Journal Homepage: - www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI: 10.21474/IJAR01/16146
DOI URL: http://dx.doi.org/10.21474/IJAR01/16146

RESEARCH ARTICLE

"A COMPARITIVE CLINICAL STUDY OF CHATURUSHAN ON MODIFIABLE FACTORS OF FRAMINGHAM HEART SCORE IN CARDIO-VASCULAR RISK"

Dr. Sonal D. Wankhede (Kamble)[1], Dr. Sumeeta S. Jain[2] and Dr. Nitesh K. Kamble[3]

1. Asst. Professor (Dept.of Swasthvritta and Yoga, GAC, Nag).
2. Professor and HOD (Dept. of Swasthavritta and Yoga, GAC, Nag).
3. Asso. Professor (Dept.of Sharirkriya, SAM Ayurved College, Bhopal (MP).

Manuscript Info

Manuscript History
Received: 30 November 2022
Final Accepted: 31 December 2022
Published: January 2023

Key words:-
Framingham Heart Score, Dyslipidemia, Chaturushan, Gomutra Haritaki, Cardiovascular Risk

Abstract

Twenty first century is the century of globalization, industrialization, and modernization. This advancement has led to a drastic increase in the incidence of lifestyle related diseases like Obesity, DM, HTN, Hyperlipidemia etc. eventually leading to the risk of number of chronic disorders such as cardio-vascular disease(CVD).

Aim & objective: In this clinical study, we are aiming to Study the Effect of "***Chaturushan"*** as dietary supplement in CVD Risk assessment as per Framingham Heart Score.

Objectives:. To assess the effect of Chaturushan on Total cholesterol, Sr.HDL and Blood Pressure in the experimental group and to compare the same for ***Gomutra Haritaki***(GH) which is an already proven drug and taken here as a control.

Materials & Methods: In this study 60 patients of Dyslipidemia bearing a risk of cardio-vascular disease were selected by using selection criteria irrespective of age, sex, and socio-economical status. In Group A (n = 30), patients were administered Chaturushan churna 2gm daily in 2 divided doses. for 3 months and in Group B (n = 30), Gomutra Haritaki churna was given in similar dose and duration. Effect of therapy was assessed objectively by Framingham Heart Score including Total cholesterol, Sr.HDL, Systolic and Daistolic BP. Also, Physical parameters like body weight, waist circumference and Body Mass Index (BMI) were assessed and subjectively by the cardinal symptoms.After completion of therapy all values were recorded and statistically analyzed and results were obtained.

Conclusion: Chaturushan a dietary supplement was found quite effective in lowering the Total cholesterol levels as per FHS But, on comparing the effects of the two groups subjectively, it can be concluded that both the supplements are equally effective in reducing the subjective scores of the disease.

Introduction:-

HUMAN HEART" –an amazing and dynamic machine in itself is considered to be one of the most important tripod of life. However, modern era has gifted humans with sedentary lifestyle and drastic changes in the food habits which

Corresponding Author:- Dr. Sonal D. Wankhede (Kamble)
Address**:-** Asst. Professor (Dept.of Swasthvritta and Yoga, Govt.Ayu College Nag,

cause the heart to be in the "Cardio-vascular Risk" Zone. In India, there has been an alarming increase in the prevalence of CVD over the past two decades so much so that accounts for 24% of all deaths among adults aged 25–69 years. The likely causes for the increase in the CVD rates include lifestyle changes associated with urbanization and the epidemiologic and nutritional transitions that accompany economic development [5].The aetiology of Cardio-vascular Disease is multifactorial. Apart from obvious ones such as increasing Age and male sex, several other factors are also responsible for the occurrence of the disease.Some factors are modifiable while other ones are immutable. Some of the major principal risk factors Responsible for Cardio-vascular risk are stated below-

Sr. no	Non- Modifiable	Modifiable major	Modifiable minor
1.	Age	**Elevated-serum cholesterol**	Obesity
2.	Sex	Hypertension	Stress
3.	Family History	Diabetes	Smoking
4.	Genetics Factors	Sedentary Habits	

Out of the above factors, **Elevated serum cholesterol also termed as DYSLIPIDEMIA**stands as the most firmly established modifiable risk factor for Cardio-Vascular accidents ultimately making Cardio-Vascular Disease "THE NUMBER ONE KILLER".

