8%)	10 (15.6%)	
Diabetic kidney disease	Yes	26 (20.3%)	9 (14.1%)	17 (26.6%)	p=0.110
	No	85 (66.4%)	48 (75.0%)	37 (57.8%)	
	Unknown	17 (13.3%)	7 (10.9%)	10 (15.6%)	
Diabetic neuropathy	Yes	45 (35.2%)	27 (42.2%)	18 (28.1%)	p=0.093
	No	79 (61.7%)	35 (54.7%)	44 (68.8%)	
	Unknown	4 (3.1%)	2 (3.1%)	2 (3.1%)	
Diabetic foot problems (current ulcer, history of DFU, amputation)	Yes	9 (7.0%)	3 (4.7%)	6 (9.4%)	p=0.492
	No	119 (93.0%)	61 (95.3%)	58 (90.6%)	
Atherosclerotic cardiovascular disease (CAD, CVD, PAD)	Yes	31 (24.2%)	12 (18.8%)	19 (29.7%)	p=0.163
	No	96 (75.0%)	51 (79.7%)	45 (70.3%)	
	Unknown	1 (0.8%)	1 (1.6%)	0 (0.0%)	
Hypertension	Yes	87 (68.0%)	44 (68.8%)	43 (67.2%)	p=0.850
	No	41 (32.0%)	20 (31.3%)	21 (32.8%)	

Dyslipidemia or on statins	Yes	125 (97.7%)	62 (96.9%)	63 (98.4%)	p=1.000
	No	3 (2.3%)	2 (3.1%)	1 (1.6%)	
Hypoglycemic events over the preceding 1 year	Yes	40 (31.2%)	20 (31.2%)	20 (31.2%)	p=1.000
	No	88 (68.8%)	44 (68.8%)	44 (68.8%)	
Hyperglycemic episode requiring hospital visit or admission over the past 1 year	Yes	19 (14.8%)	11 (17.2%)	8 (12.5%)	p=0.456
	No	109 (85.2%)	53 (82.8%)	56 (87.5%)	
Able to do SMBG	Yes	99 (77.3%)	47 (73.4%)	52 (81.3%)	p=0.291
	No	29 (22.7%)	17 (26.6%)	12 (18.7%)	
BMI (kg/m^2)		27.2 ± 4.5	27.8 ± 4.7	26.6 ± 4.1	p=0.109
Waist circumference (cms)		99.6 ±11	99.8 ± 10.7	99.4 ± 11.3	p=0.832
Blood pressure (mmHg)	SBP	136.4±17.9	137.1 ± 18.1	135.8 ±17.7	p=0.686
	DBP	77.9 ± 11	79 ± 11.7	76.7 ± 10.1	p=0.238
FBS (mg/dl)		144.6 ± 54.6	147.8 ± 66.3	141.3±39.9	p=0.977

A1C (%)	8.3 ± 1.7	8.3 ± 1.6	8.4±1.8	p=0.786
Total Cholesterol (mg/dl)	154.6 ± 44.5	158.4±43.5	150.8±45.5	p=0.308
LDL-C (mg/dl)	83.7±34.6	89.7±35.3	77.7±33.2	p=0.08
HDL-C (mg/dl)	40.4±11.5	41.4±10.3	39.4±12.6	p=0.62
Triglyceride (mg/dl)	152.5±142.0	140.6±58.7	164.5±192.1	p=0.753

4.2 Primary outcome measure

The entire study population showed a significant reduction HbA1C with mean change in HbA1C of -0.46% (95% CI: -0.67 to -0.26) (Table 3). HbA1C reduction was seen in each group as well. The fasting group showed mean change in HbA1C of -0.38% (95% CI: -0.70 to -0.05) while the non-fasting group attained a mean change in HbA1C of -0.55% (95% CI: -0.81 to -0.29) (Table 3, figure 2).

However, there was no significant difference in mean HbA1C change between the two study groups. With baseline HbA1C and relevant covariates (sex and duration of diabetes) controlled with ANCOVA, the estimated marginal mean change in HbA1C was 0.13% (95% CI: -0.24 to 0.494) (Table 3).

