Single Blind Randomized Control Clinical Study to Assess the Effect of Cow-Ghee On Lipid Profile and Blood Glucose in Healthy Volunteers

Research Article

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Abstract

Ayurveda consider cow ghee as healthiest source of dietary fat and have rejuvenating property, improves memory and strengthens nervous, eyes and protects the body from various diseases by balancing all three *Doshas (Vata, Pitta and Kaph)* and advocates it's use in daily diet to maintain health. Though, today concept of healthy eating has become synonym to avoid ghee. Aim: To assess the efficacy of Cow Ghee on Lipid Profile and Blood Sugar levels in Healthy Volunteers. Materials and methods: This was a Single blind randomized control clinical study. 60 healthy volunteers (30 in each group) between the age group 25-45 years were randomly selected. FBS was assessed based on WHO Guideline and Complete lipid profile was assessed based on ATP III Guideline. Statistical analysis used: result was assessed using Paired and unpaired t test with the help of Graph Pad InStat-3 software. Results: The slight increase in FBS, TC, TGs, VLDL, and HDL was recorded with mean difference 2.054, 2.91 (p = 0.4376), 21.568 (p = 0.0024), 4.141 (p = 0.0039), and 2.068 (p=0.0483) respectively compare to mean difference 10.260, 5.835 (p=0.2348), 16.88 (p=0.0297), 3.39 (p = 0.0274), and no change in HDL in placebo control group. While decrease in LDL by mean difference 3.291 (p = 0.3786) was recorded in cow ghee group compare to increase in mean difference 1.497 (p = 0.7844) in placebo control group. Conclusion: study reveals no adverse effect of consumption of 15-gram cow ghee daily for 45 days on lipids and FBS.

Key Words: *Go-Ghrit,* Ghee effect on cholesterol, Dietary Ghee Effect, Ghee supplement.

Introduction

Ayurveda life science gives importance for prevention and promotion of health and describe various dietary and lifestyle regimens and to fulfil this aim regular consumption of certain food items had been advocated in Ayurveda. Cow- Ghee is among them and considered as healthiest source of dietary fat, rejuvenating food and advised to use it daily in food to maintain health and vigour(1). But, since many decades the concept of healthy eating has become synonym to avoid ghee in diet due to myth of its bad effect on cholesterol. While, no such experimental evidences supported that cow ghee can cause cardio vascular diseases. Meanwhile, Various dairy research reports indicated that Cow Ghee contains a number of micronutrients such as conjugated linoleic acid (CLA), vaccenic acid, sphingolipids, butyric acid, β-carotene, *etc*. which are potential therapeutic agents.

Key Message - Since many decades the concept of healthy eating has become synonym to avoid ghee in diet due to myth of its bad effect on cholesterol. But, present study reveals no adverse effect of consumption of 15-gram cow ghee (*Go-Ghrita)* on lipids, FBS and BMI, supports the Ayurvedic concept of therapeutic and preventive potential of Cow-Ghee.

Aim
To assess the effect of oral administration of *Go-Ghrita* (Cow Ghee) on Lipid Profile and Blood Sugar levels in Healthy Volunteers.

Objectives
• To assess the effect of *Go-Ghrita* (Cow Ghee) on Lipid Profile.
• To assess the effect of *Go-Ghrita* (Cow Ghee) on Blood Sugar.

Materials & Methods

Study Design
This study was designed as single blind randomized control clinical study.

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Ethical Clearance

The study was started after approval from the Institutional Ethics Committee with Ref. No/Student Section/2017/1880, Bhopal dated 27/05/ 2017. Written informed consent was obtained from patients prior to inclusion in the study.

Selection of the Patients

70 healthy volunteers irrespective of caste, religion and socioeconomic status were selected by a screening conducted in Institute and from vicinity of Institute by survey based on inclusion criteria. Then in single day out among 70 healthy volunteers 60 healthy volunteers were selected randomly by simple random lottery method and distributed randomly in equal numbers (n = 30 in each group) in Group A and Group B.

Inclusion criteria

- Healthy volunteers of both sex between age group of 20-45 year those were physically active, diagnosed as normoglycaemic and normal lipid profile and willing to participate in the study.

