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Hypolipidaemic effect of alcoholic extracts of the plants *Curcuma longa* and *Guatteria gaumeri*

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ABSTRACT

Hyperlipidaemia is one of the commonly affecting diseases and a major risk factor for Diabetes mellitus, Obesity, Systemic Hypertension, Coronary heart disease, Stroke, etc., which alarms the essential need to maintain the blood lipid levels under normal limits. *Curcuma longa* L. belonging to Zingiberaceae family commonly called as 'Indian Turmeric' is a small perennial plant distributed in South Asia and is cultivated extensively throughout warmer parts India. It has many rhizomes on its root which are the source of Curcumin, a collection of 3-6% polyphenolic mixture of curcumin, demethoxycurcumin and bisdemethoxycurcumin. These Curcuminoids are major components responsible for various biological actions like anti-oxidant, anti-cancerous, anti-septic, anti-coagulant, anti-edematous, anti-hepatotoxic, anti-hypercholesterolemic, anti-inflammatory, etc., The alcoholic extracts of *Curcuma longa* & *Guatteria gaumeri* were compared for their Hypolipidaemic effects by means of a Randomized Control Trial on Hyperlipidaemia patients which was executed with a Placebo control group for higher significance. Pre & Post Treatment Blood Lipid Profile results were analysed statistically. By the end of the study both the extracts showed good Cholesterol Lowering effect. *Guatteria gaumeri* (Mean lowering modulation - 45.9 mgs%) has proved to be much effective than *Curcuma longa* (Mean lowering modulation - 23.1 mgs%).



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INTRODUCTION

Worldwide, high blood cholesterol levels are estimated in 56% of ischemic heart disease events and 18% of strokes, amounting to 4.4 million deaths annually. (Dennis.L.Kasper *et al.*, 2015; Brain.R.Walker *et al.*, 2014) Between 1980 and

2008, Asian & Pacific region population experienced an increase of Blood Cholesterol level greater than 0.08 mmol/L. 'Global Burden of Metabolic Risk Factors Study' reported that total cholesterol levels are increased in India and other low-income and lower-middle-income countries over this period (RamanPuri, 2016; Joshi SR *et al.*, 2014).

Hypercholesterolaemia incidents increase with age from 22.0% in the age group 18-19 years, reaching a peak of 68.8% among the 55-59 years' age group. (Joshi SR *et al.*, 2014) Cholesterol levels tend to be higher among urban residents than rural residents because of greater consumption of dietary fats primarily from animal products, processed vegetable oils and decreased physical activity. (Dennis.L.Kasper *et al.*, 2015).

The majority of patients have some combination of genetic predisposition (often polygenic) and environmental contribution (diet, lifestyle, medical condition, or drug) (Brain.R. Walker *et al.*, 2014). Hyperlipidaemia is a major risk factor for Diabetes mellitus, Obesity, Systemic Hypertension, Coronary heart disease, Stroke, etc., which alarms the essential need to maintain the blood lipid levels under normal limits.

Recent researches explore the effectiveness of many traditional herbs in the treatment of Lifestyle disorders. 'Curcuma longa - Indian Turmeric' (Chakraborty *et al.*, 2011; Ballantyne *et al.*, 2017; Hyun-Soo Shina *et al.*, 2014) and 'Guatteria gaumeri - Yumel' (Aejaz Husain *et al.*, 2017; Garduño L *et al.*, 1997; Josefina *et al.*, 1982) are such herbs which are traditionally used in treating Hyperlipidaemia. But only a few researches have been carried out with these herbs in justifying their judicious use. These details intended us to do a comparative study of the effectiveness of the Alcoholic extracts of these plants in controlling serum cholesterol levels of Hyperlipidaemia patients with a placebo control arm.

