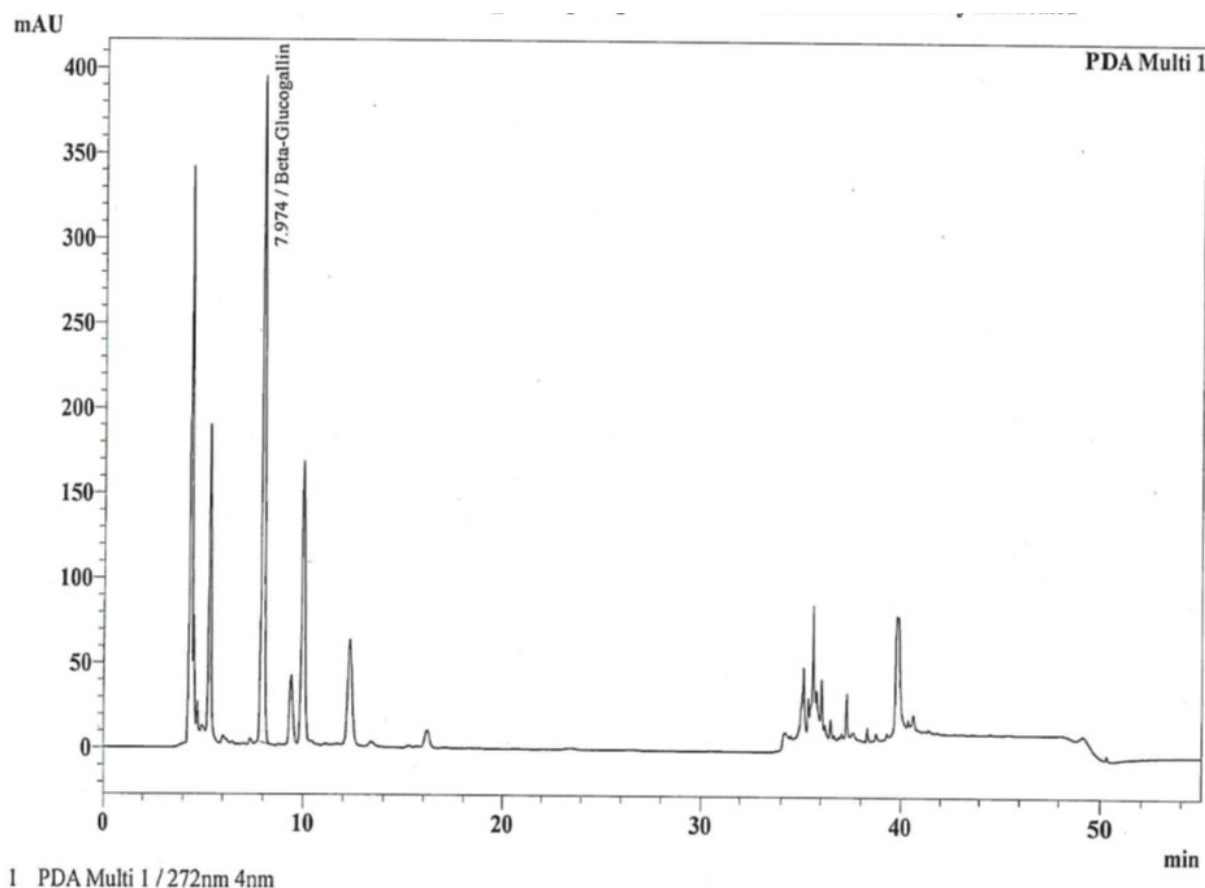


Title:

Novel *Emblica officinalis* extract containing β -Glucogallin vs. Metformin: A randomized, open-label, comparative efficacy study in newly diagnosed type 2 diabetes mellitus patients with dyslipidemia

Supplementary material

Supplementary Fig. 1: A typical HPLC chromatogram of EOE.



Supplementary Table 1: Baseline demographics

PARAMETER		Metformin (N = 42)	EOE-1g (N = 42)	EOE-2g (N = 42)	p value
Age (Years)		48.12 ± 10.42	46.17 ± 9.61	46.71 ± 9.77	0.635
Gender, (%)	Male	23 (54.76 %)	29 (69.05 %)	23 (54.76 %)	0.305
	Female	19 (45.24 %)	13 (30.95 %)	19 (45.24 %)	
Height (Cm)		159.13 ± 5.99	161.75 ± 6.08	159.93 ± 5.87	0.246
Weight (Kg)		71.04 ± 6.47	74.72 ± 6.28	72.89 ± 6.21	0.820
BMI (kg/m ²)		27.92 ± 1.54	28.50 ± 1.13	28.38 ± 1.17	0.123
SBP (mmHg)		119.17 ± 18.97	121.68 ± 7.19	122.07 ± 8.46	0.534
DBP (mmHg)		77.37 ± 6.00	77.90 ± 4.64	77.26 ± 6.02	0.936
Body Temperature (°F)		97.78 ± 1.56	98.23 ± 0.61	98.15 ± 0.75	0.134
Pulse Rate (beats/min)		81.56 ± 5.78	80.59 ± 5.28	79.88 ± 5.85	0.417
Respiratory Rate (per min)		18.02 ± 1.33	19.73 ± 10.14	18.10 ± 1.59	0.421
Smoking History, (%)	Yes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	NS
	No	42 (100.00 %)	42 (100.00 %)	42 (100.00 %)	
Alcohol History, (%)	Yes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	NS
	No	42 (100.00 %)	42 (100.00 %)	42 (100.00 %)	
Drug Abuse History, (%)	Yes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	NS
	No	42 (100.00 %)	42 (100.00 %)	42 (100.00 %)	

Values are expressed as Mean ± SD. One-way ANOVA was used to compare the means between the groups.

