

# Metabolic Effect of Orthodox Fasting Dietary Pattern in Type 2 Diabetic Patients

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# Abstract

**Background:** Lenten fasting is commonly practiced by Ethiopian Orthodox Christian with energy restriction and only vegan diets as ritual activities. In addition to religious benefits, protective role of Lenten fasting on some non-communicable diseases, cardio-metabolic and serum biochemicals have not been well explored.

Methods: A prospective longitudinal study design was conducted from February 27 to April 30, 2019 among n=52(n=27 fasting group and n=25 non-fasting group) T2DM patients. Structured questionnaire was used to collect all relevant data. The study followed at two time points: at baseline (week 0) and at the end (last week of fasting). Body fat composition determined by Bio-electric impedance analyzer (Tanita® BC-418®, Japan), while serum biochemicals analyzed by random access chemistry analyzer (A25<sup>™</sup> Biosystem, Spain). Epidata version 3.4 and SPSS 23 were used for data entry and statistical analysis.

**Results:** Calorie restriction with vegan diets significantly drops systolic blood pressure (SBP), body fat mass and lean mass among fasters compared to controls (p<0.01). Body fat percentage decreased (p=0.025) significantly among fasters compared to non-fasters. Serum levels of total cholesterol, LDL-cholesterol, non-HDL-cholesterol, total cholesterol/HDL-cholesterol, triglycerides, fasting blood sugar and uric acid also significantly decreased in fasting group than non-fasting (p<0.01). While BMI, diastolic blood pressure, HDL-c, hip and waist circumference insignificantly differed among fasting group compared to non-fasting. Moreover, fasting led to a decreased cardiovascular risks among fasters like SBP  $\geq$ 130mmHg (26.9%), DBP  $\geq$ 85mmHg (3.8%), TC  $\geq$ 200 mg/dL (38.5%) and TC/HDL-c (7.7%) when compared to baseline.

**Conclusion:** Simultaneous energy restriction (ER) and vegan dietary (VD) pattern during Lenten fasting improved lipid profiles, glycemic control and blood pressure among T2DM patients. This may reflect ER+VD become non-pharmacological option to protect/avert risks of established cardiometabolic risks and morbidity.

**Keywords:** Lenten fasting; Body composition; Serum biochemical; Blood pressure

# Introduction

Currently, in developing countries, rapid shift of healthy traditional eating pattern to excessive energy intake, manifested by increasing consumption of calorie-dense foods containing refined carbohydrates, fats, red meats, and low fiber that worthy increased incidence of obesity, chronic diseases including type 2 diabetes mellitus (T2DM) and the metabolic syndrome (MetS) [1, 2].

In past, to overcome ill effect of energy imbalance, different mechanisms were implemented. For example, long-term interdisciplinary therapy such as decreasing the intake of calories, carbohydrates and fats suggested positively change in body composition and reduced anthropometric measurements [3]. In other hand, continuous eight day fasting on non-obese healthy adults by limiting energy and using 2L water showed significant increase in total serum cholesterol and LDL cholesterol. But no change was observed (did not affect) serum concentrations of triacylglycerol and HDL cholesterol in fasting group [4]. In contrary, in randomly controlled explorative study of medically treated patients with oral hypoglycemic agents and/ or insulin of T2DM for 7-day fasting program followed by dietary advice or to usual care and only dietary advice. The results suggested decrease in mean body weight and systolic/diastolic blood pressure while glycated hemoglobin (HbA1c), insulin and homeostatic model assessment (HOMA) index showed no significant improvements. This fasting were well accepted, there were no serious adverse events [5].

Recently, energy restriction and/or intermittent fasting become more popular strategies to alleviate/reduces non-communicable diseases and cardio-vascular problems. For example, in experimental research of calorie restriction by means of intermittent fasting in different form reduces incidence of age-associated chronic diseases such as cardiovascular diseases, cancer, kidney disease and diabetes mellitus as well as prolonged lifespan [6, 7].

Likewise, reduced energy intake were practiced in many religious groups by incorporating periods of fasting into their rituals including Muslims, fast from dawn until dusk during the month of Ramadan [8]. Similarly, most Orthodox Christian communities, fasting achieved by ingesting no or minimal amounts of food and caloric beverages with caloric restriction for periods typically range from 12 hr. to 10 weeks [9, 10]. More recently, Sinaga et al., 2020, studied the metabolic effect of fasting among Ethiopian Orthodox followers in healthy subjects but this study exhibited inherent limitation of retrospective cohort studies [11]. Unfortunately, long-term evaluation of fasting practice is not available in diabetic patients.