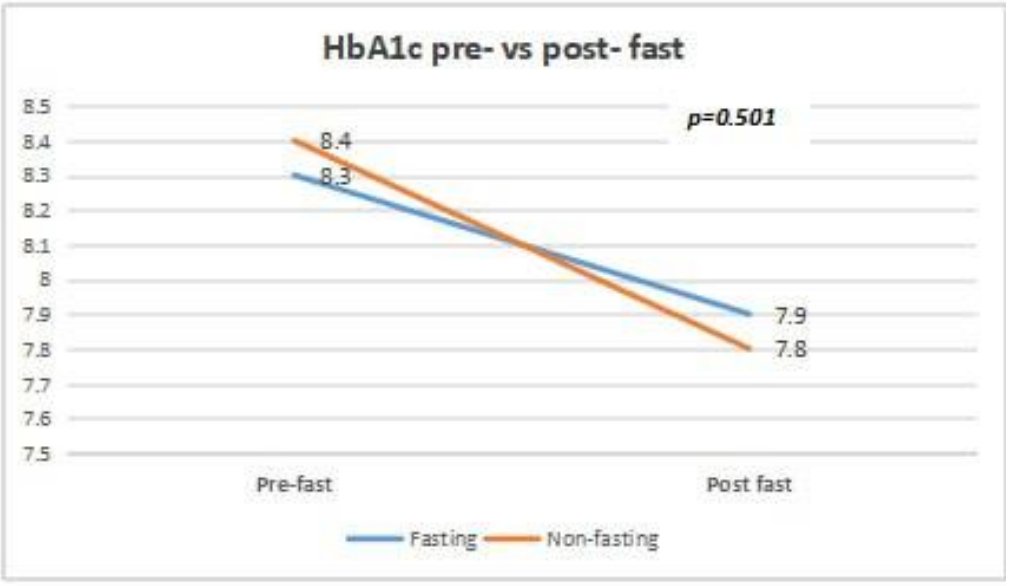

Figure 2: Change in HbA1C (%) between the fasting and non-fasting group

4.3 Secondary outcome measures

4.3.1 Blood pressure

In the total study population, there was no statistically significant difference in the mean change in SBP (1.5mmHg, 95% CI: -2.0 to 4.9) or in the mean change in DBP (1.4 mmHg, 95% CI: -0.8 to 3.7) (Table 3).

4.3.2 Anthropometric measurements

Modest reductions in weight (-1.1kg, 95% CI: -1.7, -0.5), BMI reduction (-0.4 kg/m^2, 95% CI: -0.6 to -0.2) and waist circumference (-2.8cm, 95 CI: -4.1, -1.5) was observed in the fasting group. However, no significant between group difference was noted (Table 3).

4.3.3 Fasting Blood Glucose

Interestingly, only the non-fasting group showed a statistically significant drop in FBS (-21.0 mg/dl, 95% CI: -37.6 to -4.5], with no statistically significant between group differences (Table 4).

4.3.4 Lipid profile

The fasting group showed significant reductions in total cholesterol (-15mg/dl, 95% CI: -26.1 to -3.9), LDL-C (-12.0mg/dl, 95% CI: -20.6 to -3.5) and triglyceride (-13.6mg/dl, 95% CI: -25.8 to -1.3). On the contrary, no significant reduction in any of the lipid parameters was noted within the non-fasting group. However, after controlling for baseline lipid levels and other covariates, no significant between group differences were observed for any of the lipid parameters (Table 4).

Table 3: Comparison of clinical outcome variables within and between the fasting and non-fasting groups

Outcome	**Groups**	**Pre-fast Mean ± SD**	**Post fast Mean ± SD**	**Within group Δ (95% CI)**	**p value**	**Between group difference (95% CI)**	**p value**
SBP (mmHg)	Fasting	137.1±18.1	137.5±18.7	0.5(-4.7, 5.7)	0.858	0.3 (-6.3, 6.9)	0.927
	Non-fasting	135.8±17.7	138.2±20.9	2.5(-2.3, 7.2)	0.299		

	Total	136.4±17.9	137.98±19.7	1.5(-2.0, 4.9)	0.403	-	-
DBP (mmHg)	Fasting	79.0±11.7	81.0±11.4	2.0 (-1.7, 5.6)	0.280	2.2 (-1.7, 6.1)	0.259
	Non-fasting	76.7±10.2	77.6±10.1	0.8 (-1.9, 3.6)	0.548		
	Total	77.9±11	79.3±10.9	1.4 (-0.8, 3.7)	0.218	-	-
Weight (kg)	Fasting	72.8±13.1	71.6±12.8	-1.1 (-1.7, -0.5)	0.000	-0.6(-1.5, 0.4)	0.248
	Non-fasting	73.6±11.4	72.9±11.3	-0.7(-1.3, 0.03)	0.062		
	Total	73. 2±12.2	72.3±12.0	-0.9 (1.3, -0.4)	0.000	-	-
BMI (Kg/m2)	Fasting	27.8±4.7	27.4±4.7	-0.4 (-0.6, -0.2)	0.001	-0.2 (-0.6, 0.2)	0.298

	Non-fasting	26.6±4.1	26.3±4.1	-0.2 (-0.5, 0.02)	0.075		
	Total	27.2±4.5	26.9±4.4	-0.3 (0-.5, -0.2)	0.000	-	-
Waist circumference (cms)	Fasting	99.8±10.7	97.0±9.8	-2.8 (-4.1, -1.5)	.000	-1.0(-2.7, 0.8)	.269
	Non-fasting	99.4±11.3	97.9±10.0	-1.5 (-2.8, -0.3)	0.017		
	Total	99.6±11.0	97.5±9.9	-2.2(-3.1, -1.3)	.000		

Table 4: Comparison of biochemical outcome variables within and between the fasting and non-fasting groups

Outcome	**Groups**	**Pre-fast Mean ± SD**	**Post fast Mean ± SD**	**Within group Δ (95% CI) (paired t-test)**	**p value**	**Between group Δ in EMM (95% CI)**	**p value**

HbA1C (%)	Fasting	8.3±1.6	7.9±1.5	-0.4 (-0.7, -0.1)	0.025	0.1 (-0.2, 0.5)	0.501
	Non-fasting	8.4±1.8	7.8±1.4	-0.6 (-0.8, -0.3)	0.000		
	Total	8.3±1.7	7.9±1.4	-0.5 (-0.7, -0.3)	0.000	-	-
FBS (mg/dl)	Fasting	158.9± 83.9	150.1± 64.1	-8.7 (-26.8, 9.4)	0.339	5.4 (-12.2, 22.9)	0.546
	Non-fasting	162.4 ±70.4	141.3± 39.9	-21.0 (-37.6, -4.5)	0.014		
	Total	160.6 ±77.1	145.7± 53.3	-14.9 (-27.1, -2.8)	0.016	-	-
Total Cholesterol (mg/dl)	Fasting	159.2± 43.5	144.2± 40.7	-15.0 (-26.1, -3.9)	0.009	-1.8 (-13.8,10.1)	0.76
	Non-fasting	151.0±45.8	141.9±36.9	-9.1 (-19.9, 1.7)	0.096		
	Total	155.1±44.4	143.0± 34.6	-12.0 (-19.7, -4.4)	0.002	-	-