BMI: Body Mass Index, EOE: *Emblca officinalis* Extract, DBP: Diastolic Blood Pressure SBP: Systolic Blood Pressure, NS: Not Significant.

Supplementary Table 2. Sub-analysis of the lipid parameters for male and female from screening to day 90.

Parameters		Visits	Metformin (N = 41)	EOE-1g (N = 41)	EOE-2g (N = 42)
TC (mg/dL)	Female	Screening	240.05 ±18.01	240.91 ±19.70	235.73 ± 19.94
		Day 90	208.38 ±26.95***	211.58 ±11.74***	196.36 ±31.63***
	Male	Screening	246.30±20.65	247.76±16.15	237.27 ±14.82
		Day 90	216.56 ± 34.24***	223.14 ± 17.64***	205.32 ± 21.76***#
TG (mg/dL)	Female	Screening	171.22±15.06	202.8 ± 70.89	176.42 10.09
		Day 90	148.55 ±22.45**	189.8 ± 93.08*	150.15 ± 16.62***
	Male	Screening	175.34 ±11.38	174.16 ±9.39	177.09±21.43
		Day 90	156.87 ± 15.70***	156.96 ± 18.29***	156.27 ±23.97***
LDL (mg/dL)	Female	Screening	164.43 ±14.95	153.90 ±13.30	163.51 ±13.87
		Day 90	129.46 ± 35.15***	129.41 ± 12.91***	122.36 ± 28.89***
	Male	Screening	170.0 ± 15.54	166.86 ±12.61	164.3 ± 12.67
		Day 90	140.87 ± 35.77***	145.60 ± 21.84***	130.8 ±22.37***
VLDL (mg/dL)	Female	Screening	34.65 ± 1.80	36.56 ± 5.22	34.20 ± 3.90
		Day 90	29.58 ± 4.55***	32.75 ± 6.60***	29.86 ± 3.25***
	Male	Screening	35.30 ± 2.09	33.89 ± 4.12	37.57 ± 13.27
		Day 90	31.18 ± 3.1***	31.25 ± 3.63**	31.04 ± 4.64*
HDL (mg/dL)	Female	Screening	49.94 ± 13.89	44.78± 7.12	44.94 ± 8.34
		Day 90	50.55 ± 14.17	45.24± 8.63	46.42 ± 8.13
	Male	Screening	43.08 ± 7.83	44.23± 7.94	41.63 ± 5.17
		Day 90	44.91± 7.56	45.83 ± 8.17	43.81 ± 5.05

Lipid levels at the Screening visit and Day 90; Data represented as Mean ± Standard deviation.

*p<0.05, **p<0.01; ***/***# p<0.00, EOE-1 mg or EOE-2 mg treatment compared to screening visit.

Supplementary Table 3. Body weight and blood pressure parameters

Parameters	Visits	Metformin (N=41)	EOE-1g (N= 41)	EOE-2g (N=42)
Body Weight (Kg)	Screening	71.04 ±6.55	74.54 ±6.25	72.89 ±6.21
	Day 90	71.03±6.50	74.42±6.08	72.72± 6.25
BMI (Kg/m²)	Screening	27.93±1.56	28.49±1.14	28.38±1.17
	Day 90	28.01±1.46	28.46±1.07	28.31±1.12
SBP (mmHg)	Screening	119.17±18.17	121.68±7.19	122.07±8
	Day 90	118.10±4.65	118.24±4.04*	118.88±3.97*
DBP (mmHg)	Screening	77.37±6.00	77.90±4.64	77.26±6.02
	Day 90	78.39±3.85	79.32±2.84	78.05±3.92

Values are expressed as Mean ± SD. *p<0.05 compared to the screening visit. No significant difference was observed between the groups. BMI: Body Mass Index, EOE: *E. officinalis* Extract, DBP: Diastolic Blood Pressure SBP: Systolic Blood Pressure.

Supplementary Table 4: Safety parameters

Parameters	Visits	Metformin (N = 41)	EOE-1g (N = 41)	EOE-2g (N = 42)
Hemoglobin (g/dL)	Screening	13.51±1.92	13.91±1.74	13.73±1.61
	Day 90	13.78±1.26	14.00±1.68	13.90±1.67
RBC (million/μl)	Screening	4.86±0.52	4.93±0.79	4.84±0.41
	Day 90	4.83±0.52	4.98±0.82	4.90±0.52
Total leucocytes (cells/mm³)	Screening	7955.85±1170.95	7990.24±1384.54	8043.81±1438.03
	Day 90	8051.71±1042.41	7933.41±1243.27	8039.76±1234.41
ALT(IU/L)	Screening	18.61±4.81	21.61±7.03	21.90±6.61
	Day 90	20.17±4.13	21.12±5.74	21.38±5.73
AST(IU/L)	Screening	17.90±3.91	18.61±4.86	18.81±4.47
	Day 90	19.12±2.79	19.73±4.27	19.21±3.23
ALP(IU/L)	Screening	116.66±37.10	120.90±36.91	118.50±41.04
	Day 90	117.29±37.97	116.20±31.26	108.74±34.19
Uric Acid (mg/dL)	Screening	4.47±1.42	4.41±1.67	4.53±1.44
	Day 90	4.40±1.54	4.37±1.67	4.55±1.49
Serum Creatinine (mg/dL)	Screening	0.95±0.15	0.96±0.18	0.95±0.16
	Day 90	1.11±0.97	0.96±0.16	0.96±0.22

Values are expressed as Mean ± SD. No significant difference was observed between Screening and final visit in all the three groups.