Exclusion criteria

- Healthy volunteers below the age of 20 years and above age 45 years leading to Physically inactive lifestyle were excluded.
- Subjects associated with any systemic diseases and chronic diseases like Type 2 &Type 1 Diabetes Mellitus, CVD, Essential Hypertension, Cancer, Rheumatoid Arthritis, Osteoarthritis, Hypothyroidism, Hyperthyroidism, Obesity class 1, 2 and 3 and any other Hormonal Imbalance, or associated with any mental disease, having congenital anomalies were excluded.
- Subjects those underwent on some major surgery like Cholecystectomy, Hysterectomy and those were taking medications which were known to have lowering effects on lipids and blood Glucose were excluded.
- Pregnant and lactating mothers and women those were on contraceptive pills and HRT

Grouping and Posology:

- **Group A** (Cow Ghee Group)**:** this group assigned 30 Healthy volunteers and was given to them 15 Grams Cow Ghee daily with soup prepared with any pulses in lunch for 45 days
- **Group B:** (Placebo Control Group): this group assigned 30 Healthy volunteers and was given to them 15 grams Luke warm water daily with soup prepared with any pulses in lunch for 45 days

Trial Drug Details

Cow Ghee used as food supplement in this research study was purchased from the '*Go-Vigyan Anusandhan Kendra*' Nagpur, Maharashtra.

Criteria for Assessment
Objective Parameters
- **Biochemical Examination** – Fasting Blood sugar was assessed by guideline provided by WHO (2) and Complete lipid profile was assessed based on ATP III Guideline.
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- **Physical Examination** – Body   weight, BMI(3), WHR(4) was recorded according to criteria of WHO. Blood Pressure was recorded by guideline provided by JNC-7(5).   All these parameters were assessed before and after completion of the study.

Statistical Analysis

The mean, mean difference, standard deviation, standard error was included in the analysis, statistical significance within the group was assessed by Paired t test and the comparative effect of therapy in both groups were assessed by unpaired t test. Graph Pad InStat-3 software developed by Graph Pad Software located in San Diego, California was used for statistical analysis.

Observations

Among 60 randomly selected volunteers 55 had completed the designed research schedule while 05 were discontinued the study. [Consort Flow Chart]

Consort Flow Chart:
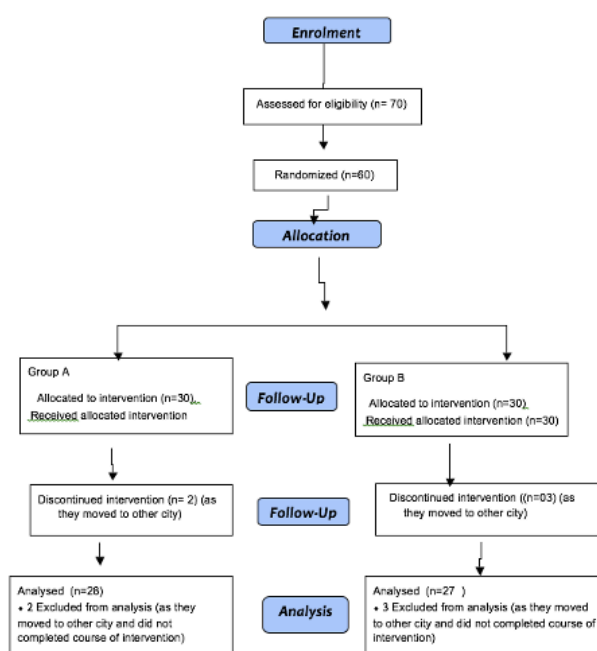
Result of observation at baseline data (*n*=60) of Healthy Volunteers has been presented in [Table No. 1].