Dyslipidemia is a condition of the blood in which there is an abnormality in the level of lipids in the blood.The incidence of dyslipidemia affects the overall health status of an individual which could lead to the hardening of the arteries later causing cardio-vascular risk in further life especially if dyslipidemia is not monitored and left untreated.

In Ayurveda, Dyslipidemia can be taken as Kapha Medo Margavarana, which denotes Samprapti (pathologenesis) rather than a clinical diagnosis. Medogat margavaran i.e dyslipidemia is one of the major risk factor in the pathology of Hridroga, Rasa dhatu, being the main Dushya and kapha being mainDosha. Also, Agnimandya takes place at Rasadhatvagni level.So taking into consideration all these concepts, the drug selected here for this clinical study is having Kapha and kledanashak properties as well as it has the efficacy to correct Aam and Rasadushti. Hence, a traditional poly herbal formulation of the drugs from the group of spices and condiments is selected for the study which is mainlyKatu Rasatmak and Ushna Viryatmak. The combination of formulation containing **Shunthi, Marich , Pippali And Pippalimool**called as **, Chaturushan**is a polyherbal combination containing exclusive properties i.e vata-Kapaha Shamak, Lekhaniya, Deepaniya–Pachananiya and Agnivruddhikar.Also on the control, already proven drug **Gomutra Haritaki** (GH) is considered. GH is referred for Kaphaja Shotha Chikitsa.[4] Haritaki (Terminalia chebula Retz.) and Gomutra (cow urine) are the constituents of this formulation. Thus, this study is a genuine attempt to evaluate and compare the actions of chaturushan and GH which can be helpful in evaluation and destruction of the etiopathogenesis of the disease.,So this study was undertaken to evaluate and compare the clinical effect of chaturushan and GH in patients suffering with the Kapha MedoMargavarana (dyslipidemia) as a modifiable risk factor in CVD.

Aim & Objectives:-

Primary Objective

To Study the Effect of "Chaturushan" as dietary supplement in Cardio Vascular Risk as per Framingham Heart Score.

Secondary Objectives

1. To assess the effect of Chaturushan on Total cholesterol, HDL and Blood Pressure.
2. To assess effect of Gomutra Haritaki on Total cholesterol, HDL and Blood Pressure as a control.
3. To Study the literature regarding Chaturushan and major modifiable factors in Cardio Vascular Risk.

Materials And Methods:-

a)Study design

It is a randomized, parallel, and interventional clinical trial. All the patients with high lipid profile with their prior consent were selected and registered at the Outdoor Patient Department of Swasthavritta and Yoga, Government ayurvedic college and hospital, Nagpur. The research protocol was approved by Institutional Ethics Committee (Ethics/2017-11/2087; dt. 30-11-2017) and registered in CTRI (No.: CTRI/2017/11/2087**)**

b)Sampling

The size of sample was calculated with the help of software named as sample size calculator available onsite (www.systemsurvey.com). According to software, size calculated was 646, which is not possible to evaluate in a short spam of time and, therefore as mentioned by Mahajan B.K. (2010), normally cut off were taken as 30 in one group i.e. group A and 30 in group B. In this study being two group one group of 30 patients and another group 30 patients were selected. Total 60 patients were studied in this study

c) Inclusion criteria

• Patients with age group 35-60 years.

- Elevated levels of serum cholesterol(160mg/dl to 240 mg/dl).
- HDL<40 mg/dl
- Patients with controlled HT.
- BMI in the range 23-35 kg/m2

d) Exclusion criteria

- Patients with age <35 and >60 years.
- Elevated levels of serum cholesterol< 160 and > 240mg/dl
- HDL>40mg/dl
- Subjects having FBS > 126 mg/dl or anti diabetic medication
- Patients who have undergone Coronary Artery bypass surgery(C.A.B.G) or Angioplasty.
- Patients with history of stroke.
- Untreated hypertension
- Patients with chronic alcoholic and smoking habits.

e) DRUG AND POSOLOGY

1.Method of preparation:

Chaturushan and Gomutra Haritaki were prepared as per the classical method of preparation of Churna mentioned in Sharangdhara. (Sh. M. 7/2) 71

