Research Article

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A CLINICAL STUDY ON EFFECT OF AMALAKI (INDIAN GOOSEBERRY) AS FOOD SUPPLEMENT IN DYSLIPIDEMIA

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ABSTRACT

Dyslipidemia is a condition which is an iceberg. Amalaki (Embelica officinalis Garten) is a fruit listed under wholesome and daily consumables in Ayurveda classics with its components said to improve lipid metabolism and prevent oxidative stress. This directed towards Amalaki to be used as food supplement in dyslipidemia. An open randomized study involving diagnosed cases of dyslipidemia with or without symptoms. The study involved subjects with age group of 20 to 70 years irrespective of the gender. The diagnostic criteria were as mentioned by American Heart Association. Study involved two groups. Amalaki group (study group) was administered with 12 grams of Amalaki choorna to be consumed with major food of the day. The Diet group (control group) was advised minimal dietary manipulations. Study duration was 2 months and biochemical analysis of lipid was done before treatment and after 2 months. Data was analysed with suitable statistical methods. Out of 116 subjects, 102 subjects completed the study. Majority (69%) had Kapha-Vata Prakriti. Majority had overweight and with waist hip ratio increased. When tested between the group, Amalaki group showed a better results in TC (p value 0.014), HDL-C (p value 0.001) and triglycerides (p value <0.002). The result of LDL between group was found to be not significant with p value 0.898 (>0.05). The study concludes that administration of Amalaki Choorna (powder of *Emblica officinalis Garten*) is a possible food supplement of choice that manages dyslipidemia significantly without causing any adverse effects.

Key words: Ayurveda, Amalaki, *Emblica officinalis Garten* Food Supplement, Lipids, dyslipidemia

INTRODUCTION

Dyslipidemia is a condition which is mostly an iceberg. There are many studies which highlighted the prevalence in types of dyslipidemia in India. An ICMR survey[1] report published in 2014 concluded that over 79% of general adult population covered in the survey has abnormality in at least one of the lipid parameters with no urban rural difference. This calls for an urgent interventional strategy which can be applied in mass, easily adaptable, natural and feasible.

The US Food and Drug Administration defines food supplement[2] as a product intended for ingestion that contains a "dietary ingredient" intended to add further nutritional value to (supplement) the diet. A "dietary ingredient" may be one, or any combination, of a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by people to supplement the diet by increasing the total dietary intake or a concentrate, metabolite, constituent, or extract. Dietary supplements may be found in many forms such as tablets, capsules, soft gels, gel caps, liquids, or powders. Some dietary supplements can help ensure to get an adequate dietary intake of essential nutrients; others may help you reduce your risk of disease.

Amalaki (*Embelica officinalis* Garten) is a fruit that is rich in nutrients acting as antioxidants[3]; flavonoids and tannins[4] protect the nutrients in Amalaki from being destroyed on processing. This is considered to be a rejuvenator[5] as well as a fruit for daily consumption[6] in classics of Ayurveda. This can be consumed any time in relation to food i.e., before, along with or after food[7] Amalaki is a fruit that is available in most part of India either as fresh fruit or in powder form. This is a fruit that is easily accepted by the population for consumption, natural and cost effective. All the above facts directed towards Amalaki to be used as food supplement in dyslipidemia.

MATERIALS AND METHODS

An open randomized study with Institutional Ethical clearance number SDM/IEC/02/2009-10 dated 16.03.2010 involving diagnosed cases of dyslipidemia with or without symptoms visiting SDM College of Ayurveda and Hospital, Hassan. The study involved subjects with age group of 20 to 70 years irrespective of the gender. Established cases of cardiovascular diseases, diabetes mellitus, hypothyroidism and those on drugs affecting the lipid levels like OC pills, statins etc were excluded from the study. The diagnostic criteria for dyslipidemia as mentioned by American Heart Association[8] was considered for the study i.e., Total cholesterol<200 mg / dl; LDL <100/dl; HDL for men <40 mg/dl and females <50mg/dl; Triglycerides <150 mg/dl and VLDL <35 mg/dl. Clinical examinations included anthrapometric examination and examination of vitals like BP, pulse, temperature. The subjects selected for study were alternatively divided in two groups where the study group (Amalaki group) was administered with 12 grams of Amalaki choorna to be consumed with major food of the day; the control group (Diet group) which was advised minimal dietary