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Therefore, the present study aimed to evaluate long term effect of Ethiopian orthodox Christian fasting that combine simultaneous energy restriction and vegan diet, abstain animal source foods, intermittent fasting (Wednesday and Friday)/week, and overnight fast during Lenten on level of on body weight, body mass index (BMI), lipid profile, fasting blood sugar (FBS), blood pressure (BP) and uric acids (UA) in free living insulin resistance patients.

#### Problem description

Simultaneous energy restriction and vegan and/or vegetarian diet type were seen in free living people of Ethiopian Orthodox Christian fasters but little is known about its' metabolic effects.

### Available Knowledge

Recently, beneficial effect of intermittent fasting, dietary habits and caloric restrictions are well established in improving metabolic activities in health of animal model, human model as well as some extreme human fasting cases (Monks).

# Rationale

Caloric restriction and/or consumption of vegan diet using different forms of intermittent fasting and some religious fasting explore health benefits. This study try to look at the beneficial effect of Lenten fasting, combine both caloric restriction and consumption of vegan diet together.

# Specific aim

This study aimed to evaluate metabolic effect of Lenten fasting dietary pattern among T2DM patients.

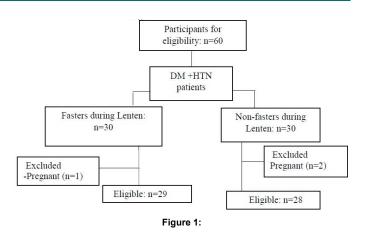
#### Methods

#### Intervention

This prospective longitudinal study design was conducted among 52 T2DM patients in Hawassa city administration, Sidama Regional State, Southern Ethiopia from February 27/2019 to April 30/2019. Two groups are involved in the study, fasting group (case) and non-fasting (control).

# Study of the Intervention and group allocation

The subjects were Orthodox Christian communities with diabetes and hypertension with age range of 30-50 years old. The subjects were permanently living in the study area with no plan of leaving before the completion of the study. In addition, those patients who have only a good adherence towards diabetes self-care practice were eligible for the study. The group allocation was done based on an Ethiopian Orthodox church fasting season and dietary pattern during Lenten fasting. Following this, 29 subjects (16 males, 13 females) with mean ( $\pm$  standard deviation (SD)) age of 42.31  $\pm$  4.81 years old those who have been rigorously fasting experiences for mean of  $19 \pm 15$  years, and aiming to continue to fast and adopt to use simultaneously vegan diet and energy restriction during study period were included in the study group (fasters). Whereas 27 subjects (15 males, 12 females) with mean ( $\pm$ SD) age of 41.27  $\pm$  4.34 years old, those who have stopped fasting (fasted for  $17 \pm 10$  years) before one of study period and those not willing to continue fasting during study period were included in the control group (non-fasters). However, pregnant mothers or lactating mothers, participants on lipid lowering therapy or antiretroviral treatments, patients having chronic liver disease and or renal disease were excluded in figure 1.



#### Measures

Two measurements were taken from the study subjects for each parameter, which means before fasting, at baseline (week 0) and end of fasting (last week of fasting). Structured questionnaires were used to collect socio-demographic, anthropometric, clinical and other pertinent information. Following this, measurements of blood pressure [12], height and weight, hip and waist circumference of the study subjects was done by trained clinical nurses. A digital electronic sphygmomanometer (Omron, Healthcare, Japan) was used to measure blood pressure after patients rested and completely stabilized for at least 5 min in the assessment room [12]. Two readings of BP was taken within 2-3 min differences to maintain the accuracy of measurement and lastly the mean value was taken and documented to assess BP status. In addition, the third BP measurement was taken, when the two measurements varied by 10 mmHg within 2-3 min differences in a single study subject, and lastly the mean value of three measurements was taken to determine BP status.

Body weight, height waist and hip circumference were assessed based on world health organization (WHO) stepwise techniques was applied to collect data [13]. Weight and height was measured when patients stood wearing light cloths and wearing no shoes. A digital electronic Adult scale (ASTO) that contain both weight scale and height scale was used to measure body weight to the nearest 0.1kilogram(kg), and height to the nearest 0.1 centimeter (cm). Moreover, body mass index (BMI) was calculated as weight in kilogram divided by squared height in meter.