Table No. 01: Shows Result of Observation of 60 Healthy Volunteers

Result of observation of baseline data (*n*=60) of Healthy Volunteers	
Observation in Percentage	**Observation**
51.67% and 48.33%	Volunteers were registered between the age group of 25-35 years and 36-45 years respectively
60% and 40%	Volunteers were male and female respectively
93.33%	Volunteers were Hindu
60% and 40%	Volunteers were married and unmarried respectively
51.67% and 23.33%	volunteers were having Post Graduate and Graduate degree respectively
Maximum 51.67% and 13.33%	Volunteers were student and home maker respectively
55%, 18.34%, 15% and 11.66%	Volunteers were belonged to upper-middle class, upper-lower class, upper class and lower middle class respectively, based on Kuppuswamy socio economic status scale
Maximum 53.33%	Volunteers were taking mixed diet.
85% and 15%	Volunteers were had tea and coffee habits respectively
61.67% and 8.66%	Volunteers were insufficiently active and inactive respectively
85% and 15%	Volunteers had good sleep quality and poor sleep quality respectively
35%, 33.33% and 31.67%	Were belonged to *Vata-Pittaj Prakriti*, *Vata-Kaphaj Prakriti* and *Pitta- Kaphaj Prakriti* respectively

Result

Very slight increase in BMI with mean difference 0.3468 and 0.2650, Waist/Hip ratio with mean difference 0.001 and 0.005 and FBS with mean difference 2.054 ($P = 0.3863$) and 10.260 ($P = 0.0120$) were recorded in group A and B respectively.

Slight increase in Total Cholesterol with mean difference 2.91 ($P = 0.4376$) and 5.835 ($P = 0.2348$) and increase in serum Triglyceride with mean difference 21.568 ($P = 0.0024$) and 16.88 ($P = 0.0297$) were recorded in group A and B respectively. Increase in HDL with mean difference 2.068 ($P = 0.0483$) recorded in group A though unchanged HDL level was recorded in group B ($P = 0.9999$). while decrease in serum LDL with mean difference 3.291 ($P = 0.3786$) was reported in group A while slight increase in LDL with mean difference 1.497 was recorded ($P = 0.7844$) in group B volunteers. Increase in serum VLDL which was with mean difference 4.141 ($P = 0.0039$) and 3.39 ($P = 0.0274$) was recorded in group A and B respectively. In Group A Serum Risk Factor was reduced with mean difference 0.091 ($P = 0.4506$) while, in group B it was increase with mean difference 0.117 ($P = 0.4587$) [Table No. 2 and 3].

Table No.2 Statistical Result of Physical and Biochemical Parameter of Group A

Parameter	Mean		M.D.	S.D.	S.E.	Paired t test value	P value	Significance
	BT	AT						
Hip Circumference	93.028	93.489	0.4615	0.806	0.152	t = 3.028	p=0.005	VS
Waist Circumference	79.292	79.809	0.5171	2.192	0.4143	t = 1.248	p=0.2228	NS
W/H ratio	0.857	0.858	0.001	0.024	0.004	t = 0.229	P=0.820	NS
Weight	59.875	60.750	0.8750	1.024	0.1935	t = 4.521	P =0.0001	ES
BMI	22.889	23.236	0.3468	0.3949	0.07463	t = 4.647	P <0.0001	ES
FBS	81.546	83.600	2.054	12.340	2.332	t = 0.8806	p = 0.386	NS
TC	145.73	148.64	2.911	19.549	3.694	t = 0.7879	P =0.4376	NS
TG	101.04	122.61	21.568	34.049	6.435	t = 3.352	P = 0.0024	VS
HDL	43.611	45.679	-2.068	5.290	0.9997	t = 2.069	P =0.0483	S
LDL	81.922	78.631	3.291	19.450	3.676	t = 0.8953	P = 0.3786	NS
VLDL	20.388	24.529	4.141	6.932	1.310	t = 3.161	p = 0.0039	VS
RF	3.318	3.226	0.091	0.6296	0.1190	t = 0.7655	p = 0.4506	NS