manipulations. Both groups were studied for a period of 2 months and biochemical analysis of lipid was done before treatment and after 2 months. Because the purpose of the study is to evaluate the Amalaki churna as food supplement which can be taken on daily basis as a part of food, follow up after treatment was not done for those who completed the course of study. They were asked to continue consume Amalaki on daily basis if possible.

OBSERVATIONS AND RESULTS

A total of 116 subjects volunteered to participate in study who fulfilled both diagnostic and inclusion criteria by giving a written consent to be a part of study. A total of 102 subjects completed the study The Amalaki group (study group) involved a total of 57 subjects among which 52 completed the intervention period; diet manipulation group had 59 subjects out of which a total of 50 completed study period (Table 1). Study had 50% of both males and females which indicating equal or nearly equal gender distribution in dyslipidemia (Table 2). The condition was dominated by subjects in age group 30 to 39 years (44%) followed by age group 20 to 29 years (34.5 %) indicating the shift of condition from older age group to younger age group (Table 3). The nature of work based on physical activity involved majority of sedentary workers (75.9%) showing sedentary life as a risk factor for dyslipidemia (Table 4). Majority (69%) of subjects were with Kapha-Vata prakriti (Table No. 5). The condition dyslipidemia involves Kapha and Vata dosha and the subjects with Kapha-Vata prakriti will always be at risk for diseases/conditions predominated by such dosha.

Prevalence of no symptoms (Table 6) and the subjects presented with very few clinical signs i.e., Xanthealsma palpebrum in one; Xanthomata of elbow in one and transient ischemic attack in two subjects; Majority of them presented no symptoms. This indicates that dyslipidemia is an iceberg condition. The anthapometric examinations viz., body mass index (Table 7) majority of overweight (51.7%) and obesity (31.9%); waist hip ratio (Table 8) was increased in a total of 90.6% subjects among whom 46.6% were males and 44% were females. These findings position them as risk factors for dyslipidemia[9] Among the lipids in lipid profile (Table 9), the low density lipoprotein abnormality was seen in majority of the subjects (84.5%) followed by abnormality of triglycerides (69%).

There was no trouble in majority of subjects in consuming 12 grams of Amalaki powder as it was used along the major food of the day. No adverse reactions were reported in both groups. Four subjects reported relief from constipation and two had improvement in symptoms of gastritis in Amalaki group. Amalaki group showed a highly significant results in the BMI, Total cholesterol, LDL-C, HDL-C, VLDL-C and Triglycerides with P value <0.001. The Dietary intervention group showed a highly significant results in the BMI, Total cholesterol, LDL-C and Triglycerides with P value <0.001 while HDL-C and VLDL-C showed significant results (p value <0.05) with p values 0.004 and 0.006 respectively. When tested between the group, Amalaki group showed a highly significant results in the BMI, Total cholesterol, LDL-C, HDL-C, VLDL-C and Triglycerides with P value <0.001. The Dietary intervention group showed a highly significant results in the BMI, Total cholesterol, LDL-C and Triglycerides with P value <0.001 while HDL-C and VLDL-C showed significant results (p value <0.05) with p values 0.004 and 0.006 respectively. When tested between the group, Amalaki group showed a better results in TC (p value 0.014), HDL-C (p value 0.001) and triglycerides (p value <0.002). Diet group was better with mean difference -0.6262 in BMI (p value <0.001). The result of LDL between group was found to be not significant with p value 0.898 (>0.05).