Hip circumference (HC) was measured at the level of the above trochanter with stretching resistant tape. While waist circumference (WC) was measured at the navel using a non-stretching type of tape (to the nearest 0.1 cm) when participants stood in upright position after the end of a usual exhalation [14].

Body composition of the subjects was measured using bio-electric impedance analyzer (Model Tanita<sup>®</sup> BC-418<sup>\*</sup>, Tokyo, Japan) with a range of 0-200 kg and with an accuracy of within 100 g. Measurements were taken between meals among well-hydrated subjects, without shoes and clothing (except underwear), that is, proper time gap should be there between measurement/analysis and meal.

#### Blood specimen collection and laboratory diagnosis

About 4-5 milliliter of venous blood for prospective determination of serum biochemicals was collected at baseline (before start of fasting) and at last of week of fasting (fasting end time) from each study participant after 12 hours overnight fasting in the morning (from 9:00 to 9:30AM) using serum separator tube (SST). Then, the collected blood sample was allowed to form proper clot within 20-25 min at room temperature. Following this, the samples were centrifuged at 2500-3000 rotation per minute (rpm) to separate serum from clot. Moreover, the serum specimen of each participant was analyzed to determine total cholesterol (TC), high density lipoprotein cholesterol (HDL-c), low density lipoprotein cholesterol (LDL-c), triglycerides (TGs), fasting blood sugar (FBS) and uric acid (UA) using A25<sup>™</sup> Biosystem random chemistry analyzer (BioSystems<sup>™</sup>, Barcelona, Spain).

Finally, enzymatic colorimetric assay technique was applied for UA (Uricase-Peroxidase method), FBS by glucose-oxidase method (GOD-PAP), TC (CHODPAP method) and triglyceride (GPO-PAP method). Whereas HDL-c and LDL-c were determined by the direct homogeneous enzymatic colorimetric assay approach. All biochemicals assay reagents were from Linear manufacturers (Linear chemicals, Montgat, Spain).

# **Operational definitions**

# Fasting and abstinence in the Ethiopian Orthodox Tewahedo Church

There are 250 fasting days through the year in Ethiopian Orthodox Christian church. Of these, 180 days are considered as obligatory and the others only for the clergy. The Lenten fasting, known as Abiy Tsom/ Hudade in Amharic or great fasting, is the longest continuous fasting period, lasting 55 days. The consumption of meat, milk products, or eggs are not allowed during these days. Ethiopian cuisine contains many dishes that can be considered vegan diet such as split peas and lentils or vegetables such as potatoes, carrots and chard are common in fasting dishes. Sauce, made from ground chickpeas, is also particularly popular as a fasting food [15].

Dyslipidemia: It was defined according to the United States National Cholesterol Education Program, Adult Treatment Panel (NCEP-ATP) III guideline, which describes as TC  $\geq$  200 mg/dl, HDL-c < 40 mg/dl, LDL-c  $\geq$  130 mg/dl, TG  $\geq$  150 mg/dl and TC/HDL-c ratio  $\geq$  5 [16].

Glycemic control for diabetes patients: Based on the American Diabetic Association (ADA) 2017 guideline recommendation, good glycemic control is defined as those diabetes patient whose fasting blood glucose level is in between 80-130 mg/dL while those patients who have fasting blood glucose of > 130 mg/dL categorized under poor glycemic control [17].

Hypertension: defined as either having a systolic blood pressure (SBP)  $\geq$  140 mmHg and/or a diastolic blood pressure (DBP)  $\geq$ 90 mmHg and/or self-report of earlier diagnosis of hypertension by a health professionals and/or if presently receiving anti-hypertensive agents.

### **Outcome measurement**

The study outcome of anthropometric, body composition and cardiovascular parameters like BMI, WC, HC, fat percent and fat mass, fat free mass, SBP and DBP were assessed between week 0 (baseline) and last of week of fasting (end time) of fasting. For each study subject at each specific study time was calculated as value at last week minus value at baseline divided by concentration at baseline multiplied by 100 [18]. In addition, the study outcome of TC, UA, FBS, and HDL-c, LDL-c, non-HDL-c, TC: HDL-c ratio, and TGs between baseline of fasting and last week of fasting (fasting end time) were assessed in similar manner. For each patient, we calculated percent change as

concentration at last week of fasting minus concentration at baseline divided by concentration at baseline, multiplied by 100.