GOMUTRA HARITAKI CHURNA

=

HARITKI

GOMUTRA

MARICH

CHATURUSHAN CHURNA

PIPPALI

PIPPALI MOOL

SHUNTHI

Dose And Duration-

Particulars	Group A	Group B
DRUG	**Chaturushan**	**Gomutra Haritaki**
DOSE	2 gm in 2 divided doses	2gm in 2 divided doses
Anupaan	Koshna jala	Koshna jala
Bhaishaj kala	Samudga kala	Samudga Kala
Duration	Three consecutive months	Three consecutive months

Diagnostic Criteria:

Objective-Framingham Heart Risk Score

It is a Gold Standard risk score for predicting stroke or death due to it, in individuals with new onset of heart disease in community. Its main objective is to derive risk scores for stroke or death due to C.V.D in individuals. This risk estimation model is based on age, treated and untreated systolic blood Pressure, diabetes, smoking, Body Mass Index(BMI). Framingham Heart Study is a simple model based non laboratory predictors for estimating 10 years risk of developing coronary heart disease (CHD) in an individual.

Sr. no	FRAMINGHAM HEART RISK SCORE	
1	Age	……..yrs
2	S. Total Cholesterol	…….mg/dl
3	Smoker	Yes/no
4	S. HDL	…….mg/dl
5	Blood Pressure	…….mmHg

6.	TOTAL	……..

Sr. No	Anthropometric Measurements			
1.	Weight in kg			
2.	Body mass Index(kg/m^2)			
3.	Waist Circumference			
	MEN	Score	WOMEN	Score
	Waist <94 cm	0	Waist <80 cm	0
	Waist 95-101 cm	25	Waist 81-87 cm	25
	Waist >102 cm	50	Waist >88 cm	50
4	Framingham Risk Score			

Subjective Assessment

The overall effect was assessed on the basis of relief in chief complaints (as subjective criteria) After completion of three months of treatment, the efficacy of the therapy was assessed on the basis of the following subjective as well as objective criteria.

Sr. No	**Symptoms**
1	Dyspnea
2	Pitting edema
3	Chest pain
4	Cough
5	Palpitations
6	Fatigue
7	Weakness
8	Xanthomas
9	Corneal Arcus

Diet:

Regular food as patient was taking in the past. No special dietary regime was advised during the study period.

Follow-up:

1) Clinically patients were screened on Day 0, Day 45, Day 60,and on next day of 90th day.
2) Lipid Profile was done on Day 0, Day 45th and Day 90th

Statistical Analysis

The Wilcoxon signed rank test method was used to check the significance of the subjective criteria and paired t test was used for objective criteria in a single group. To compare the effect of therapy of two groups, Wilcoxan Mann whitney test was carried out for the subjective criteria,for objective criteria and for physical parameters.. The obtained results were interpreted as, insignificant $P > 0.05$, significant $P < 0.01$, highly significant $P < 0.001$.

Observations And Results:-

In this study, patients were diagnosed by using the criteria of diagnosis i.e the Framingham Heart Score and a specially prepared proforma was used to fill the information of all patients included in the study. Patients were recruited by allotting numbers from1-60(considering dropouts).Packets each of Chaturushan Churna and Gomutra Haritaki were prepared under the supervision of head of department of Rasashastra and Bhaishajya Kalpana of the institute, packing of bothgroups were such that they look similar in order to avoid discrimination. The drug in Group A(Experimental group) or Group B(Control Group) were given to all patients through generated randomization list . After completion of therapy, all observational values were statistically analysed and results obtained were presented as below-

Subjective Criteria

Table 3.1:- showing results of Application of Wilcoxon Rank Signed test to subjective parameters of Experimental group