Table 1: Clinical Group

	Included for study	Completed	Dropouts
Amalaki Choorna	57	52	05
Diet control	59	50	09
Total	116	102	14

Table 2: Gender

	Frequency	Percent
Men	58	50
Women	58	50
Total	116	100

Table 3: Age Group

	Frequency	Percent
20 - 29 years	40	34.5
30-39 years	51	44
40 - 49 years	21	18.1
50-59 Years	4	3.4
Total	116	100

Table 4: Nature of Work

	Frequency	Percent
Sedentary worker	88	75.9
Moderate worker	28	24.1
Total	116	100

Table 5: Prakriti

	Frequency	Percent
Kapha-Vata	80	69
Kapha-Pitta	15	12.9
Pitta-Vata	2	1.7
Pitta-Kapha	2	1.7
Vata-Pitta	2	1.7
Vata-Kapha	15	12.9
Total	116	100

Table 6: Symptoms on 0th Day

		Frequency	Percent
Dizziness	Absent	116	100
	Present	0	0
Impairment of balance	Absent	116	100
	Present	0	0
Difficulty in speaking	Absent	116	100
	Present	0	0
Problem with vision	Absent	111	95.7
	Present	5	4.3
Chest pain	Absent	116	100
	Present	0	0
Calf pain	Absent	113	97.4
	Present	3	2.6
Yellowish patches underneath skin of eyelid	Absent	115	99.1
	Present	1	0.9
Soft yellowish mass in the palms/knees/elbows	Absent	115	99.1
	Present	1	0.9
Tiredness (Dourbalya)	Absent	116	100
	Present	0	0
Bad smell from body (dourgandhya)	Absent	109	94
	Present	7	6
Minimal/no sweat (Swedabadha)	Absent	116	100
	Present	0	0
Excessive hunger (Atikshudha)	Absent	3	2.6
	Present	113	97.4
Excessive thirst (Ati pipasa)	Absent	116	100
	Present	0	0
Lethargy (Javoparodha)	Absent	103	88.8
	Present	13	11.2

Table 7: Body Mass Index

	Frequency	Percent
normal weight	19	16.4
over weight	60	51.7
obese	37	31.9
Total	116	100

Table 8: Waist Hip Ratio

		Frequency	Percent
Men	Normal*	04	3.4
	Increased	54	46.6
Women	Normal*	07	6.0
	Increased	51	44.0
*Normal - Men: <0.9; Women: <0.8			

Table 9: Lipid Profile

Lipid Varieties		Frequency	Percent
Total Cholesterol	Normal	49	42.2
	increased	67	57.8
Low Density Lipoprotein - Cholesterol	Normal	18	15.5
	Increased	98	84.5
High Density Lipoprotein - Cholesterol	Normal	51	44
	Decreased	65	56
Triglycerides	Normal	36	31
	Increased	80	69
Very Low Density Lipoprotein - Cholesterol	Normal	60	51.7
	Increased	56	48.3

Table 10: Paired Samples Test (Amalaki Group)

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
BMI BT - BMI AT	.14692	.21910	.03038	.08592	.20792	4.836	51	<0.001
TC AT - TC AT	13.3000	10.8739	1.5079	10.2727	16.3273	8.820	51	<0.001
HDL on 0 - HDL AT	-6.5538	12.5990	1.7472	-10.0614	-3.0463	-3.751	51	<0.001
LDL on 0 - LDL on 61	8.4615	12.1908	1.6906	5.0676	11.8555	5.005	51	<0.001
Triglycerides BT - Triglycerides AT	22.8000	22.6049	3.1347	16.5067	29.0933	7.273	51	<0.001
VLDL BT - VLDL AT	5.3308	4.9871	.6916	3.9424	6.7192	7.708	51	<0.001

BT: Before Treatment, AT: After Treatment

Table 11: Paired Samples Test (Diet manipulation Group)