### Data quality issue

Data collection tool was evaluated by pretesting of 20% questionnaires before collecting actual data and all vital amendment was done following a pretest result feedback. Data collection was done by trained clinical nurses; while blood sample collection and laboratory analysis was managed by laboratory technologists. In addition, at the initial day of contact, patients have got detailed information about the study and its protocol. In the study baseline and end time, blood samples were drawn from those who come only with overnight fasting. Standard operating procedure was strictly followed from patient preparation to result releasing, while the accuracy and precision of laboratory determination, instrument condition and technical performance were maintained by running commercially prepared quality control samples (controls with known target value) before actual samples and along with actual samples.

# Data processing and statistical analysis

All data were visually checked for consistency and its completeness, coded and entered into Epidata version 3.4. Statistical Package for Social Sciences (SPSS) version 23.0 software was used statistically for data analysis. Normality of the continuous data distribution was checked using Shapiro-Wilk test. Descriptive statistics like frequency and percentages were also used to describe dependent variable in relation to different categorical data, while mean (percent increase) and SD or standard error was used for continuous data. In addition, estimate of variances in means of study groups was assessed using student's t-test at 95% confidence interval (CI) level and finally a p-values< 0.05 was considered for statistical significance.

#### Ethical approval and consent to participate

The protocol and the questionnaires were reviewed and cleared by the institution review board of Natural and Computational Science of Addis Ababa University, Ethiopia (IRB/035/2018). The nature of the study was fully explained to the study participant and written consent was obtained from each participant prior to conducting the study. All studies on humans defined in the current study were conducted with the endorsement of the accountable ethics committee and in agreement with national law and the Helsinki Declaration of 1975 (in its recent, revised form).

# Results

#### General characteristics of study participants

Of the 57 previously diagnosed known diabetes + hypertensive (29 fasting and 28 non-fasting group) patients were enrolled in the study; however, 5 participants (2 from fasting and 3 from non-fasting group) were lost to follow-up. Therefore data of these 5 patients were not considered in this statistical analysis. A total number of 52[28(53.8%) males and 24(46.2%) females] were participated in the study and completed study follow-up. The mean age of the study subjects was  $41.8 \pm 4.6$  with the age range of 32 to 50 years. Regarding marital status, 63.5% (n=33), 11.5% (n=6), 21.2% (n =11) and 3.8% (n=2) of the study participants were married, unmarried, separated and widowed respectively. Majority, 90.4% (n=47) and 78.8% (n=41) study participants were educationally greater than or equal to college levels and government employed respectively. The physical activity status of about 40.4% (n =21), 21.2% (n=11), and 38.5% (n=20) study participants were identified as having sedentary, less physically active

and moderate to intensive physical activity performance respectively. The mean monthly income of the study participants was 4966.7  $\pm$  1417.8 with the range of 3200 to 9000 of Ethiopian Birr. Regarding behavioral characteristics, none of study participants drank alcohol, chewing chat and smoke cigarette.

# Baseline characteristics of the study participants

From a total of 52 patients with type 2 diabetes and hypertension (27 were fasting group and rest 25 were non-fasting group). The mean age of fasting group was  $42.31 \pm 4.81$ , while the mean age of non-fasting group was  $41.27 \pm 4.34$  (p >0.05). Anthropometric parameters such as BMI, WC and HC and body composition such as fat percent, fat mass and fat free mass were done for 52 participants and they did not show a significant difference between the study groups (p>0.05). Diastolic blood pressure also did not show a significant difference between fasting and non-fasting group, while systolic blood pressure and TC/HDL-c ratio were significantly higher in fasting group when compared to non-fasting group (144.1±14.1 vs. 131.8±13, p= 0.001), and (6.1±1.6 vs. 5.1± 1.7, p=0.003) respectively. In addition, lipid profiles (TC, HDL-c, LDL-c, TG, and non-HDL-c) and other serum biochemicals like FBS and UA also were insignificantly differ at baseline between groups (Table 1).

 Table 1: Baseline characteristics of anthropometric, cardiovascular and biochemical parameters among the study participants.

