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RESEARCH ARTICLE

EFFECT OF ALLIUM SATIVUM ON LIPID PROFILE IN POSTMENOPAUSAL WOMEN WITH MODERATE HYPERLIPIDEMIA: A RANDOMIZED CLINICAL TRIAL

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Abstract

Introduction: CVD is the leading cause of death in women around the world. Garlic has been used as a therapeutic agent for many illnesses as evident from various studies. The lipid-lowering effects of garlic (Allium sativum) have been demonstrated in animal experiments and garlic's efficacy in lowering lipid levels in humans has been the subject of randomized clinical trials.

Scope of the Study, Objective: This Study was conducted to find out the efficacy of garlic in lowering lipid levels among postmenopausal women in Bangalore.

Methodology: In this clinical trial 180 respondents willing to participate in intervention program, who met inclusion criteria, were divided into three groups, control (n=60), Exp-I (garlic eaters n=60) and Exp-II (non-garlic eaters n=60). 500 mg of dry garlic powder capsules two per day were given to the respondents for 12 weeks. Biochemical analysis for Cholesterol levels were measured in the standard laboratory before and after the study.

Results: Mean age(53. 6±0.89) years. Both the experimental groups respond well to the intervention reduction in total cholesterol was (Exp-I 17%), (Exp-II 18%), LDL was (Exp-I 9.35%), (Exp-II 9.59%), HDL was (Exp-I; 5.9%), (Exp-II 6.8%), whereas Triglycerides were (Exp-I 7.3%) , (Exp-II 8.1%), the results are statistically significant at 1% level. However, changes in control group was found to be non-significant.

Conclusion: It can be concluded that administration of allium sativus resulted in significant improvement of lipid level in postmenopausal women with hyperlipidemia.

Introduction:-

Menopause is not a disease, but rather the point in a women's life at which she is no longer fertile, and menstrual periods have ceased. During this time, ovulation stops and estrogen hormones drop it is usually a gradual process. The menopausal period affects each woman differently. The major endocrinal changes occur in women between 45 to 50 years of age with a decline in the ovarian function resulting in lowered estrogen production responsible for a

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series of changes commonly known as menopausal changes. The average age of menopause is 51 years old, but menopause may occur as early as the 30s or as late as the 60s. Menopause can be seen as a positive beginning of a new phase of life, with opportunities to take preventive action against major health risks like osteoporosis, dyslipidemia, obesity, and heart diseases. Dyslipidemia is the elevation of plasma cholesterol, triglycerides (TGs), or both, or a low high-density lipoprotein level that contributes to the development of atherosclerosis. Levels are normally slightly higher in men than in women, but levels increase in women after menopause. The increase in levels of lipoproteins that occurs with age can result in dyslipidemia. The global burden of cardiovascular diseases (CVDs) is rapidly increasing. CVD is the leading cause of death in women around the world. Estrogen deficiency has been linked to the rapid increase in CVD in women who have undergone natural or surgical menopause. More than 450,000 women succumb to heart disease annually, and 250,000 die of coronary artery disease. Giardina EG (2014) CVD risk increases after the menopause, which may be related to metabolic and hormonal changes(Zárate A et.al., 2015). Cardiovascular diseases (CVDs) are multifactorial disorders which are characterized by multiple metabolic dysfunctions. Epidemiologic studies indicate that increased serum lipids profiles play critical roles.[Wood D, 2001] CVDs are the major cause of mortality and morbidity in the world. Unfortunately, they lead to 17 million deaths every year. It has been estimated that this number will reach 24.8 million people in 2030 worldwide.[Estruch R et.al., 2013].Treatment of dyslipidemia can reduce the risk of heart disease by 30% over a 5-year period (Grundy SM et al,. 2014). Epidemiologic studies noticed that diets rich in vegetables and fruits are affiliated with a lower risk of mortality, particularly cardiovascular diseases related deaths.[Rahman K,2001 &Genkinger JM,2004] It has also been indicated that the benefits of vegetable and fruit intake appear to be related to CVD.[Hung HC, et.al.,2004] These food groups contain different phytochemicals which can demonstrate anti-inflammatory properties. One of the most well-known sources of anti-CVD phytochemicals is garlic, which plays an effective role in the suppression and treatment of CVDs.[Rahman K,2006] Even though pharmacological interventions cause a significant reduction in high blood pressure and dyslipidemia, lifestyle modification and correcting the dietary regime can be a key step in the management of CVD.[Miyake Y et.al., 2007]Lipid-lowering drugs used for treating high-risk persons include 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors (statins), bile acid sequestrants, fi- brates, and nicotinates (NCEP 2013). None of these pharmacologic options are free of adverse effects (NCEP 2013), and some have been associated with potential carcinogenicity (Newman TB, Hulley SB 2014). A harmless yet effective therapy for lowering cholesterol levels would therefore be of considerable interest. Garlic has been used as a therapeutic agent for many illnesses over centuries as evident from various studies. Garlic is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration. Garlic's efficacy in lowering cholesterol levels in humans has been the subject of randomized clinical trials. This Study was conducted to find out the efficacy of garlic in lowering lipid level among postmenopausal women. The aim of research is to assess the effect of dry garlic powder on lipid profile of postmenopausal women with dyslipidemia.