LDL-Cholesterol (mg/dl)	Fasting	90.5±34.9	78.5±24.6	-12.0 (-20.6, -3.5)	0.007	-3.6 (-12.0,4.8)	0.4
	Non-fasting	77.6±33.5	78.3±24.6	0.8(-7.1, 8.6)	0.847		
	Total	84.1±34.7	78.4± 24.1	-5.7 (-11.5, 0.2)	.056	-	-
HDL-Cholesterol (mg/dl)	Fasting	41.4±10.1	40.5+9.1	-0.9 (-2.6,0.8)	0.293	-0.6 (-2.9,1.8)	0.641
	Non-fasting	39.5±12.7	39.0+10.6	-0.6(-2.6, 1.4)	0.564		
	Total	40.5±11.5	39.7±9.8	-0.7 (-2.1, 0.6)	0.261	-	-
Triglyceride (mg/dl)	Fasting	141.2±59.4	127.8±62.8	-13.6(-25.8, -1.3)	0.031	1.4 (-21.4, 24.2)	0.904
	Non-fasting	142.1±81.1	134.7+75.4	-7.5(-30.0, 15.0)	0.510		
	Total	141.7±70.9	131.2+69.2	-10.5(-23.2, 2.2)	0.105	-	-

4.3.5 Adverse events

Hypoglycemia among the total study population

32 (25%) of the study population had at least one episode of hypoglycemia. Hypoglycemia occurred in similar frequency in both groups [fasting group: 17 (26.6%) vs non-fasting group: 15 (23.4%)] (Table 5). Level 3 hypoglycemia occurred in only 3 (9.4%) of patients and all were in the fasting group. Frequent hypoglycemia (5 or more episodes per person) in 7 fasting participants and 3 non-fasting participants) (Table 5).

Hypoglycemia occurred in 36.0% of patients on insulin-based regimens, compared to only 9.4% on non-insulin-based therapies. Among sulfonylurea users, 25% reported hypoglycemia. No hypoglycemia occurred among those on metformin monotherapy, or combinations with DPP4-inhibitor or SGLT2-inhibitors.

Table 5: Adverse events reported in the total study population during the study period.

Adverse event	**Category**	**Total (n=128)**	**Fasting group (n=64)**	**Non-fasting group (n=64)**	**p-value**
Hypoglycemia	**All**	32 (25.0%)	17 (26.6%)	15 (23.4%)	0.683
	Severe (Level 3)	3 (9.4%)	3 (17.6%)	0 (0%)	0.229
Hypoglycemia frequency	Only once	5 (15.6%)	3 (17.6%)	2 (13.3%)	0.331
	2 to 4 times	17 (53.1%)	7 (41.2%)	10 (66.7%)	
	≥5 times	10 (31.3%)	7 (41.2%)	3 (20.0%)	
Severe hyperglycemia (>= 300mg/dl)		10 (7.8%)	2 (3.1%)	8 (12.5%)	0.048

Need for DM medication adjustment	33 (25.8%)	16 (25.0%)	17 (26.6%)	0.840
Break fast	14 (21.9%)	14 (21.9%)	-	-

Hypoglycemia among the fasting participants

In the fasting group, the median number of days to the first episode of hypoglycemia was 7 with IQR of 7-15 (range: 1-30 days). Hypoglycemia occurred less frequently in those who received pre-fast physician consultation than who didn't [5 (15.4%) vs 10 (32.1%)) (Table 6). Presence of DKD was independently associated with a significantly increased risk of fasting period hypoglycemia (aOR=10.9, 95% CI: 1.4 to 86.3) (Table 6).

Table 6: Crude and adjusted Odd's ratios from Binary Logistic Regression Analysis of Factors associated with hypoglycemia in fasting group.

Variable		**Hypoglycemia**		**Unadjusted OR (95% CI)**	**Adjusted OR (95% CI)**	**p value**
		Yes n (%)	No n (%)			
Age	≥60 years	11 (36.7)	19 (63.3)	2.7 (0.9,8.6)	2.8 (0.5,15.8)	0.254
	<60	6 (17.6)	28 (82.4)			
Hypoglycemia over 1year	Yes	10 (50.0)	10 (50.0)	5.3 (1.6,17.4)	2.3 (0.4,13.7)	0.334

	No	7 (15.9)	37 (84.1)			
Insulin use	Yes	14 (42.4)	19 (57.6)	6.9 (17,27.2)	4.5 (0.7,29.6)	0.113
	No	3 (9.7)	28 (90.3)			
DKD	Yes	5 (55.6)	4 (44.4)	4.8 (1.1, 21.0)	10.9 (1.4,86.3)	**0.023**
	No	10 (20.8)	38 (79.2)			
Pre-fast consultation	No	9 (32.1)	19 (67.9)	2.6 (0.7,9.8)	2.3 (0.4,12.9)	0.353
	Yes	4 (15.4)	22 (84.6)			

Other adverse events

Severe hyperglycemia ($\geq$ 300mg/dl) was seen more in the non-fasting group (8) compared to only 2 in the fasting group). No hospitalization for severe hyperglycemia or hyperglycemic crisis (DKA/HHS) was reported. (Table 5). A fifth (21.9%) of the fasting participants were forced to break their fast at least once due to diabetes related problems. Total number fasting days lost to hypoglycemia or severe hyperglycemia was 110 (mean: 11$\pm$12.3 days; range of 2-40 days). Need for dose adjustment was similar in the two groups (16 (25.0%) in the fasting group vs 17 (26.6%) in the non-fasting group). Insulin dose reduction or discontinuation was the commonest medication adjustment observed in 14 (37.8%) of the participants. (Table 5).