Variables	Study groups	Mean(±SD)	t statistics	p-value	
WC	Non-fasting	83.5(10.93)	-0.251	0.803	
	Fasting	84.1 (5.18)	_		
	Non-fasting				
BMI	Fasting	25.8(2.38)	-0.528	0.6	
	Non-fasting	26.1(1.89)			
HC	Fasting	96.1(11.45)	0.647	0.52	
	Non-fasting	94.5(5.55)			
Fat percent	Fasting	32.3(5.82)	1.104	0.275	
	Non-fasting	30.6(5.13)			
Fat mass	Fasting	23.1(4.49)	-0.866	0.391	
	Non-fasting	24.1(3.87)			
FFM	Fasting	46.2(3.61)	1.367	0.178	
	Non-fasting	44.1(6.84)			
SBP	Fasting	131.8(12.97)	-3.669	0.001	
	Non-fasting	144.1(11.15)			
DBP	Fasting	79.7(10.32)	-1.176	0.245	
	Non-fasting	82.8(8.19)			
FBS	Fasting	153.1(56.27)	-1.471	0.147	
	Non-fasting	172.6(37.02)			
TG	Fasting	399.2(97.40)	0.27	0.788	
	Non-fasting	392.7(73.50)	_		
тс	Fasting	179.92(39.347)	-1.329	0.19	
	Non-fasting	192.19(25.94)	_		
LDL	Fasting	90.62(15.74)	0.34	0.191	
	Non-fasting	89.30(11.84)	_		
HDL	Fasting	38.12(9.73)	1.843	0.071	
	Non-fasting	33.46(8.42)			
UA	Fasting	5.93(1.99)	-0.069	0.945	
	Non-fasting	5.97(1.60)			
Non-HDL-c	Fasting	141.8(39.5)	-1.8	0.08	
	Non-fasting	158.7(28.1)			
TC/HDL-c	Fasting	5.1(1.7)	-2.2	0.03	
		6.1(1.6)	1		

BMI, body mass index; WC, circumference; HC, hip circumference; SBP, systolic blood pressure; DBP, diastolic blood pressure; FBS, fasting blood sugar; TG;, triglyceride; TC, total cholesterol; LDL, low density lipoprotein; HDL, high density lipoprotein; UA, uric acid.

# Changes in Anthropometric parameters, blood pressure and body composition

All changes within the treatment groups on body composition levels were statistically significant at last week of fasting except anthropometric parameters like BMI, WC and HC. There was no statistically a significant change observed in WC in the fasting group (0.0%) when compared to non-fasting group (1.2%), (95% CI: -3.3 to 0.89), p = 0.25). In contrast, the decrease of fat percentage was 3.0% (95% CI: -0.4 to -5.7) and larger in the non-fasting group (6.67%) than in the fasting group (3.6%). This change was statistically significant (p =0.025). The decrease in fat mass was higher in the fasting group (6.7%) than in the non-fasting group (3.3%), and this difference (3.4%; 95% CI: 5.0 to 1.7) was statistically significant (p < 0.0001) (Table 2).

The change of SBP was 14.5% (95% CI: -11.7 to -17.2) and it was decreased 7.3% in the fasting group and increased 7.18% in the non-fasting group. This difference was statistically significant (p < 0.0001). In contrast, the DBP was decreased 0.63% in the non-fasting group but it increased 2.69% in the fasting group, this difference was not statistically significant (3.3%; 95% CI:-2.0 to 8.6; p = 0.216) (Table 3).

#### Changes in lipids profiles and other serum biochemicals

Except HDL-c concentration, all changes within the study groups such as lipid profile, fasting blood glucose, uric acid as well as TC: HDL-c ratio were statistically significant at last week of fasting. The change of TC was 15.1% (95%: -19.2 to -11.1) at last week of fasting and decreased 10.16% in the fasting group but increased 4.97% in the non-fasting group, the difference was statistically significant (p<0.0001).

TC: HDL-c ratio was decreased 18.2% in the fasting group but it increased 1.9% in the non-fasting group (p<0.0001). The decrease of TGs was 36.9% (95% CI: -13.6 to -60.2) and lesser in the fasting group (82.59%) than in the non-fasting group (119.5%). This difference was statistically significant (p<0.0001). Moreover a significant decrease in FBS and UA was observed in the fasting group when compared to non-fasting group (p<0.001 for both parameters) (Table 4).

In contrast, the increase in HDL-c was higher in the fasting group (7.78%) when compared to the non-fasting group (3.85%), but the difference was not statistically significant (3.9%; 95% CI: -1.3 to 9.2, p=0.138). Some abnormal parameters showed decreasing pattern at last week of fasting when compared to baseline value like SBP (from 100 to 73.1%), FBS (from 96.1 to 76.9%), TC (from 53.8 to 15.4%) and TC/HDL-c ratio (from 65.4 to 57.7%). Other lipid profile such as TG and LDL-c and HDL-c did not show any change at last week of fasting in comparison with baseline abnormality according to NCEP ATP III criteria (Figure 2).