	Subjective parameters	BT/ AT	Mean	Median	SD	Range	Z	p-value	Significance
1	Kshudrashwas (Dyspnea)	BT	3.06	3	0.45	2-4	4.91	<0.001	HS
		AT	1.50	1.5	0.51	1-2	4.89		
2	Shotha (Oedema)	BT	3.3	3	0.65	2-4	4.89	<0.001	HS
		AT	1.76	2	0.50	1-3	4.81		
3	Urahshool (chest pain)	BT	3.3	3	0.46	3-4	4.92	<0.001	HS
		AT	1.5	1.5	0.50	1-2	4.88		
4	Palpitations	BT	3.36	3	0.67	1-4	4.95	<0.001	HS
		AT	1.60	2	0.49	1-2	4.81		
5	Diwaswaap (day sleep)	BT	3.06	3	0.45	2-4	4.86	<0.001	HS
		AT	1.46	1	0.50	1-2	4.87		
6	Daurbalya (weakness)	BT	3.13	3	0.68	1-4	4.51	<0.001	HS
		AT	1.43	1	0.50	1-2	4.89		
7	Kasa(cough)	BT	3.36	3	0.67	1-4	4.95	<0.001	HS
		AT	1.60	2	0.40	1-2	4.97		
8	Angamarda (Fatigue)	BT	3.36	3	0.67	1-4	4.78	<0.001	HS
		AT	1.56	2	0.50	1-2	4.88		

Ssubjective parameters of Control group

Sr.no	Subjective parameters	BT/AT	Mean	Median	SD	Range	Z	p-value	Significance
1	Kshudrashwas (Dyspnea)	BT	3.06	3	0.45	2-4	4.89	<0.001	HS
		AT	1.60	2	0.50	1-3			
2	Shotha (Oedema)	BT	3.36	3	0.64	2-4	4.81	<0.001	HS
		AT	1.86	2	0.68	1-4			
3	Urahshool (chest pain)	BT	3.3	3	0.46	3-4	4.88	<0.001	HS
		AT	1.56	1.5	0.62	3-4			
4	Palpitations	BT	3.36	3	0.55	2-4	4.81	<0.001	HS
		AT	1.70	2	0.59	1-3			
5	Diwaswaap (day sleep)	BT	3.0	3	0.52	2-4	4.87	<0.001	HS
		AT	1.46	1	0.50	1-2			
6	Daurbalya (weakness)	BT	3.16	3	0.64	1-4	4.89	<0.001	HS
		AT	1.50	1.5	0.50	1-2			
7	Kasa(cou)gh	BT	3.46	3	0.50	3-4	4.97	<0.001	HS
		AT	1.66	2	0.50	1-3			
8	Angamarda (Fatigue)	BT	3.43	3	0.67	3-4	4.88	<0.001	HS
		AT	1.56	2	0.50	1-2			

Table 3.3:- showing results of comparison between two groups by Applying Wilcoxon Mann-Whitney test for Subjective parameters.

10	Subjective Parameters	MeanChange(Mean±SD)		Z-value	p-value	Significance
		Group A	Group B			
1	Kshudrashwas	1.56±0.57	1.46±0.62	0.600	<0.548	NS

	(Dyspnea)					
2	Shotha (Oedema)	1.53±0.63	1.40±0.72	0.687	<0.491	NS
3	Urahshool (chest pain	1.80±0.61	1.73±0.74	0.152	<0.879	NS
4	Palpitations	1.76±0.62	1.62±0.83	0.315	<0.752	NS
5	Diwaswaap (day sleep)	1.60±0.77	1.56±0.76	0.404	<0.686	NS
6	Daurbalya (weakness)	1.70±0.65	1.66±0.71	0.085	<0.932	NS
7	Kasa(cough)	1.76±0.62	1.75±0.62	0.071	<0.943	NS
8	Angamarda (Fatigue)	1.80±0.84	1.86±0.68	0.073	<0.941	NS

Comparison in both the groups before and after treatment by applying Wilcoxan Mann Whitney test shows that, there was no significant difference observed in the mean change in the subjective parameters between both the groups. Hence, it can be concluded that both the treatments were equally effective in reducing the symptoms of dyslipidemia**.**

Objective Parameters

Table 3.4:- Showing Results of Application of Paired-t test to for Objective parameters of Experimental Group.