5. Discussion

This study evaluated the impact of EOTC fasting on glycemic control and related metabolic parameters in patients with type 2 diabetes mellitus. After adjusting for baseline values, the change in HbA1C did not differ significantly between the fasting and non-fasting groups. Although FBS improved significantly in the overall cohort, no significant between group difference was observed. The effect of religious fasting on glycemic control has been mixed in the literature. Coptic Orthodox Christian fasting in Egypt showed significant FBS and HbA1C improvements (14,15). Similarly, some Ramadan studies have shown significant HbA1C benefit (7,16–19) while others failed to do so (20). However, all of these studies had a pre- post- design and did not have a control group making it difficult to control confounders.

In the present study, it was evident that the fasting group had a significant reduction in HbA1C after the fasting period when compared to the baseline. That said, the non-fasting group also showed a significant decline in HbA1C attenuating the between group differences. There are a few potential explanations. First, differences in fasting practices and calorie intake among the fasting participants may have contributed. Second, during the Lent in Ethiopia, changes in dietary habits (more plant-based diet and less animal products) are common even in people who don't observe the fast. Third, the non-fasting participants may have become more adherent to lifestyle and medications due to study enrollment (Hawthorne's effect).

Fasting was not associated with any beneficial changes in blood pressure (both SBP and DBP) in our study. This is in contrast to findings from Egyptian Coptic orthodox fasting studies (14,21) and also some Ramadan studies (6,22). Conversely, some studies of time-restricted eating and intermittent fasting have failed to show meaningful blood pressure reducing benefit of fasting (23,24).

Within the fasting group, body weight, body mass index (BMI) and waist circumference decreased significantly. However, similar reductions were also seen in the non-fasting group diminishing the between group differences. This aligns with many of the pre-post studies showing improvements in these anthropometric measures (14,17,25–27). As noted earlier, healthier dietary habits during the Lent season among non-fasting individuals may have

contributed to these changes. Total cholesterol, LDL-C and triglyceride decreased significantly within the fasting group. Although between-group differences did not reach statistical significance, there was a trend toward greater benefit in total cholesterol and LDL-C among those who fasted. Similar lipid benefits from fasting have been reported in both non-diabetic (28–30) and diabetic populations (6,17). In this study, one-fifth of the participants were on SGLT2 inhibitors which are knowns to induce modest weight loss. Though the proportion of patients on SLGT2 inhibitors was similar in the two groups, it may have contributed to the within group weight and BMI reductions.

Hypoglycemia was reported in a quarter of the participants, with similar rates across both groups. While hypoglycemia is not well described in most of the Christian fasting studies, it has been widely reported during Ramadan (9,16,19,20,31). Conversely, some studies- mostly involving patients on oral agents- have found no significant increase in hypoglycemia during fasting (7,32,33). Notably, even studies involving largely insulin treated patients, similar to our cohort, have reported low rates of hypoglycemia (34,35).

In the fasting group, older age, insulin use, hypoglycemia in the preceding year and lack of pre-fasting consultation were associated with a higher risk of hypoglycemia. Notably, presence of diabetic kidney disease (DKD) emerged as the strongest independent predictor of hypoglycemia during the fasting period. These associations are well documented in Ramadan studies (9,36,37) and aligns with ADA high-risk groups for fasting (38). Other predictors noted in the literature are hypoglycemia unawareness, poor glycemic control and advanced macrovascular complications (38).

In our study, level 3 hypoglycemia (39) occurred exclusively in the fasting group, and frequent episodes ($\geq$ 5) were more common among those who fasted. This mirrors findings from Ramadan studies, such as the EPIDIAR study, which reported a 7.5-fold increased risk of severe hypoglycemia during fasting (8). Comparably, the incidence of severe hypoglycemia rose from 0.2% to 0.9% during Ramadan in another study (40). By the same token, recurrent hypoglycemia was shown to be more common during fasting periods (9,37). However, data on predictors of hypoglycemia during Christian fasting are scarce making this study among the first to systematically explore the issue in the context of Ethiopian Orthodox Christian (EOTC) fasting. About 22% of the fasting participants were forced to break their fast, with hypoglycemia being

the leading cause. Nearly half (47.1) of the patients who experienced hypoglycemia broke their fast compared to just 12.8% among those without such episodes- a trend also seen in Ramadan studies (37,41).

This study offers new insights into the metabolic and safety profiles of EOTC fasting in individuals with type 2 diabetes. Although changes in HbA1C, weight, BMI and waist circumference were not statistically significant between the groups, both fasting and non-fasting participants experienced meaningful within group improvements, likely reflecting seasonal or behavioral influences. While favorable lipid trends were observed in the fasting group, between group differences were not statistically significance. Overall, while the overall hypoglycemia rates were similar, the fasting group experienced more frequent and severe episodes, raising safety concerns. Presence of DKD was the key predictor of fasting period hypoglycemia, with older age, insulin use, hypoglycemia in the preceding year, and lack of pre-fasting consultation as potential contributors. The absence of hyperglycemia-related hospitalizations suggests that EOTC fasting may be safe in selected patients, when accompanied by appropriate education and management.