Research Method:-

In this clinical trial 180 respondents willing to participate in intervention programme, who met inclusion criteria, were divided into three groups, control (n=60), Exp-I (garlic eaters n=60) and Exp-II (non-garlic eaters n=60) depicted in figure-1. All women with a cardiovascular, renal, liver, and other endocrine or metabolic disorders that might affect lipid metabolism were excluded from the study. None of them were on hormonal contraception, or taking medications which are known to interfere with lipid metabolism at the time of participation. Informed consent was taken from the study population.Women were evaluated in the morning after 12-14 hours fast. The investigator performed all evaluations. In the evaluation the investigator used a pre coded questionnaire including a full clinical history, socio-economic and personal information, dietary habits, a complete history of weight variations during the subject life. Biochemical investigations- Primary data from respondents before and after the intervention (n=180) Total cholesterol, Triglycerides, HDL&LDL. 500 mg of dry garlic powder capsules two per day were given to the respondents for 12 weeks along with individual dietary counseling. Dry garlic powder capsules were prepared using standard procedures and analyzed using standard methods depicted in figure-2. Biochemical analysis was measured using standard methods before and after the study shown in figure-3. Results were expressed as mean +SD or as percentage, as suitable. The significance of comparisons was tested using chi-square, t-test test as appropriate.

Figure Captions:

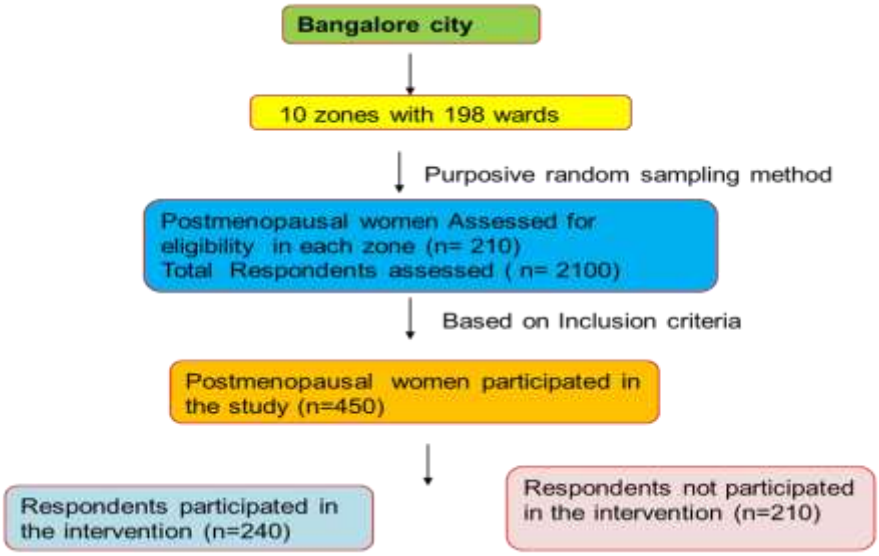


Fig 1:- Methodology Phase-I.