MATERIALS AND METHODS

The methodology used was a Single Blind Comparative Experimental Study design of two parallel groups with a placebo control group. Patient Selection (Sampling) was made according to the following inclusion, exclusion criteria 30 patients were selected by Random Sampling Method. Inclusion criteria: Patient with Hyperlipidaemia; Both male and female were included; Patients in the age group of 25 - 75 yrs. (Joshi SR *et al.*, 2014) Fasting blood total cholesterol level more than or equal to 200 mg/dl. (Joshi SR *et al.*, 2014) Exclusion criteria: Hyperlipidaemia with systemic complications; Hyperlipidaemia with other systemic diseases. 'Systematic Random Sampling' method was adopted to assign patients in 3 Treatment Groups. Data collection was made by Case taking, Investigatory findings, Past history, Medical Reports & Hyperlipidaemia Risk Questionnaire. Also, every patient was assessed for their Cardio Vascular Disease risk by 'QRISK®2-2017 cardiovascular disease risk calculator'. (Qrisk, 2017)

Operational Design: As per the study protocol 30 Hyperlipidaemia patients were selected randomly from Medical Unit IV of Vinayaka Mission's Homoeopathic Medical College Hospital, Salem, Tamilnadu in the period between 11.11.2017 to 20.12.2017. The Institutional Ethics Committee approval for this study was ordered on 10.11.2017. This Study was registered under the Clinical Trial Registry of India with Reg. No: CTRI/2018/01/011255. The selection of cases was made on careful consideration of the Inclusion

and Exclusion Criteria. The 'Case History' of each patient was recorded in a Standardized Case Format to evaluate and to rule out any co-morbid diseases or complications. 'Informed Patient Consent' in their local language was obtained from each patient. Then these selected patients were allotted equally in the 3 Treatment Groups by 'Systematic Random Sampling Procedure' such that each group carried 10 patients. Considered Treatment Groups were, Group-A: Alcoholic extract of *Curcuma longa*; Group-B: Alcoholic extract of *Guatteria gaumeri* & Group-C: Dispensing alcohol as Placebo. The Pre-treatment Fasting Blood Lipid Profile of each patient were tested and recorded. The Lipid Profile was incorporated with Total Serum Cholesterol (TC), Triglycerides (TGL), High-Density Lipoprotein (HDL), Low-Density Lipoprotein (LDL), Very Low-Density Lipoprotein (VLDL) and Total Cholesterol/HDL Ratio. Few patients were found already under other Medications for Hyperlipidaemia; they were prescribed with placebo for a month and then included in the study.

Each patient was given their respective Treatment for at least 3 months, i.e., 90 days. They were prescribed with 20 drops of their respective alcoholic plant extracts / Dispensing alcohol mixed with 10 ml of water orally in morning and night every day after food. The Patients were blinded to know the name of the medicines they were prescribed with, by coding the medicines as A / B / C. Also the placebo was prescribed in the form of "Dispensing Alcohol" so as to make it similar to other extracts. All the patients were explained about 'Hyperlipidaemic Diet' and advised to follow, which was closely monitored. The Fasting Blood Lipid Profiles of each patient were tested at the end of Treatment. Some Sample Characters like Age Distribution, Gender Distribution, etc., were analyzed. This study was carried out during November 2017 to March 2018 at Medical Unit IV of Vinayaka Mission's Homoeopathic Medical College Hospital, NH 47, Sakari Main Road, Seeragapadi, Salem, Tamilnadu, Pincode - 636308.

Statistical Analysis of Outcome: The Pre Treatment and Post Treatment Fasting Blood Lipid Profile Levels were considered for Statistical Analysis using "Analysis of Variance - ANOVA". Also 'Correlation Analysis' was made Cholesterol Modulations together. (Kothari C R., 2004; Mahajan B K., 2008) The Statistical Analysis was prepared both manually and with the 'Statistical Package for Social Sciences.22 - SPSS' software.

Laboratory Investigatory Method / Procedure

Serum Total Cholesterol Measurements were made by 'CHOD / POD Method' using the Diagnostic Kit of 'Robotnik India Pvt Ltd'. The Standard Normal Serum Total Cholesterol Value for this

kit/method is ≤ 200 mg /dL. Serum Triglyceride Measurements were made by 'GPO Method' using Diagnostic Kit of 'Jeev Diagnostics Pvt Ltd'. The Standard Normal Serum Triglyceride Value for this kit/method is up to 150 mg /dL. Serum HDL Measurements were made by 'CHOD / POD Method' using the Diagnostic Kit of 'Beacon Diagnostics Pvt Ltd'. The Standard Normal Serum HDL Value for this kit/method is ranging from 30 to 70 mg /dL. Serum LDL Measurements were calculated by "The Friedewald equation" ((LDL-C = TC - HDL-C - (TG/2.2) mmol/L; or LDL-C = TC - HDL-C - (TG/5) mg/dL); Brain.R. Walker *et al.*, 2014) Serum VLDL Values and Total Cholesterol & HDL Ratios are numerically calculated.