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
BMI BT – AT	0.62620	0.68429	0.09677	0.43173	0.82067	6.471	49	<0.001
TC BT – AT	8.6089	6.1940	0.9233	6.7480	10.4698	9.324	44	<0.001
HDL BT –AT	-0.8222	1.7902	0.2669	-1.3601	-.2844	-3.081	44	0.004 (<0.05)
LDL BT –AT	8.5742	8.5016	1.2673	6.0200	11.1284	6.765	44	<0.001
Triglycerides BT –AT	10.1267	10.1412	1.5118	7.0799	13.1734	6.699	44	<0.001
VLDL BT –AT	1.0778	2.4834	0.3702	0.3317	1.8239	2.911	44	0.006 (<0.05)

BT: Before Treatment, AT: After Treatment

Table 12: Statistics between the Groups

	Clinical Group	N	Mean	Std. Deviation	Std. Error Mean
BMI AT - BT	Amalaki Choorna	52	-0.1469	0.2191	0.03038
	Diet control	50	-0.6262	0.68429	0.09677
TC AT - BT	Amalaki Choorna	52	-13.3	10.8739	1.5079
	Diet control	50	-8.82	6.6198	0.9362
LDL AT - BT	Amalaki Choorna	52	-8.415	12.1755	1.6884
	Diet control	50	-8.682	8.248	1.1664
TGL AT - BT	Amalaki Choorna	52	-21.808	23.5821	3.2703
	Diet control	50	-9.8	9.6976	1.3714
HDL AT -BT	Amalaki Choorna	52	6.554	12.599	1.7472
	Diet control	50	0.814	1.7628	0.2493
VLDL AT - BT	Amalaki Choorna	52	-5.173	5.1536	0.7147
	Diet control	50	-0.822	2.7569	0.3899

BT: Before Treatment, AT: After Treatment

Table 13: Independent Samples Test (between the groups)

	t-test for Equality of Means						
	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
BMI AT - BT	4.802	100	<0.001	0.47928	0.09981	0.28126	0.67729
TC AT - BT	-2.501	100	0.014 (<0.05)	-4.4800	1.7911	-8.0335	-0.9265
LDL AT - BT	0.129	100	0.898	0.2666	2.0673	-3.8349	4.3681
TGL AT - BT	-3.339	100	0.001 (<0.05)	-12.0077	3.5964	-19.1429	-4.8725
HDL AT -BT	3.191	100	0.002 (<0.05)	5.7398	1.7988	2.1711	9.3086
VLDL AT - BT	-5.286	100	<0.001	-4.3511	0.8231	-5.9841	-2.7180

BT: Before Treatment, AT: After Treatment

DISCUSSION

The condition dyslipidemia has its pathophysiology that can be compared to 'Shonitabhishyanda' whose causes (Nidana) of can be of two groups i.e., Excessive and / or regular consumption of foods with Atisnigdha (excessively unctuous) – Pichchila (slimy)- Madhura (sweet) quality as well as excessive consumption of foods with Snigdha (unctous)-Ushna (hot)-Vidahi (producing burning effects) properties. When these causes coupled with sedentary lifestyle will lead to Shonitabhishyanda i.e., Abhishyanda in blood (Rakta) caused by increased moisture level (Kledata) in blood.

The present study demonstrated the utility of Amalaki as a possible food supplement in dyslipidemia. Food (Ahara) is brings about its effect via its flavor (Rasa) and not by potency (Veerya)[10]. Amalaki is a fruit for daily consumption[11]. When it comes to storage, powder is the safe and best form[12]. This, when added to food as supplement, will have its mode of action similar to food. Hence, acts via it's flavor rather its potency. Amalaki is highly appreciated as Rasayana i.e. once consumed gives stability to all the dhatus; enhances quantity and quality of life[13] and Vayasthapaka[14] (anti aging). Such actions are well demonstrated by its cytoprotective and immunomodulating actions[15]. It can be well consumed any time before, during or after in relation to consumption of food without causing any distrubance in the level of Doshas[16]. It pacifies all the three doshas[17]. It has Lavana Varjita Pancha rasa (five flavours except salty); Sheeta (cold), Ruksha (causing dryness in body tissues) and Laghu (gets digested easily) Guna (qualities)[18]. Dyslipidemia demonstrates increased Apyamsha (liquidity) and Kledabhava (moisture) in Rakta. The break in pathology (Samprapti vighatana) takes place by the reduction in or managing apyamsha and kleda bhava in Rakta. Sneha guna is reduced by Ruksha guna of Amalaki; brings about Shoshana (causing dryness) action (reduces Apyamsha by its Ruksha guna). The presence of Tikta (bitter)-kashaya (Astringent) rasa dries up the moisture (Kledopashoshana) as well as pacifies both Kapha and Pitta; pacifies Rakta. The stability in serum level of lipids is brought about by its Rasayana (rejuvenating) action. The ill effects of the dyslipidemia (increased oxidative stress) are prevented by the Vayasthapana (antiaging) action.