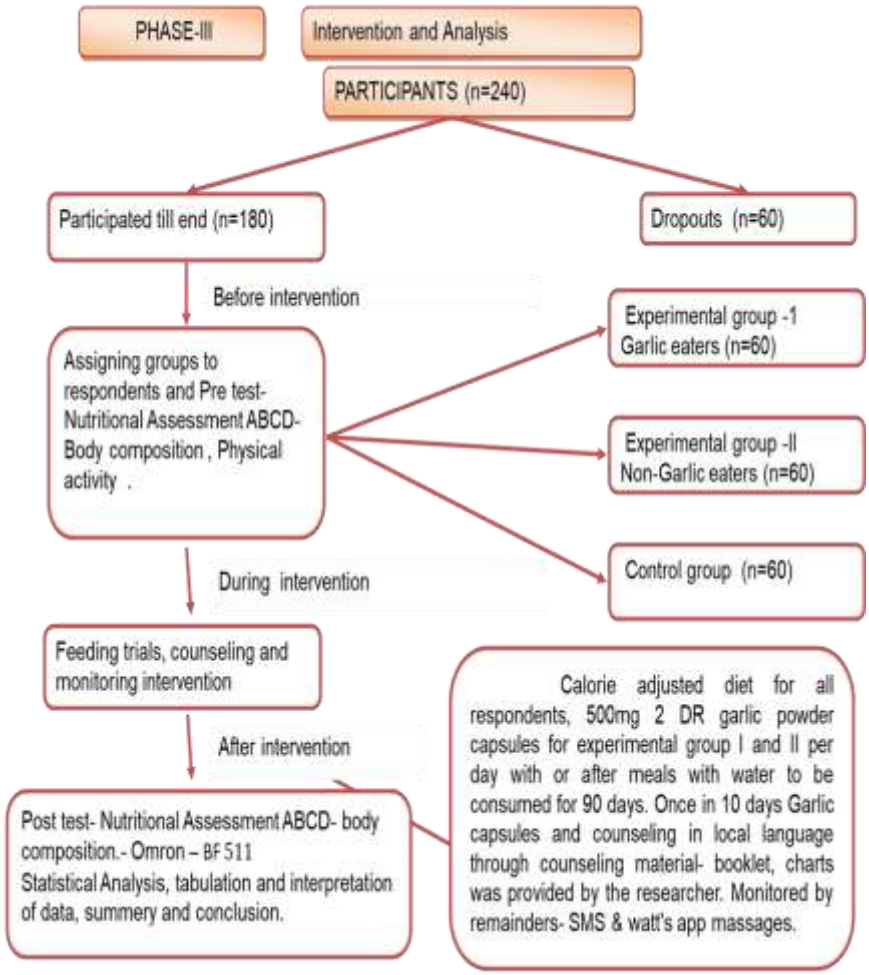
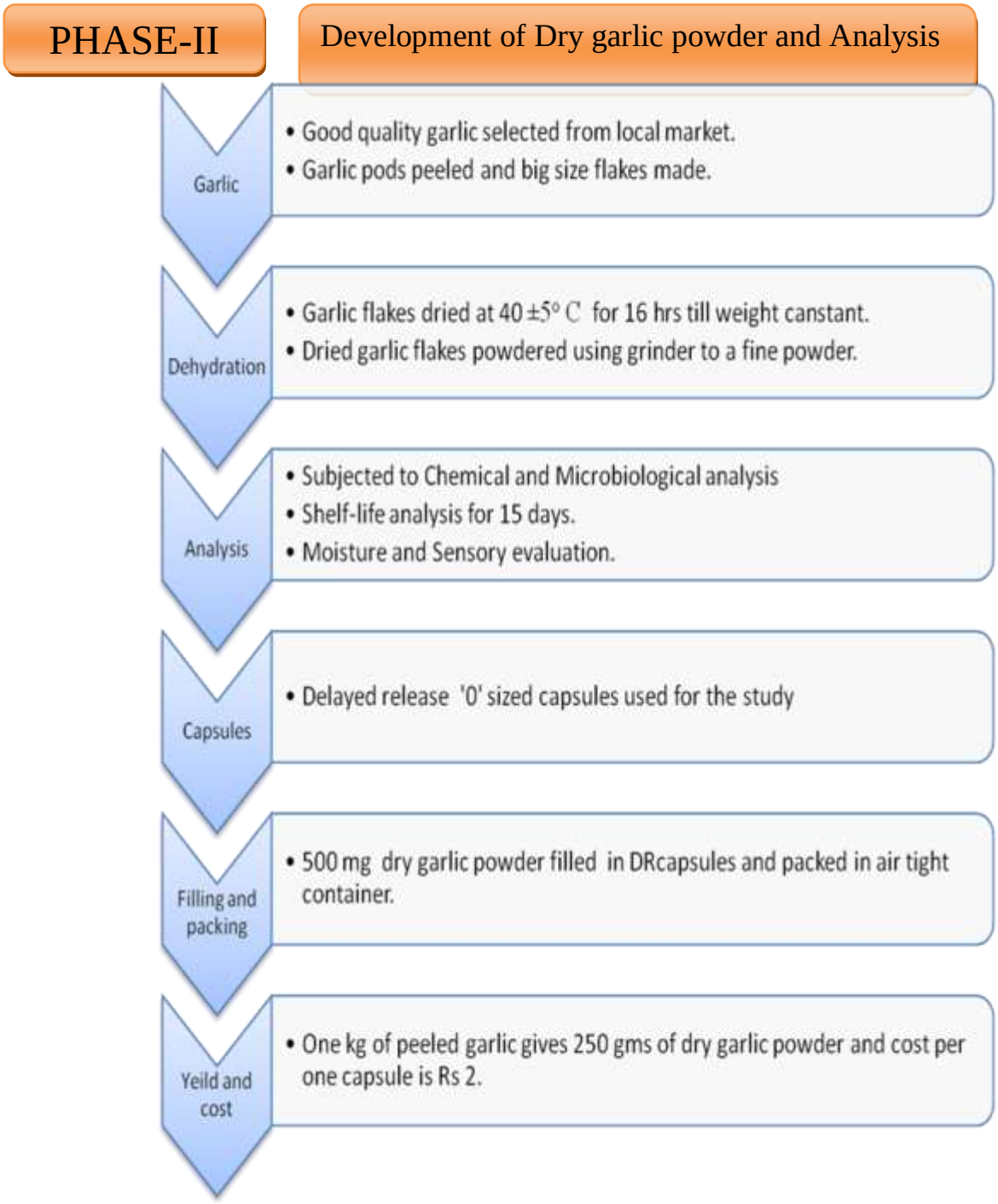