Properties of the Plants

Curcuma longa. L belonging to Zingiberaceae family commonly called as 'Indian Turmeric' is a small perennial plant distributed in South Asia and is cultivated extensively throughout warmer parts India. It has many rhizomes on its root which are the source of Curcumin, a collection of 3-6% polyphenolic mixture of curcumin, demethoxycurcumin and bisdemethoxycurcumin. These Curcuminoids are major components responsible for various biological actions like anti-oxidant, anti-cancerous, anti-septic, anti-coagulant, anti-edematic, anti-hepatotoxic, anti-hypercholesterolemic, anti-inflammatory, etc., (Chaudhari SP *et al.*, 2015; Krup V *et al.*, 2013).

Guatteria gaumeri belonging to Annonaceae family commonly called as 'Yumel' is a tree that grows in Southeast Mexico. α - and β -asarone present in this plant possess a wide range of pharmacological activities such as antidepressant, anti-epileptic, anti-hyperlipidemic, anti-thrombotic, anti-cholestatic and radioprotective activities through its interaction with multiple molecular targets. (Josefina *et al.*, 1982; Chamorro G *et al.*, 1993; Husain A *et al.*, 2017).

Alcoholic Extracts of the Plants

The preparation of the alcoholic extract of *Curcuma longa* is to be done by macerating 1 part of freshly collected powder of its rhizome with 10 parts of 95 v/v % alcohol for 14 to 28 days. The alcoholic extract of *Guatteria gaumeri* should be prepared by macerating 1 part of coarse powder of its bark with 10 parts of 95 v/v % alcohol for 14 to 28 days. It should be shaken occasionally and filtered. So obtained alcoholic extracts will be having the drug strength of 1/10, and this will be called as Homeopathic Mother Tincture. Such prepared extracts should be standardised by using various physical, chemical and chromatographic parameters. For this study, the alcoholic extracts manufac-

ured by BJain Pharmaceuticals Pvt. Ltd, A-98, Sector 63, Noida, Uttar Pradesh 201307 were used. B. Jain Pharmaceuticals is an ISO 9001:2008 certified company and the products produced by it are GMP certified, and NSF audited which makes them genuine. (B Jain., 2017)

RESULTS

The observations and results obtained are as follows.

The study showed a Maximum Prevalence of Hyperlipidaemia in the Age Group between 36 & 65 Years (93.33%; Table 1) and in Males (63.33%; Table 2). 20 patients (66.67%) belonged to Lower / Middle Socio-Economic Class; 10 patients (33.33%) are already Known Hyperlipidaemic; Only 10 (50%) patients of 20 newly diagnosed Hyperlipidaemic patients showed Risk by 'Hyperlipidaemia Risk Questionnaire'. 13 (43.33%) patients are found to be at Risk for getting future Cardio Vascular Diseases by 'Cardio Vascular Disease Risk Calculator' and are advised to have Regular Cardiac Health Check-ups for the same.

ANOVA Results

'Analysis of Variance' of before & after treatment modulations in Fasting Blood Lipid Profile levels between the groups is highly statistically significant both at 95% and 99% Confidence Levels with a P-Value < 0.0001 . Since the p-Value calculated is < 0.0001 , the modulation is highly significant, and this is not due to any chance.

Correlation Analysis

The modulations of the paired Fasting Blood Lipid Levels of the groups were analysed for Linear Correlation using 'Pearson Correlation Coefficient Method / Factor'. It is found that there is a Strong +ve Linear Correlation pattern in the modulation of Fasting Blood Lipid Profile Levels of the Group A & Group B patients treated with Plant extracts. Group C patients showed Strong -ve Linear Correlation pattern when compared with Group A & Group B respectively. (Table 3; Fig 4)

DISCUSSION

The modulation of Cholesterol levels in the three groups is shown in (Fig 1, 2, 3).