# Discussion

The fasters abstain from the consumption of animal source foods but they experienced by energy restriction with only utilization of vegan diets for 10 weeks prolonged time according to Ethiopian Orthodox Church ritual practice. During this period participants consume only plant origin diets such as whole grains, cereals, green leafy vegetables, legumes, peas, beans, fruits [19].

This study compared the changes on anthropometric, blood pressure, body composition and biochemical parameters of diabetic fasters (study group) with diabetic non-fasters (controls) for about 10 weeks. Both groups were similar with age, sex distribution and geographical location. We found out that abstinence of meat, dairy products and eggs for 10 weeks in the Lent period was significantly

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Variables	Fasting group (n=27)				Non fasting (n=25)	Difference (95% CI)	p-value	
	Baseline	Last Week	% increase	Baseline	Last Week	% increase	(Fasting-Non fasting)	for difference
	Mean ±SD	Mean ±SD	Mean ±SE	Mean ±SD	Mean ±SD	Mean ±SE		
BMI (Kg/M <sup>2)</sup>	26.1(1.89)	25.93(1.81)	86(1.47)	25.8(2.38)	25.72(2.49)	51(2.21)	-0.34(-1.4 to 0.7)	0.513
WC (cm)	84.1 (5.18)	84.15(5.18)	.00(.00)	83.5(10.93)	84.52(11.36)	1.21(5.32)	-1.2(-3.3 to 0.89)	0.252
HC (cm)	94.5(5.55)	94.50(5.55)	.00(.00)	96.1(11.45)	96.09(11.45)	02(.10)	0.02(-0.02 to 0.06)	0.322
Fat%	30.6(5.13)	31.77(5.37)	3.64(2.01)	32.3(5.82)	34.47(6.29)	6.67(6.37)	-3.0(-0.4 to -5.7)	0.025
Fat mass	24.1(3.87)	25.65(4.03)	6.72(2.74)	23.1(4.49)	23.79(4.55)	3.32(3.18)	-3.4 (5.0 to 1.7)	<0.0001
FFM	44.1(6.84)	41.91(6.68)	-5.10(2.35)	46.2(3.61)	45.63(3.81)	-1.31(2.29)	-3.8(-2.5 to -5.1)	<0.0001

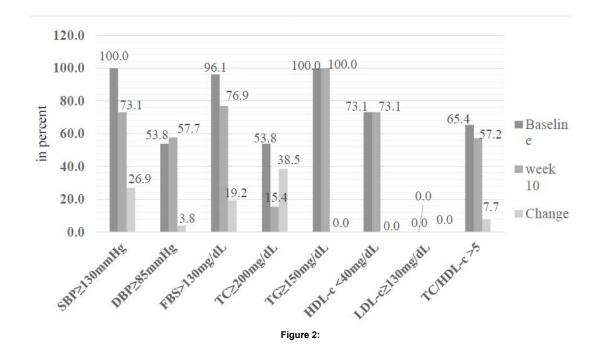
#### Table 2: Anthropometric and body composition parameters at baseline and last week of fasting and their mean percentage change.

Table 3: Blood pressure at Baseline and last week and their mean percentage change.

	Fasting group (n=27)			N	lon fasting (n=25)	Difference (95% CI)	p-value		
Variables	Baseline	Last Week	% increase	Baseline	Last Week	% increase	(Fasting-Non fasting)	for difference	
	Mean ±SD	Mean ±SD	Mean ±SE	Mean ±SD	Mean ±SD	Mean ±SE			
SBP (mmHg)	144.1(11.15)	133.19(6.64)	-7.29(5.52)	131.8(12.97)	141.19(13.56)	7.18(4.40)	-14.5(-11.7 to -17.2)	<0.0001	
DBP(mmHg)	82.8(8.19)	84.23(3.67)	2.69(11.04)	79.7(10.32)	79.11(11.26)	63(7.83)	3.3(-2.0 to 8.6)	0.216	
DBP, diastolic bloc	DBP, diastolic blood pressure; CI, confidence interval; mmHg, millimeter of mercury; SBP, systolic blood pressure; SD, standard deviation								

Table 4: Serum biochemical tests at baseline and last week and mean percentage change of the study participants.