Fig 2:- Intervention and Analysis.

Fig 3:- Development of dry garlic powder.



Results and Analysis:-

The data in table-1 depicts the profile of subjects based on their personal and related characteristics. The results portraits that majority of the respondents were in the age group between 53-55 years in control and experimental group. Majority of the study population were Hindus, followed by Muslims and Christians in control group, whereas experimental -1 (garlic eaters), Maximum percentage were Muslims followed by Christian and in experimental -II (non-garlic eaters) all are from Hindu community. Most of the respondents were married, graduates and employed in all the groups. The results subjected to analysis indicate that the percentage response between sample groups with

respect to age, education, occupation, marital status were found to be non-significant, except for religion which was found to be highly significant. Since respondents require for experimental group II are non- garlic eaters which are mainly from Hindu sub -community where use of raw garlic is limited for ritual propose.

Table 1:- Personal Characteristics of Respondents (n=180).

Characteristics	Category	Respondents						χ^2 Test
		Control (n=60)		Exp-I (n=60)		Exp-II (n=60)		
		N	%	N	%	N	%	
Age	51-52.9	10	16.7	15	25	10	16.7	2.86^{NS}
	53-54.9	48	80	41	68.3	46	76.7	
	55-56.9	2	3.3	4	6.7	4	6.6	
Religion	Hindu	27	45	0	0	60	100	120.72*
	Muslim	20	33.3	34	56.7	0	0.0	
	Christian	13	21.7	26	43.3	0	0.0	
Education	Primary	1	1.7	4	6.7	0	0.0	11.73^{NS}
	High sec/PUC	5	8.3	8	13.3	2	3.3	
	Graduate	39	65.0	33	55.0	35	58.3	
	Post graduate	15	25.0	15	25.0	23	38.3	
Current occupation	Not working	8	13.3	15	25.0	6	10.0	12.50^{NS}
	Office assistant	24	40.0	20	33.3	27	45.0	
	Teacher	23	38.3	22	36.7	16	26.7	
	Any other	5	8.3	3	5.0	11	18.3	
Marital Status	Married	48	80.0	45	75.0	59	98.3	15.25^{NS}
	Unmarried	6	10.0	9	15.0	0	0.0	
	Widow	3	5.0	2	3.3	1	1.7	
	Divorcee	3	5.0	4	6.7	0	0.0	

^{NS}: Non-Significant *: Significant at 5% level

Note: Exp-I group (garlic eaters) & Exp-II group (non-garlic eaters**)**

Nutrient intake of the respondents:

The table -2 depicts the Macronutrient intake of the experimental groups in the pre and post test. The results revealed that the Energy, Total fat intake in pre test was higher than the recommended values which was statistically significant, whereas intake of Proteins was lower. In post test intake of macronutrients was as per the recommendations in all the groups, which was statistically non-significant.