It is a well known fruit for its anti-inflammatory action [19, 20, 21] and hepato-protective action[22]. Amalaki is a well known antioxidant[23]. The major chemical constituents of Amalaki (*Emblica officinalis Garten*) are Ascorbic acid, Gallic acid, Chebulinic acid, Chebulagic acid, Ellagic Acid, 3-ethyl gallic acid, corilagin, emblicanin A and B, Punigluconin, quercetin[24]. It has phytosterols and saponins. Ascorbic acid (Vitamin C) is a dietary antioxidant, helping in reduction of oxidative stress[25] The fruits have 28% of the total tannins distributed in the whole plant. It contains two hydrolysable tannins Emblicanin A and B, which have antioxidant properties[26]one on hydrolysis gives gallic acid, ellagic acid and glucose wherein the other gives ellagic acid and glucose. The fruit also contains Phyllemblin. The active principles are tannins and Gallic acid[27]. In the current study, Amalaki choorna when subjected to HPTLC revealed that it had Gallic acid, a product on hydrolysis of Emblicanin A. and that helps prevent oxidative stress leading to dyslipidemia It's HPTLC also revealed that there is Ascorbic acid (Vitamin C), a dietary antioxidant, helping in reduction of oxidative stress[28]. The fruit yields good amount of dietary fibers. Dietary fibers are reported to increase the excretion of cholesterol by interfering with enterohepatic circulation of cholesterol[29,30]. Phytosterols are known to inhibit cholesterol absorption from the intestine due to their greater hydrophobicity and greater affinity for micelles than cholesterol itself and displace the intestinal cholesterol[31] Saponins are capable of precipitating cholesterol from micelles and interfere with enterohepatic circulation of bile acids, making them unavailable for intestinal absorption, leading to a reduction in plasma and hepatic cholesterol levels[32]. All these explain the significant result of Amalaki choorna as food supplement over the minimal diet manipulations.

CONCLUSION

Amalaki is a fruit for daily consumption that can be consumed in powder form added food as food supplement. The study concludes that administration of Amalaki Choorna (powder of *Emblica officinalis Garten*) is a possible food supplement of choice that manages dyslipidemia significantly without causing any adverse effects. It can also significantly manage weight. It can be tried in constipation and gastritis as a part of food adding it in powder form spreaded throughout the day. The other observations of study reveal that Dyslipidemia is an iceberg disease that is seen equally in both the genders. The younger age group (20-39 years) is at risk of having dyslipidemia. Sedentary lifestyle, overweight and obesity tend to put the subjects at risk of dyslipidemia. People with Kapha Vata Prakriti are at risk of having dyslipidemia when compared to others. Multiple lipid abnormality is a common pattern in dyslipidemia of which abnormal total cholesterol and triglycerides are commonest. Dyslipidemia does not exhibit any symptoms most of the time and hence is less reported. This proves it to be an iceberg condition. There is appreciable reduction in the sleeping hours which may influence on digestion mechanism, thereby influencing the lipid levels. Reduced time gap between food and sleep at night is prevailing practice might have an influence indirectly on the lipid metabolism.

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