These findings highlight the importance of individualized risk assessment, structured education, and treatment modifications, for patients with diabetes observing religious fasts. Further longitudinal studies are needed to validate these findings and guide culturally clinical recommendations.

Limitations of the study

The study was conducted at a single tertiary center with a relatively modest sample size which may limit generalizability. Dietary intake and physical activity were not formally quantified and standardized; however, participants were advised to follow their usual routines throughout the study period. The fasting and non-fasting groups were self-selected rather than randomized which could introduce selection bias, though the baseline characteristics were comparable between the two groups. Additionally, although the fasting duration in our study (~8 weeks) was longer than that reported in most fasting related studies, it may still not fully capture the full impact on some parameters, particularly HbA1C. Finally, the study assessed short term glycemic and metabolic; longer follow up is warranted to evaluate long term metabolic impacts and cardiovascular implications.

6. Conclusion

No statistically significant differences were observed in HbA1C, weight, BMI and waist circumference between the two groups. While trends in better lipid improvements were seen in the fasting group, these changes were not statistically significant. Hypoglycemia occurred in similar rates in both groups, but the fasting group experienced a greater burden of frequent and severe episodes. Importantly, a history of hypoglycemia in the preceding year was identified as an independent predictor of hypoglycemia in the fasting period. Notably, no hospitalization for severe hyperglycemia or hyperglycemic crisis occurred in the entire cohort.

In summary, EOTC fasting may be practiced safely by many individuals with type 2 diabetes, but tailored education, careful medication adjustment, and individualized clinical oversight are critical. This study provides foundational data to guide clinicians and inform culturally relevant recommendations for faith-based fasting diabetes care.

7. Recommendations

- Clinicians should incorporate structured risk assessment and pre-fasting counselling for patients with type 2 diabetes intending to fast, especially those with a history of hypoglycemia.

- Fasting guidelines should incorporate Christian religious context, including Ethiopian Orthodox fasting practices

- Further multi-center, longitudinal or randomized controlled trials are needed to better understand the long-term safety and metabolic effects of religious fasting among people with diabetes

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ANNEXES

Annex I: English Version Information Sheet

Identification Number _____

My name is _____

I am working as data collector in the research Conducted by **Dr. Brook Alemayehu** who is conducting this research for the partial fulfillment of his Sub-specialty certificate in Endocrinology and Metabolism in Addis Ababa University, College of Health Sciences. We are trying to assess the impact and associated factors of religious fasting on diabetic control among patients having follow-up in Tikur Anbessa Specialized Hospital Diabetic clinic. We would like your honest opinion pertaining to the questions.

- **Name of advisor**; Dr. Tedla Kebede (Associate Professor of Medicine, Consultant Internist and Endocrinologist)
- **Name of the organization**: Addis Ababa University, College of Health Sciences, Department of Internal Medicine, Endocrinology and Metabolism unit

Introduction: You are selected to participate in this study because you are currently attending in the mentioned diabetic clinic. Your participation is purely based on your willingness & you have the right to choose not to take part in this study.

Purpose: I am hopeful that this research will benefit in improving our understanding of the positive effects of religious fasting on diabetic care as well as the possible risks that should be prevented. No such studies have been done in our country. Thus the results of the study will be hugely informative to the medical community. Up on completion of the research, the results of the study will be provided to all concerned body for intervention.

Procedure: If you are willing to participate in this project, please say yes on the agreement form. Then after, you will be interviewed by the data collector at 2 points in time, i.e. now (before the fasting starts) and after completion of the fasting period. Relevant data from your medical records (such as Blood pressure, weight, height, laboratory parameters, and list of medications prescribed) will be utilized as well. The mentioned parameters including the laboratory tests will be repeated after the completion of the study to make necessary comparisons. All your responses, clinical data and laboratory parameters obtained will be kept confidential by using coding system whereby no one will have access to your response.

Risk/ Discomfort: By participating in this research project, you may feel that it has some discomfort especially on spending time about 30 minutes each on both time points of interview. We hope you will participate in the study for the sake of the anticipated benefits of the research result. We assure you sure that there is no risk in participating in this research project.

Benefits: There will not be any direct benefit to you but your participation is likely to help us come up with culturally-sensitive recommendations and to improve our general diabetic care and counselling in relation to religious fasting. You will not be provided any incentive or payment to take part in this project.

Confidentiality: The information collected from this research project will be kept confidential and information about you that will be collected by this study will be stored in a file, without your name, but a code number assigned to it. In addition, it will not be revealed to anyone except the principal investigator and will be kept locked with password key.

Right to refuse or withdraw: You have full right to refuse from participating in this research. You can choose not to respond to some or all questions if you do not want to give your response. You have also the full right to withdraw from this study at any time you wish, without losing any of your right. If you have any question, you can ask at any time. If you have additional questions about the study please feel free to contact the principal investigator.

Dr. Brook Alemayehu Tesfaye (Principal Investigator)

Tel: +251-943-801272

Email: brookalemayehu30@gmail.com

Annex II: English Version Consent Form

I understand all conditions stated above. I have understood that participation in this study is entirely voluntarily. I have been told that my answers to the questions will not be given to anyone else and no reports of this study ever identify me in any way. Therefore, I am willing to participate in this study.

FOR INTERVIEW-1 (pre-fasting)

Participant's signature _____

Date _____

Supervisor name _____ Signature_____

Date_____/_____/____E.C.