	F	asting group (n=2	group (n=27)		Non fasting (n=25)			p-value
Parameter						(Fasting-Non fasting)		
	Baseline	Last Week	% increase	Baseline	Last Week	% increase		for difference
	Mean ±SD	Mean ±SD	Mean ±SE	Mean ±SD	Mean ±SD	Mean ±SE		
FBS (mg/dL)	172.6(37.02)	148.08(21.06)	-12.79(8.24)	153.1(56.27)	170.00(49.42)	18.33(31.74)	-31.1(-18.2 to -44)	<0.0001
TG (mg/dL)	392.7(73.50)	347.45(57.63)	-82.58(29.86)	399.2(97.40)	388.76(95.62)	119.48(51.0)	-36.9(-13.6 to -60.2)	<0.0001
TC (mg/dL)	192.19(25.9)	172.31(27.14)	-10.16(9.65)	179.92(39.35)	188.35(39.31)	4.97(3.54)	-15.1(-11.1 to -19.2)	<0.0001
LDL-c (mg/dL)	89.30(11.8)	83.91(14.39)	-6.25(7.81)	90.62(15.74)	91.31(17.94)	.75(8.28)	-7.0(-11.5 to -2.5)	0.003
HDL-c (mg/dL)	33.46(8.42)	35.86(8.50)	7.78(9.55)	38.12(9.73)	39.41(9.99)	3.85(9.28)	3.9(-1.3 to 9.2)	0.138
UA (mg/dL)	5.97(1.60)	4.48(1.04)	-22.60(15.61)	5.93(1.99)	5.71(1.89)	6.72(49.03)	-29.3(-9.1 to -49.6)	0.005
Non-HDL-c (mg/dL)	158.7(28.1)	136.4(28.3)	-13.9(2.3)	141.8(39.4)	148.9(38.2)	5.8(1.1)	-19.7(-14.6 to -24.8)	<0.0001
TC/HDL-c ratio	6.1(1.6)	5.0(1.3)	-16.4(1.8)	5.1(1.7)	5.1(1.6)	1.9(1.9)	-18.2(-13 to -23.4)	<0.0001
FBS, fasting blood suga	ar; TG, triglyceride;	TC, total cholester	ol; LDL-c, low der	nsity lipoprotein ch	nolesterol; HDL-c, I	high density lipop	rotein cholesterol; UA,	uric acid



In addition, we observed significantly lower in mean change of FBS, TGs, TC, LDL-c, UA, non-HDL-c and TC/HDL-c ratio) in the fasters when compared to non-fasters. But insignificantly increased HDL-c value was seen among fasters than non-fasters. Moreover, fasting led to highly decreased abnormal values like SBP≥130mmHg, FBS >130mg/dL, and TC≥200 mg/dL at least 19% in each parameters the fasters at last week of fasting, while fasting did not show any change on TG≥150 mg/dL and HDL-c<40mg/dL. Our finding in line with higher compliance and promise strategies of intermittent fasting in the improvement of metabolic risk factors, body composition, and weight loss in obese and diabetic patients [20-22].

We noticed that Ethiopian orthodox Christian Lenten fasting showed insignificant change on anthropometric parameters such as BMI, HC and WC. Studies from Egyptian Christian Lenten fasting was consistent with our results but other two studies in Ramadan fasting have reported insignificant change [23, 24]. On the contrary, several studies reported a significant improvement on anthropometric measurements (body weight, BMI, WC and HC) and a significant decrease in body weight and BMI following Lenten fasting [25-27].

Fasting led to a significant decrease of mean body fat percent among fasters compared to non-fasters. The finding is in line with the studies conducted in a different place [28, 29].

Our study noted that Lenten fasting for 10 weeks is associated with a significantly lower SBP levels when compared to non-fasters. The finding is comparable with the studies conducted in elsewhere [26, 30, 31]. The consumption of vegan diet [32], intake of high-fiber, low-fat, low-protein and vegan diet effect and or consumption of vegetables that augmented with fibers and potassium content might be a plausible reason for the decreasing effect of blood pressure among fasters [32, 33].

A significant low mean change of FBS, TGs, TC, LDL-c, TC/ HDL-c ratio and non-HDL-c were seen in the fasters when compared to non-fasters after 10 weeks of vegan diet consumption. Comparably different international studies reported that vegan diet significantly decreased the described serum biochemical profile [7, 34-38]. Similarly, the consumption of vegetables particularly in Lenten could have a good opportunity to consume increased amount of fiber containing vegetables when compared to non-fasters and this might have a chance to improve lipid profiles among fasters [39]. However, the study conducted in Addis Ababa, Ethiopia indicates insignificant increasing of TGs after 7 weeks of fasting [30]. This is not in line with the finding of present study, which indicates a significant decrease of mean TG after 10 weeks of fasting. The difference in sample size between the studies and individuals' trend in the consumption of varieties of vegan diet might be a possible reasons for the variation, that is why some studies have pointed out an association between raised TGs level and an intake of a vegetarian diet [40].