Table No.3 Statistical Result of Physical and Biochemical Parameter of Group B

Parameter	Mean		M.D.	S.D.	S.E.	Paired t test Value	P value	Significance
	BT	AT						
Hip Circumference	93.700	94.200	0.5000	1.670	0.373	t = 1.339	p=0.196	NS
Waist Circumference	80.350	80.650	0.3000	1.302	0.2911	t = 1.031	p=0.3157	NS
W/H ratio	0.857	0.862	0.005	0.031	0.006	t = 0.764	P=0.453	NS
Weight	60.350	61.075	0.7250	1.371	0.3067	t = 2.364	P =0.0289	S
BMI	23.030	23.295	0.2650	0.5461	0.1221	t = 2.170	P =0.0429	S
FBS	94.160	104.42	10.260	16.525	3.695	t = 2.777	p = 0.012	S
TC	138.91	144.74	5.835	21.266	4.755	t = 1.227	P = 0.2348	NS
TG	115.27	132.15	16.880	16.880	7.181	t = 2.351	P = 0.0297	S
HDL	44.350	44.350	0.000	7.226	1.616	t = 0.000	P >0.9999	NS
LDL	71.957	73.454	1.497	24.123	5.394	t = 0.2775	P = 0.7844	NS
VLDL	23.074	26.466	3.392	6.350	1.420	t = 2.389	p = 0.0274	S
RF	3.125	3.242	0.1170	0.6918	0.1547	t = 0.7563	p = 0.4587	NS

BT: Before treatment, AT: After treatment, SD: Standard deviation, W/H ratio: waist hip ratio, BMI: Body mass index, FBS: Fasting Blood Sugar, TC: Total cholesterol, TG: Triglycerides, HDL: High-density lipoproteins, LDL: low-density lipoproteins, VLDL: Very low-density lipoproteins, RF: Serum risk Factor

Comparative Effect of Therapy

In inter group comparison of both group A (cow ghee group) and B (placebo control group) statistically not significant result found on serum cholesterol (P = 0.6247), on serum TG level (P = 0.6325), on Serum LDL (P = 0.4508), on Serum VLDL (P =0.7042), on Serum HDL (p = 0.2577), on Serum Risk Factor (P = 0.8932) and on BMI (P = 0.5495). While statistically significant (P = 0.0547) on FBS. This result indicating that both groups had equal effect on serum cholesterol, S TG, S LDL, S VLDL, S HDL, Serum Risk Factor and on BMI that means no adverse effect of consumption of cow ghee had been reported on lipids and BMI. Only slight impact was reported on fasting blood sugar in comparison of both groups though it was reported within the normal blood sugar range [Table No.4].

Table No. 4: Comparative Effects (Between Group A and B) of the Therapy on Lipid Profile, FBS and BMI

Parameter (mg/dl)	Mean difference		SD		Unpaired t test Value	p-value	Significance
	Group A	Group B	Group A	Group B			
Serum Cholesterol	2.911	5.835	19.549	21.266	t = 0.4926	p = 0.6247	NS
Serum Triglyceride	21.568	16.880	34.049	16.880	t = 0.4814	p = 0.6325	NS
Serum HDL	2.068	0.000	5.290	7.226	t = 1.146	p = 0.2577	NS
Serum LDL	-3.291	1.497	19.450	24.123	t = 0.7605	p = 0.4508	NS
Serum VLDL	4.141	3.392	6.932	6.350	t = 0.3820	p =0.7042	NS
Risk factor	-0.091	0.1170	0.6296	0.6918	t = 0.1350	p = 0.8932	NS
FBS	2.054	10.260	12.340	16.525	t = 1.971	p = 0.0547	S
BMI	0.3468	0.2650	0.3949	0.5461	t = 0.6030	p = 0.5495	NS

Effect of Cow-Ghee on *Agni*

The assessment of *Agni* was done with the help of *Abhyavaharana Shakti* (food intake capacity)*, Jaran Shakti* (digestion power). In the present study increase in *Abhyavaharana Shakti*, *Jarana Shakti* was reported in all volunteers of Go-*Ghrita* group.

Discussion

In present study slight increase in weight and in BMI in group A compare to group B was recorded. Nirmala KS.et al. found similar increase in weight on mice for 8 weeks consumption of ghee [6]. In present study, slight increase in waist/hip ratio was also recorded in both groups with mean difference 0.001 (P >0.05) in group A and 0.005 (P >0.05) in group B. Hence, results indicating that increase in waist-hip ratio, BMI and weight were not completely linked with consumption of Ghee, because increase in waist-hip ratio was very less and almost similar in both cow ghee and placebo groups.

Slight increase in fasting blood sugar (2.054 mean difference) was recorded in group A compare to mean difference 10.260 in control group B. Though, it was within the normal blood sugar range in both groups.