Time Interview-1 Started- Hour: _____ Minute: _____ Time Interview-1 Ended: Hour: __ Minute: __

Name of data collector: _____ Signature_____

FOR INTERVIEW-2 (post-fasting)

Participant's signature _____

Date _____

Supervisor name _____ Signature_____

Date_____/_____/____E.C.

Time Interview-2 started- Hour: _____ Minute: _____ Time Interview-2 ended: Hour: __ Minute: __

Name of data collector: _____ Signature_____

Annex III: Amharic Version Information Sheet

መለያ ቁጥር _____

እኔ (ስም) _____

በአዲስ አበባ ዩኒቨርሲቲ በጤና ሳይንስ ኮሌጅ የኢንዶክሪኖሎጂ እና ሜታቦሊዝም የሰብ ስፔሻሊቲ ፌሎው በሆንው በዶ/ር ብሩክ አለማየሁ እየተካሄደ ባለው ጥናት ላይ መረጃ ሰብሳቢ ሆኜ እየሰራሁ እገኛለሁ። ጥናቱ በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል የስኳር ህክምና ክሊኒክ ውስጥ የሚካሄድ ሲሆን ሃይማኖታዊ ጾም በስኳር በሽታ ቁጥጥር ላይ ያለውን ተጽእኖ እና ተያያዥ ጉዳዮችን ለመገምገም ያለመ ነው። ከጥያቄዎቹ ጋር በተያያዘ የእርስዎን ትክክለኛ አስተያየት እንፈልጋለን።

- **የአማካሪ ስም**፡- ዶ/ር ተድላ ከበደ (በውስጥ ደዌ ህክምና ተባባሪ ፕሮፌሰር፣ ሲኒየር ኢንተርኒስት እና ኢንዶክሪኖሎጂስት)
- **የድርጅቱ ስም**፡- አዲስ አበባ ዩኒቨርሲቲ፣ ጤና ሳይንስ ኮሌጅ፣ የውስጥ ደዌ ዲፓርትመንት፣ ኢንዶክሪኖሎጂ እና ሜታቦሊዝም ክፍል

<u>መግቢያ</u>፡ በዚህ ጥናት ላይ ለመሳተፍ የተመረጡት በተጠቀሰው የስኳር ህክምና ክሊኒክ ውስጥ ክትትል ስለሚያድርጉ ነው። የእርስዎ ተሳትፎ በእርስዎ ፍላጎት ላይ ብቻ የተመሰረተ ነው እና በዚህ ጥናት ውስጥ ላለመሳተፍ የመምረጥ መብት አለዎት።

ዓላማው፡ ይህ ጥናት ጾም በስኳር ህመም ላይ ስላለው አወንታዊ ተጽእኖ እና መከላከል ሊኖሩ ስለሚችሉ ላሉታዊ ተጽእኖዎች ያለንን ግንዛቤ ለማሻሻል ይጠቅማል የሚል እምነት አለን። በአገራችን እንዲህ ዓይነት ጥናቶች ከዚህ በፊት አልተደረጉም። ስለዚህ የጥናቱ ውጤት ለህክምናው ማህበረሰብ ትልቅ መረጃ ሰጪ ይሆናል ብለን አንጠብቃለን። ጥናቱ ሲጠናቀቅ የጥናቱ ውጤት ለሚመለከተው አካል ሁሉ ይቀርባል።

<u>አካሄድ</u>፡ በዚህ ፕሮጀክት ለመሳተፍ ፈቃደኛ ከሆኑ፣ እባክዎ በስምምነቱ ቅጽ ላይ አዎ ይበሉ። ከዚያም በሁዋላ በ2 ጊዜያተ ማለትም አሁን (ፆሙ ከመጀመሩ በፊት) እና የፆም ወቅቱ ካለቀ በኋላ ቃለ መጠይቅ ይደረግልዎታል ። ከእርስዎ የሕክምና መዝብ (እንደ የደም ግፊት, ክብደት, ቁመት, የላብራቶሪ መለኪያዎች እና የታዘዙ መድሃኒቶች ዝርዝር ያሉ) ተዛማጅ መረጃዎች ጥቅም ላይ ይውላሉ. የላብራቶሪ ምርመራዎችን ጨምሮ የተጠቀሱት መለኪያዎች ከፆሙ በፊት እና የፆሙ ወቅት ከተጠናቀቀ በኋላ አስፈላጊውን ንጽጽር ለማድረግ ይወሰዳሉ። ሁሉም የእርስዎ ምላሾች፣ የሃኪሙ ኣካላዊ ግምገማዎች እና

የተወሰዱ የላብራቶሪ መለኪያዎች ማንም ሰው የእርስዎን ምላሽ ማግኘት በማይችልበት የኮድ ስርዓት በመጠቀም ሚስጥራዊ ይሆናሉ።

ስጋት/ አለመመቸት፡ በዚህ የምርምር ፕሮጀክት ውስጥ ሲሳተፉ በተለይ እያንዳንዳቸው ቃለ መጠይቆች አስከ 30 ደቂቃ ያህል ጊዜ ሲያሳልፉ አንዳንድ ምቾት ማጣቶች ሊሰማዎት ይችላል። ሆኖም ግን የጥናቱ ውጤት ሊሰጠው ከሚችለው ጠቀሜታ አንፃር በጥናቱ እንደሚሳተፉ ተስፋ እናደርጋለን። በዚህ የምርምር ፕሮጀክት ውስጥ መሳተፍ ምንም አይነት ስጋት እንደሌለው እናረጋግጥልዎታለን።