The major outcomes of this Randomized Control Trial are as follows;

- Both the extracts of *Curcuma longa* (23.1 mgs%) & *Guatteria gaumeri* (45.9 mgs%) have Cholesterol-lowering effect. *Guatteria gaumeri* had a marked two times more Cholesterol-lowering effect than the *Curcuma longa*. (Table 4)
- Both the extracts of *Curcuma longa* (31.7 mgs%) & *Guatteria gaumeri* (40.6 mgs%) have

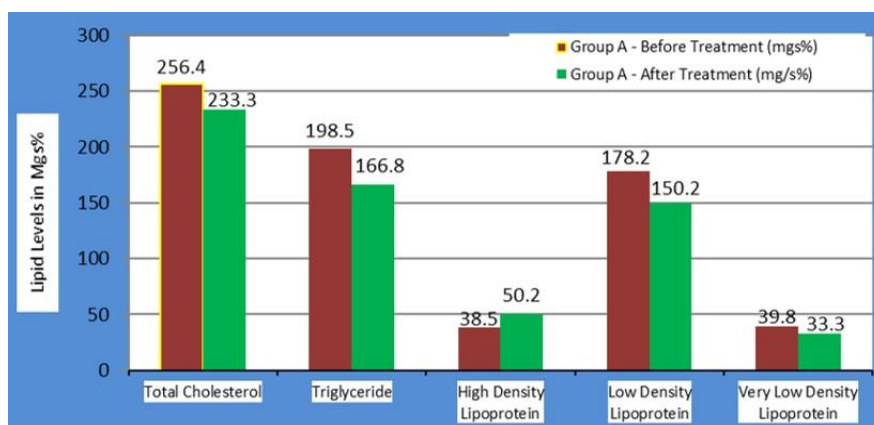


Figure 1: Average 'Blood Lipid Profile' Levels of 'Group A' Patients Before & After Treatment

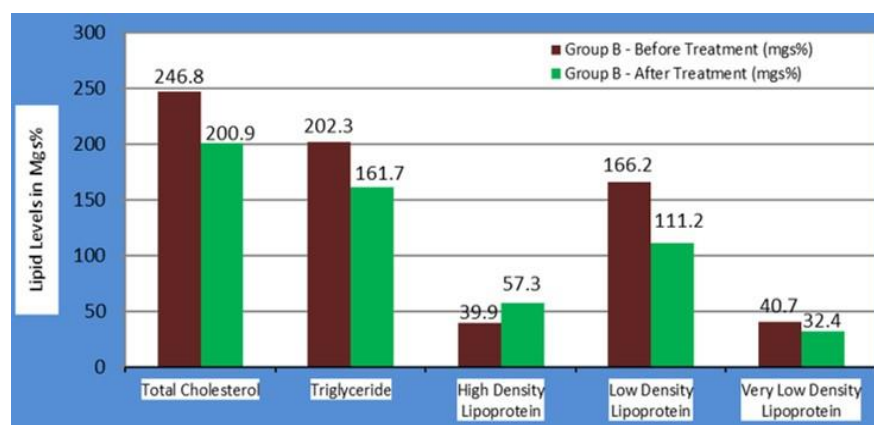


Figure 2: Average 'Blood Lipid Profile' Levels of 'Group B' Patients Before & After Treatment