Table 2:- Macronutrient intake of the respondents (n=180).

Groups	Energy (Kcals)					't' Test	
	Pre test		Post test		Recommended	Post test to Recommended	Pre test to post test
	Mean	SD	Mean	SD			
Control	1857.7	74.2	1756.2	28.5	1751.3	1.95^{NS}	6.04*
Exp-I	1859.6	81.3	1748.9	28.1	1737.4	1.40^{NS}	5.54*
Exp-II	1861.5	64.3	1750.3	32.8	1744.8	1.51^{NS}	3.22*
	Proteins (gms)						
Control	55.8	3.2	78.2	6.4	78.8	1.17^{NS}	7.84*
Exp-I	55.6	1.2	75.8	7.4	76.3	1.16^{NS}	6.44*
Exp-II	55.7	0.9	73.5	5.0	74.1	1.19^{NS}	6.85*
	Fats (g)- Total Fat (gms)						
Control	57.4	6.0	39.3	1.9	38.9	1.36^{NS}	8.29*
Exp-I	57.1	6.6	38.9	0.9	39.6	1.93^{NS}	8.36*
Exp-II	58.5	6.5	39.1	1.1	38.7	1.58^{NS}	3.18*

^{NS}: Non-Significant *: Significant at 5% level

Lipid Profile of the respondents:

Table 3:- Lipid profile of the respondents (n=180).

Groups	Sample	Total cholesterol mg/dL						Paired 't' Test	Percentage Reduction
		Pre test		Post test		Difference			
		Mean	SD	Mean	SD	Mean	SD		
Control	60	211.2	6.24	203.80	6.57	7.4	1.3	1.28^{NS}	3.5
Exp-I	60	212.25	6.41	175.36	5.43	36.88	2.47	5.31**	17.3
Exp-II	60	212.48	6.74	173.80	5.01	38.68	3.32	9.06**	18.2
F-Test		0.67^{NS}		7.08**					
		LDLmg/dL							
Control	60	135.96	8.4	135.21	8.9	0.75	2.0	1.13^{NS}	0.55
Exp-I	60	134.75	7.62	122.21	6.7	12.5	3.99	4.31**	9.35
Exp-II	60	135.90	6.59	122.86	5.1	13.03	3.14	8.09**	9.59
F-Test		0.486^{NS}		15.8**					
		HDLmg/dL							
Control	60	47.25	4.88	47.58	4.78	0.33	0.68	1.37^{NS}	0.69
Exp-I	60	48.83	5.19	51.75	5.58	2.91	0.82	7.24**	5.9
Exp-II	60	47.01	4.62	50.22	4.57	3.21	0.84	9.46**	6.8
F-Test		2.46^{NS}		14.2**					
		Triglycerides mg/dL							
Control	60	156.43	23.13	155.85	22.86	0.58	2.4	1.83^{NS}	0.37
Exp-I	60	150.9	19.661	140.18	17.0	10.71	5.23	15.85**	7.3
Exp-II	60	157.5	26.33	143.71	22.51	13.78	4.90	19.77**	8.1
F-Test		1.39^{NS}		8.14**					

^{NS}: Non-Significant **: Significant at 1% level (59df,p-value <0.001)

Table -3 reveals the pre test and post test lipid profile of the experimental groups. The total cholesterol level, LDL cholesterol and Triglyceride levels of all the respondents from the experimental group was found to be significantly lowered in the post test when compared to pre test However, there was reduction in total cholesterol level, LDL cholesterol and Triglyceride levels in control group which was non-significant. From statistical analysis finding in the difference between pre test performance with respect to groups found to be highly significant (F=7.08**, 15.8**, 8.14**) respectively.

Intervention with garlic showed eighteen percent reduction in total cholesterol in exp-II (non-garlic eater) group followed by seventeen percent in exp-I (garlic eater) group**.** Nine percent reduction in LDL cholesterol was noticed in post test compare to pretest. Seven to eight percent reduction in Triglycerides level in exp-I (garlic eater) group and Exp-II (non- garlic eater) group respectively and it is interesting to know that non-garlic eater group showed higher significance when compared to garlic eater group.