ጥቅማ ጥቅሞች፡ በዚህ ምርምር ለእርስዎ ምንም አይነት ቀጥተኛ ጥቅም አይኖርዎትም። ነገር ግን የእርስዎ ተሳትፎ ከሃይማኖታዊ ጾም ጋር በተያያዘ አጠቃላይ የስኳር ህክምና እንክብካቤ ለማሻሻል እና የአገራችንን ባህልና ሃይማኖትን ያማከለ ምክረ ሃሳቦችን ለማምጣት ይረዳናል። በዚህ ፕሮጀክት ላይ በመሳተፍዎ ምንም አይነት ማበረታቻ ወይም ክፍያ አይሰጥዎትም።

ምስጢራዊነት፡- ለዚህ ምርምር ከርስዎ የሚሰበሰቡት መረጃዎች ሰሞት ሳይጠቅስ በኮድ ቁጥር በይለፍ ቃል በተቆልፈ ልዩ ፋይል ውስጥ ይቀመጣሉ። የቱም አይነት መርጃ ከዋናው ተመርማሪ በስተቀር ለማንም አይገለጽም።

ያለመሳተፍ ወይም ከጥናቱ የመውጣት መብት፡ በዚህ ጥናት ውስጥ ላለመሳተፍ ሙሉ መብት አለዎት። ምላሽዎን መስጠት ካልፈለጉ ለአንዳንድ ወይም ለሁሉም ጥያቄዎች ምላሽ ላለመስጠት መምረጥ ይችላሉ። እንዲሁም በፈለጉት ጊዜ ከዚህ ጥናት የመውጣት ሙሉ መብት አለዎት። በዚያም የትኛውንም መብትዎን አያጡም። ማንኛውም ጥያቄ ካለዎት, በማንኛውም ጊዜ መጠየቅ ይችላሉ። ስለ ጥናቱ ተጨማሪ ጥያቄዎች ካሉዎት እባክዎን ዋናውን ተመርማሪ ያነጋግሩ።

ዶ/ር ብሩክ አለማየሁ ተስፋዬ (ዋና ተመርማሪ)

ስልክ፡ +251-943-801272

ኢሜል፡ brookalemayehu30@gmail.com

Annex IV: Amharic Version Consent Form

ከላይ የተጠቀሱትን ሁሉንም ሁኔታዎች ተረድቻለሁ። በዚህ ጥናት ውስጥ የምሳተፈው ሙሉ በሙሉ በራሴ ፈቃደኝነት እንደሆነ ተገልጦልኛል። የሰጠሁዋቸው መልሶችና የሚወሰዱት መርጃዎች ለሌላ ሰው ተላልፈው እንደማይሰጡ ተነግሮኛል። ጥናቱ ተጠናቆ ሲወጣመ የእኔን መለያዎች በምንም መልኩ ለይቶ አይጠቅስም። ስለዚህ በዚህ ጥናት ውስጥ ለመሳተፍ ፈቃደኛ ነኝ።

<u>ለቃለ መጠይቅ-1 (ቅድመ-ጾም)</u>

የተሳታፊ ፊርማ _____

ቀን _____

የተቆጣጣሪ ስም _____ ፊርማ_____

ቀን_____/_____/____ኢ.ሲ.

ቃለ-መጠይቅ-1 የጀመረበት- ሰዓት: _____ ደቂቃ: _____ ቃለ-መጠይቅ-1 የተጠናቀቀበት ሰዓት: __ ደቂቃ: __

የመረጃ ሰብሳቢ ስም፡- _____ ፊርማ_____

<u>ለቃለ መጠይቅ-2 (ድህረ-ጾም)</u>

የተሳታፊ ፊርማ _____

ቀን _____

የተቆጣጣሪ ስም _____ ፊርማ_____

ቀን_____/_____/____ኢ.ሲ.

ቃለ-መጠይቅ-2 የጀመረበት- ሰዓት: _____ ደቂቃ: _____ ቃለ-መጠይቅ-2 የተጠናቀቀበት ሰዓት: ____ ደቂቃ: ____

የመረጃ ሰብሳቢ ስም፡- _____ ፊርማ_____

Supplementary File 1. English Version of the Study Questionnaire

Title: Ethiopian Orthodox Christian Fasting and Glycemic Outcomes in Type 2 Diabetes

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Introduction

This questionnaire was used to collect socio-demographic, clinical, and biochemical data from patients with Type 2 Diabetes Mellitus attending Tikur Anbessa Specialized Hospital. Data were collected before and after the Ethiopian Orthodox Christian Great Lent fasting period of 2025. The questionnaire was administered in person by trained diabetes nurses during clinic visits.

Section 1: Baseline (Pre-Fasting) Assessment

Study Code: _____

Date of data collection: _____

Code	Question	Response Options / Instructions
1.	Subsection 1.1: Socio-demographic characteristics	
101	How old are you?	_____ years
102	Sex	Male / Female
103	What is your marital status?	Single / Married / Divorced / Widowed / Other (specify): _____
104	Where do you currently live?	Urban / Rural
105	What is your level of education?	No formal education / Read and write / Primary (1–8) / Secondary (9–12) / College and above
106	What is your occupation?	Unemployed / Housewife / Private sector employee / Government employee / Merchant / Student / Daily laborer / Other (specify): _____
107	Plan to observe upcoming Great Lent fasting	Yes / No / Not sure / Other (specify): _____
108	If yes to question 107, have you sought pre-fasting diabetes education	Yes / No
2.	Subsection 1.2: Baseline Diabetes related parameters	