Similarly, our results is agreed with study of intermittent fasting in adults on lipid profile for about six weeks ~12 h during day time, three times per week indicated larger reduction in body weight, BMI and waist circumference in intermittently fasting group than control. Lipid profiles such as total cholesterol, triglycerides, LDL-c were significantly decreased while HDL-c significantly increased [41]. These beneficial effects are due in part of shifting from the utilization of glucose to fatty acids and ketones as the body's preferred source of fuel during fasting. During this transition/reprogramming in the body, switches

from the synthesis and storage of lipids to mobilization of fat in the form of ketone that highlighted as a potential mechanism for many of the beneficial effects of intermittent fasting. [20]. Fasting in free living Ethiopian Orthodox may follow the same mechanisms of metabolism as intermittent fasting.

Even, our finding in line with different studies during Ramadan fasting. It is resulted by significantly decreased in blood lipid profile such as increase of HDL-c while decrease in total cholesterol, LDL-c and blood glucose after fasting among normal healthy individuals and diabetic patients [42-44]. Also, after Ramadan it is noted significant decrease in blood glucose level, triglycerides, cholesterol and creatinine in diabetic patients [44,45]. Controversially, no significant effect on fasting/postprandial glucose levels and blood lipid levels was observed in insulin resistance [46].

We noted that fasting led to highly decreased cardiovascular/ metabolic risks like SBP≥130mmHg, TC≥200 mg/dL and TC/HDL-c among fasters after week 10 when compared to baseline value. Our study is supported by several studies that revealed fasting is the utmost reasonable intervention that limits cardiovascular diseases and other risks of cardiovascular diseases [47, 48]. Besides, one reports from Ramadan fasting indicated a significant improvement in10 year's coronary heart disease risk (according to Framingham risk score) as well as other cardiovascular risk factors [27]. Further, consuming diets especially plant source during religious fasting as well as in our daily life play an important role to avert risks of cardiovascular diseases [30].

In general, even though it may be difficult to convince patients to give up or severely restrict calories for an entire 24 h period fasting like Ethiopian orthodox Christian was good practice for T2DM patients to reduce risk of chronic diseases. As patients become more comfortable with overnight fasting, energy restriction and vegan diet eating pattern and abstinence of animal source foods, the feeding window can be restricted further to16 h fast followed by an 8 h feed by checking nutrient balance.

#### Limitations

The principal limitation of this study was small sample size, which focus only on fasting dietary pattern and we did not comprise the nondiabetic population as a comparative group. Furthermore, it is also true that the hydration status of the participants could have modified the results of the body fat% measured with bioelectrical impedance analysis which is not tightly followed. Since, most BIA prediction equations assume that the fat mass and fat-free mass consist of 73% water [49]. Irrespective of the described limits, this study adds supportive information in the limited data condition of Ethiopia.

# Conclusion

In conclusion, energy restriction with vegan dietary pattern in the Lenten fasting significantly improved TC, LDL-c, TG, Non-HDL-c, FBS, SBP, UA and some body composition variables in patients with type 2 diabetes mellitus. The findings of this study suggested that Ethiopian Lenten fasting may be beneficial to improve CVD and metabolic syndrome (MetS) risk factors. There is also a need for large and well-designed randomized control trials to identify clinical characteristics and to assess more imperative clinical outcomes in order to prevent and or limit adverse effects in people living with type 2 diabetes mellitus.

# Abbreviations

BMI, body mass index; CI, confidence interval; DM, diabetes

mellitus; FBS, fasting blood sugar; HDL-c, HDL-cholesterol; LDL-c, LDL-cholesterol; TC, total cholesterol; HP, hip circumference; SD, standard deviation; WC, waist circumference; TG, triglycerides; SPSS, Statistical package for social sciences; UA, uric acid

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#### Authors' contributions

All authors were involved in the study. AM and KB designed the research; AM performed the research; AM and KB analyzed data and prepared the manuscript including critical appraisal. All authors read and approved final version of the manuscript.

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#### Availability of data and materials

The dataset of this article is not openly accessible, but it can be available on reasonable request from the corresponding author.

#### **Consent for publication**

Not applicable

## **Competing interests**

The authors declare that they have no competing interest with respect to the research, authorship, and/or publication of this article.

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