The HDL cholesterol level of all the respondents from the experimental group was found to be significantly increased in the post test when compared to pre test However, there was increase in the HDL cholesterol level in the control group which was non-significant from statistical finding and the difference in the pre test performance with respect to groups and the study found to be highly significant **(F=14.2**).** Intervention with garlic showed seven percent increase in HDL cholesterol in non-garlic eater group followed by six percent in garlic eater groupand it is interesting to know that non-garlic eater group showed higher significance when compared to garlic eater group.

Discussions:-

Similar results obtained in the study conducted by Ashraf R, et al., (2005) on Effects of garlic on dyslipidemia in patients. 12 week randomized, single-blind, placebo controlled study was conducted. After 12 weeks the garlic treated group (n = 33) had a significant reduction in total cholesterol (- 12.03 %), LDL - C (- 7.99 %) while the placebo treated group (n=32) had a non significant decrease in total cholesterol and LDL-C. HDL cholesterol was significantly increased in patients treated with garlic (8.81%) compared with placebo group and in also studies conducted by (Mahmoodi M, et al., 2006).

A garlic-derived organosulfur, alliin which is converted to allicin in presence of allinase, has been reported to reduce lipid accumulation by depressing HMG-CoA reductase activity (Keophiphath M, et al., 2009). The hypolipidemic potency of garlic has been attributed mainly to allicin and its derived sulfur compounds. This could be the reason for more reduction in lipid profile in experimental group compare to Control group which was on calorie control diet. This indicates diet along with garlic supplement has significant effect on lipids.Much research has concentrated on garlic for preventing atherosclerosis. Multiple useful cardiovascular effects have been discovered including enhancement of fibrinolytic activity, lowering of blood pressure, reduction in cholesterol, and triglyceride. Different extracts of garlic alone have been demonstrated to lower serum cholesterol, triglycerides, and LDL in rodents and humans.[Rahman K, 2003] Maha and Khalil showed that adding 8% raw garlic along with 2% cholesterol to the diet of rats decreased plasma TC and LDL-C.[Maha EB, 2008] A number of human studies have shown that raw garlic favorably affects important risk factors for CVD. Mechanisms that explain the observed effects of garlic include a decrease in cholesterol absorption, cholesterol, and fatty acid synthesis.[Matsuura H, 2001] However, there is some evidence that garlic powder does not lower cholesterol levels, which may reflect a loss of active compound(s) during processing. The formation of these active compounds is impressed by crushing garlic, a period of the drying process, the temperature at which garlic is dried, and humidity.Therefore, we used fresh garlic powder in this study. Direct measurements of enzyme activity have demonstrated that garlic and various constituents prohibit human 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase and squalene monooxygenase, enzymes required in cholesterol biosynthesis.[Yeh YY, 2001] This prohibition of HMG-CoA reductase by garlic has also been supported in a recent study.[Augusti KT.et. al., 2005] In addition, LDL-C reduction by garlic extract may be owing to decreases of hepatic 3-hydroxy-3-methylglutaryl-CoA reductase, cholesterol 7α-hydroxylase, pentose-phosphate pathway activities,[Qureshi AA,1983] cholesteryl ester transfer protein activity, microsomal triglyceride transfer protein,enhanced bile acid excretion, and prohibition of hepatic fatty acid synthesisby allicin and/or other components.[Qureshi AA,1983] It should also be emphasized that certain garlic preparations (e.g., garlic oils) do not indicate the degree of cholesterol lowering seen with specific powdered formulations.[Dc A Santos OS,1995] In this study, we observe significant changes in HDL-C levels between groups. Aouadi showed that adding 10% fresh crushed garlic and 2% cholesterol to diet led to significant reduction in LDL-C levels, and increased HDL-C levels in rats.In this study, we observed a significant reduction in triglycerides in the experimental group compared with control group.

Conclusion:-

It can be concluded that Dyslipidemia is highly prevalent among women. With menopause, women experience a worsening of their lipid profile, with the transition to higher and more atherogenic dyslipidemia. The management of dyslipidemia is a cornerstone in the prevention of both primary and secondary cardiovascular events. This study demonstrated that a 12-week garlic supplementation could decrease total cholesterol level, LDL, HDL and Triglyceridesamong postmenopausal women. Further studies with stronger design, longer periods are necessary.

Conflicts of interest:

There are no conflicts of interest.

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