Code	Question	Response Options / Instructions
201	Type of diabetes	Type 1 / Type 2 / Other (specify): _____
202	Duration of diabetes (in years)	_____
204	Current antidiabetic medication(s)	Metformin only / Glibenclamide-containing combination / Other sulfonylurea combination / Metformin + DPP-4 inhibitor / Metformin + SGLT2 inhibitor / Basal insulin (±Metformin) / Basal-bolus insulin (±Metformin) / Premixed insulin (±Metformin) / Other (specify): _____
205	Presence of diabetic retinopathy	Yes / No
206	Presence of diabetic nephropathy	Yes / No
207	Presence of diabetic neuropathy	Yes / No
208	Presence of atherosclerotic cardiovascular disease (ASCVD)	Yes / No / Unknown
209	History of diabetic foot problems	Yes / No / Unknown
209-1	If yes, specify type of foot problem	Ulcer / Infection / Amputation / Deformities / Other (specify): _____
210	History of hypertension	Yes / No / Unknown
210-1	If yes, antihypertensive medication(s) used	Calcium channel blockers / Diuretics / ACE inhibitors or ARBs / Beta blockers / Other (specify): _____
211	Presence of dyslipidemia or statin use	Yes / No / Unknown
212	History of hypoglycemia in past year (non-fasting)	Yes / No / Unknown
212-1	If yes, severity	Symptoms only / 54–70 mg/dL (Level 1) / <54 mg/dL self-managed (Level 2) / <54 mg/dL requiring assistance or hospital visit (Level 3)
213	History of hyperglycemia requiring hospital visit (past year, non-fasting)	Yes / No / Not sure
214	Prior fasting experience	Uneventful / Had hypoglycemia / Had hyperglycemia (>300 mg/dL or hospitalization) / Required medication adjustment / Other (specify): _____

Code	Question	Response Options / Instructions
3.	Subsection 1.3: Pre-fast metabolic and anthropometric profile	
301	Current systolic blood pressure (mmHg)	_____
302	Current diastolic blood pressure (mmHg)	_____
303	Current body weight (kg)	_____
304	Height (cm)	_____
305	Waist circumference (cm)	_____
306	Current BMI (kg/m²)	_____
307	Current fasting blood sugar (mg/dL)	_____
308	Current glycated hemoglobin (HbA1c, %)	_____
309	Total cholesterol (mg/dL)	_____
310	LDL-C (mg/dL)	_____
311	HDL-C (mg/dL)	_____
312	Triglycerides (mg/dL)	_____
313	Ability to self-monitor blood glucose (SMBG) during fasting	Yes / No / Not sure

Thank You for your cooperation!

Note: This questionnaire was administered in person by trained diabetes nurses at baseline (within the 2 weeks leading to the Great Lent fast of 2025)

Section 2: Post-Fasting Assessment

Study Code (same code to section 1): _____

Date of data collection: _____

Code	Question	Response Options / Instructions
401	Total number of fasting days completed	_____
402	Minimum hours fasted per day	_____
403	Systolic blood pressure (mmHg)	_____
404	Diastolic blood pressure (mmHg)	_____
405	Body weight (kg)	_____
406	BMI (kg/m²)	_____
407	Waist circumference (cm)	_____
408	Fasting blood sugar (mg/dL, mean of ≥3 readings)	_____
409	Glycated hemoglobin (HbA1c, %)	_____
410	Total cholesterol (mg/dL)	_____
411	LDL-C (mg/dL)	_____
412	HDL-C (mg/dL)	_____
413	Triglycerides (mg/dL)	_____
414	Experienced hypoglycemia (<70 mg/dL) during fasting	Yes / No / Not sure
414-1	If yes, time to first episode (days from start of fasting)	_____

Code	Question	Response Options / Instructions
414-2	If yes, severity	Symptoms only / 54–70 mg/dL (Level 1) / <54 mg/dL self-managed (Level 2) / <54 mg/dL requiring assistance or hospital visit (Level 3)
414-3	Frequency of hypoglycemia episodes	Once / 2–5 times / >5 times
414-4	Timing of hypoglycemia	Early morning / Midday / Afternoon / Evening / Nocturnal / Other (specify): _____
415	Experienced hyperglycemia (>300 mg/dL) during fasting	Yes / No / Not sure
415-1	If yes, required hospital visit	Yes / No
416	Experienced hyperglycemic crisis (DKA or HHS) during fasting	Yes / No
417	Medication adjustments made during fasting	Yes / No / Don’t remember
417-1	If yes, type of adjustment	Insulin dose reduced or stopped / Glibenclamide dose reduced or stopped / Other sulfonylurea reduced or stopped / Other medications adjusted / New medication started / Class of medication changed (specify): _____
417-2	Outcome after adjustment	Hypoglycemia improved / Hyperglycemia improved / Worsened / No change / Other (specify): _____
418	Broke the fast due to diabetes-related issues	Yes / No / Don’t remember
418-1	If yes, number of days fasting was broken	_____
419	SMBG: Minimum blood glucose recorded (mg/dL)	_____

Code	Question	Response Options / Instructions
420	SMBG: Maximum blood glucose recorded (mg/dL)	_____
421	SMBG: Average blood glucose recorded (mg/dL)	_____
422	In your opinion, is religious fasting safe for people with diabetes?	Strongly agree / Agree / Neutral / Disagree / Strongly disagree

Thank You for your cooperation!

Note: This questionnaire was administered in person by trained diabetes nurses within one week after the end of the Great Lent fasting period.