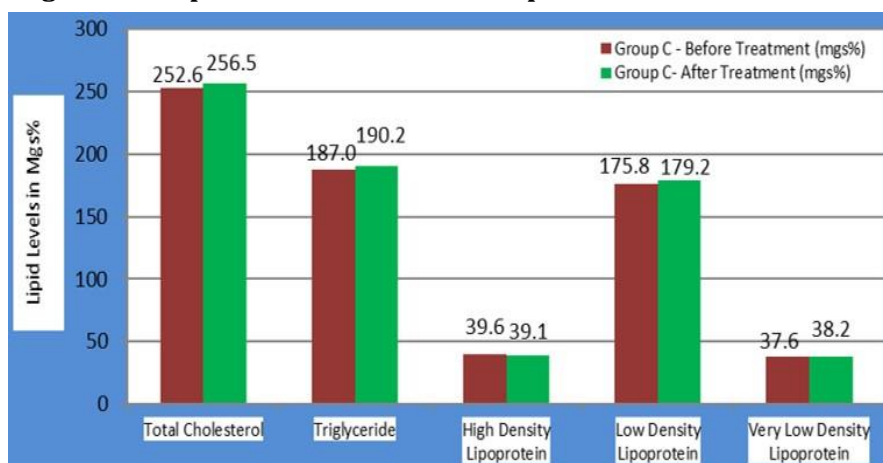


Figure 3: Average 'Blood Lipid Profile' Levels of 'Group C' Patients Before & After Treatment

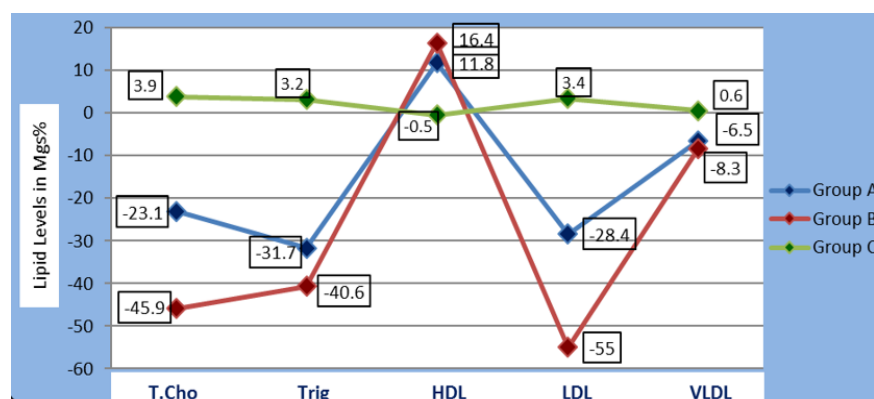


Figure 4: 'Line Diagram' of Average Modulation of 'Blood Lipid Profile' Levels Before & After Treatment

Table 1: Age wise distribution of Patients in Each Group

S. No	Age Groups	No. of Patients			Total
		Group A	Group B	Group C	
1.	25 - 35	00	00	01	01
2.	36 -45	03	02	05	10
3.	46 - 55	03	01	03	07
4.	56 - 65	03	07	01	11
5.	66 - 75	01	00	00	01

Table 2: Gender wise distribution of Patients in Each Group

S. No	Gender	No. of Patients			Total
		Group A	Group B	Group C	
1.	Male	7	5	7	19
2.	Female	3	5	3	11

Table 3: 'Linear Correlation Coefficient' between the Groups

Compared Study Groups	The Correlation Coefficient - 'R'	Result
Group A & Group B	+0.96153	Strong +ve Correlation
Group B & Group C	-0.97466	Strong -ve Correlation
Group C & Group A	-0.94128	Strong -ve Correlation

Table 4: Descriptive Statistics of Total Cholesterol Levels before & after Treatment

Treatment Group	Total Cholesterol (mgs%)	Minimum	Maximum	Median	Mean	Standard Deviation	Confidence Interval @ 95% LOS
Group.A	Pre Treatment	216	282	264	256.4	22.1	256.4 ± 13.7
	Post Treatment	186	290	236	233.3	27.2	233.3 ± 16.9
Group.B	Pre Treatment	209	302	243	246.8	26.1	246.8 ± 16.2
	Post Treatment	160	267	186	200.9	38.3	200.9 ± 23.7
Group.C	Pre Treatment	229	284	249	252.6	17.9	252.6 ± 11.1
	Post Treatment	227	292	252	256.5	20.5	256.5 ± 12.7