Effect on Cholesterol - The slight increase in Total Cholesterol, in serum Triglyceride and in serum VLDL was recorded in group A compare to group B volunteers. The decrease in LDL was recorded with mean difference 3.291 (P = 0.3786) in group A compare to increase in mean difference 1.497 (P = 0.7844) in group B though it was insignificant. And increase in HDL was recorded with mean difference 2.068 and significance (P =0.0483) in group A compare to no change in mean difference in group B (P = 0.9999). Result reveals positive health impact of cow ghee on LDL and HDL cholesterol levels.

Results of the effect of cow ghee on cholesterol of present study was found similar with Kumar and colleague's studies that 5 to 10% dietary Ghee did not enhances serum total cholesterol and triglyceride levels in rats. In-fact dose-dependent decrease in TC, LDL, VLDL, and TGs were reported when ghee was given at levels greater than 2.5% in the diet (7). Kumar and Kathirvelan reported a significant decrease in plasma triglycerides in Ghee-fed animals in their study (8, 9). It may be because Cow-Ghee is a good source of short chain saturated fatty acid this does not raise serum LDL and also increases the excretion of dietary cholesterol and bile acids from gastrointestinal tract. This might be the reason for decrease in LDL levels in cow ghee group compare to control group in the present study.

And the rise in HDL cholesterol in cow ghee group in present study might be due to presence of considerable amount of MUFA in it. Kathirvelan C. et al reported an increase in HDL due to conjugated linoleic acid enriched Ghee (10). Sharma H, et al. found that 10% ghee for a period of 4 weeks did not have any significant effect on the serum total cholesterol level and on liver microsomal lipid peroxidation levels that are linked to a higher risk of cardiovascular disease (11).

Shankar et al. found Ghee has no significant effect on the serum lipid profile when it is consumed in <10% of total energy intake as compare to mustard oil (12). While, introducing ghee as a partial replacement for mustard oil leads to rise in TC as well as HDL-C levels, but no significant change reported on TC/HDL-C ratio. They concluded rise in HDL might be due to the MUFA content of ghee (13).

In present study, the Serum Risk Factor was reported to reduce with mean difference 0.091 (P = 0.4506) in group A volunteers. While, in group B it was slight increase with mean difference 0.11 (P =0.4587). This result again reveals the positive effect of cow ghee on health. National Cholesterol Education Program

report suggested that the concentration of HDL cholesterol is inversely associated with the risk of developing CVD (14).

Functions of Cow Ghee

Cow Ghee contains MUF (27.4% oleic acid) and PUF. Kris-Etherton PM, et al reported MUF in the cis configuration reduces cardiovascular risk (15). While, PUF present in Cow Ghee is esterify cholesterol and promotes its excretion from body (16, 17).

Cow Ghee also contains Alpha-Linoleic acid (w-3 PUFAs), is a precursor to eicosapentaenoic acid and docosahexaenoic acid those are reported to have anti-thrombotic effects (18). Sandker GW, et al observed that the traditional diets in Crete and Japan contain high content of linolenic acid and because of this coronary disease incidence found low there (19). Mckeigue suggested that these benefits of linolenic acid are due to its conversion to eicosapentaenoic acid (20). Plasma HDL levels inversely correlate with atherosclerotic cardiovascular disease (21) as HDL regulates reverse cholesterol transport thorough plasma to the liver(22). Also, presence of antioxidants in Cow-Ghee resist to the oxidation process of lipids. While, Butyric acid shown to be anti-inflammatory and insulin sensitivity effects (23).

Conclusion

Present study reveals that 15-gram cow ghee (*Go-Ghrita)* in inter group comparison no adverse effect of consumption of cow ghee had been reported on lipids, FBS and BMI.

Limitation

The present study was conducted in limited time, on limited number of subjects and biomarkers of atherosclerosis or other cardio-specific parameters were not assessed in this study.

Further Recommendation

Further study can be plan with larger number of participants with duration 3 to 6 months by taking specific biological parameters such as Cardiac biomarkers and HbA1c.

Conflict of Interest: Nil
Acknowledgement: Nil

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