Table 5: Descriptive Statistics of Triglyceride Levels before & after Treatment

Treatment Group	Tri glyceride (mgs%)	Minimum	Maximum	Median	Mean	Standard Deviation	Confidence Interval @ 95% LOS
Group.A	Pre Treatment	170	219	203	198.5	18.4	198.5 ± 11.4
	Post Treatment	147	182	170	166.8	13.3	166.8 ± 08.2
Group.B	Pre Treatment	152	265	199	202.3	29.5	202.3 ± 18.3
	Post Treatment	130	204	156	161.7	23.2	161.7 ± 14.4
Group.C	Pre Treatment	124	229	204	187.0	39.0	187.0 ± 24.2
	Post Treatment	130	239	198	190.2	39.8	190.2 ± 24.7

- Triglyceride lowering effect. Guatteria gaumeri had a slight more Triglyceride lowering effect than the Curcuma longa. (Table 5)
- Both the extracts of Curcuma longa (11.8 mgs%) & Guatteria gaumeri (16.4 mgs%) have HDL increasing effect. Guatteria gaumeri had a slightly more efficient than the Curcuma longa. (Table 6).

Table 6: Descriptive Statistics of HDL Levels before & after Treatment

Treatment Group	HDL (mgs%)	Minimum	Maximum	Median	Mean	Standard Deviation	Confidence Interval @ 95% LOS
Group.A	Pre Treatment	35	44	38	38.4	3.1	38.4 ± 1.9
	Post Treatment	40	60	50	50.2	6.8	50.2 ± 4.2
Group.B	Pre Treatment	34	44	40	39.9	3.1	39.9 ± 1.9
	Post Treatment	40	65	59	57.3	7.7	57.3 ± 4.8
Group.C	Pre Treatment	36	44	40	39.6	2.3	39.6 ± 1.4
	Post Treatment	37	42	39	39.1	1.4	39.1 ± 0.9

Table 7: Descriptive Statistics of LDL Levels before & after Treatment

Treatment Group	LDL (mgs%)	Minimum	Maximum	Median	Mean	Standard Deviation	Confidence Interval @ 95% LOS
Group.A	Pre Treatment	136	204	184	178.2	22.3	178.2 ± 13.8
	Post Treatment	95	216	149	149.8	30.4	149.8 ± 18.8
Group.B	Pre Treatment	124	215	167	166.2	25.9	166.2 ± 16.1
	Post Treatment	67	188	99	111.2	40.8	111.2 ± 25.3
Group.C	Pre Treatment	150	202	176	175.8	18.9	175.8 ± 11.7
	Post Treatment	149	211	176	179.2	21.8	179.2 ± 13.5

Table 8: Descriptive Statistics of VLDL before & after Treatment

Treatment Group	VLDL (mgs%)	Minimum	Maximum	Median	Mean	Standard Deviation	Confidence Interval @ 95% LOS
Group.A	Pre Treatment	34	44	41	39.8	3.8	39.8 ± 2.4
	Post Treatment	29	36	34	33.3	2.6	33.3 ± 1.6
Group.B	Pre Treatment	31	53	40	40.7	5.8	40.7 ± 3.6
	Post Treatment	26	41	31	32.4	4.7	32.4 ± 2.9
Group.C	Pre Treatment	25	46	41	37.6	7.8	37.6 ± 4.8
	Post Treatment	26	48	40	38.2	8.0	38.2 ± 5.0

- Both the extracts of *Curcuma longa* (28.4 mgs%) & *Guatteria gaumeri* (55.0 mgs%) lowers LDL. *Guatteria gaumeri* had a marked two times more LDL lowering effect than the *Curcuma long*. (Table 7)
- Both the extracts of *Curcuma longa* (6.5 mgs%) & *Guatteria gaumeri* (8.3 mgs%) lowers VLDL. (Table 8)
- The Placebo Control Group C does not show any such effects.

CONCLUSION

This 'Single-Blind Placebo-Controlled Comparative Experimental Study' proved that both the alcoholic plant extracts of *Curcuma longa* and *Guatteria gaumeri* had a Good Cholesterol-lowering effect on

Hyperlipidaemia patients. *Guatteria gaumeri* showed a higher significant effect than *Curcuma longa*. Such that both the plant extracts can widely be used in the treatment of Hyperlipidaemic patients to maintain their blood lipid levels within normal range.

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