	Framingham Heart Score Sheet	BT/AT	Mean	Median	SD	Range	T-value	p-value	Significance
1	Serum Total Cholesterol	BT	218.31	214.6	18.80	185.5-280	9.124	<0.001	HS
		AT	174.80	179.9	25.24	180.5-202.8			
2	Serum High Density Lipid(HDL)	BT	41.63	41.8	2.95	36.3-48.1	0.223	<0.825	NS
		AT	41.5	41.0	3.77	34.0-49.0			
3	Systolic Blood Pressure(SBP)	BT	136.3	140	8.84	110.0-150.0	2.671	<0.123	S
		AT	132.6	130	6.80	130.0-150.0			
4	Diastolic Blood Pressure(DBP)	BT	89.33	90	6.39	70.0-100.0	1.222	<0.231	NS
		AT	87.67	90	5.68	70-100			

Table 3.5:- Showing Results of Application of Paired-t test for Objective parameters of Control Group.

Sr.no	**Framingham Heart Score Sheet**	BT/AT	Mean	Median	SD	Range	T	p-value	Significance
1	Serum Total Cholesterol	BT	217.45	210.0	23.18	169-267	7.539	<0.001	HS
		AT	187.09	190.0	21.47	133.5-232.0			
2	Serum High Density Lipid(HDL)	BT	40.37	41.8	3.67	36.0-51.9	2.529	<0.017	S
		AT	41.89	41.0	2.78	39.0-49.0			
3	Systolic Blood	BT	135.63	140	8.52	110.0-	2.451	<0.020	S

	Pressure(SBP)					150.0			
		AT	132.3	130	6.70	130.0-150.0			
4	Diastolic Blood Pressure(DBP)	BT	89.0	90	6.61	70.0-100.0	0.941	<0.354	NS
		AT	87.67	90	5.68	70-100			

Table 3.6:- showing results of Comparison between two groups by Applying Wilcoxon Mann Whitney for Objective parameters.

Sr.no	Subjective Parameters	MeanChange(Mean±SD)		Z-value	p-value	Significance
		Group A	Group B			
1	Sr.Total Cholesterol	43.51±26.1	29.36±21.3	2.45	<0.014	HS
2	Sr. HDL	0.13±3.34	-1.52±3.29	2.000	<0.0449	HS
3	Systolic Blood Pressure(SBP)	3.67±6.88	3.33±7.44	1.018	<0.308	NS
4	Diastolic Blood Pressure(DBP)	1.67±5.68	1.33±7.68	0.170	<0.865	NS

The above table shows that, **in case of Serum Total Cholesterol, the experimental treatment was more effective than that of the control, as therewas a highly significant difference observed in the mean change in the cholesterol in both the groups**. Similarly, comparing the mean change in the Serum HDL values, we found that control group was more effective than the study group as the mean change was significant. However, both systolic and diastolic blood pressure was not statistically significant on comparing both the groups, which indicates that both the treatments were equally effective in case of systolic Blood Pressure and more groups were not effective in case of diastolic blood Pressure

Table 3.7:- showing Results of Application of Paired-t test to for Physical parameters of Experimental Group.

Sr.no	**Physical Parameters**	BT/AT	Mean	SD	Median	Range	T-value	p-value	Significance
1	Weight in kg	BT	76.5	1.01	18.80	66-93	8.600	<0.000	HS
		AT	73.76	6.37	25.24	62-90			
2	B.M.I(kg/$m^{2)}$	BT	28.54	3.12	28.3	23.5-33.7	9.752	<0.000	HS
		AT	27.37	3.11	26.95	34.0-49.0			
3	Waist circumference	BT	105.26	6.51	109	90-116	7.319	<0.000	HS
		AT	103.85	6.90	107	89-115			

Table 3.8:- Showing Results of Application of Paired-t test to for Physical parameters of control Group.

Sr.no	**Physical Parameters**	BT/AT	Mean	SD	Median	Range	T-value	p-value	Significance
1	Weight in kg	BT	72.06	7.24	71.5	60-91	24.88	<0.000	HS
		AT	65.46	7.33	64.5	52-91			
2	B.M.I(kg/$m^{2)}$	BT	28.60	2.49	27.12	25.1-36.5	20.15	<0.000	HS
		AT	25.70	2.46	25.12	34.0-49.0			
3	Waist circumference	BT	104.26	6.52	109	92-116	16.08	<0.000	HS
		AT	102.78	6.51	107	90-115			

Table 3.9:- showing results of Comparison between two groups by Applying Wilcoxon Mann Whitney- test for Physical.

Sr.no	Physical Parameters	MeanChange(Mean±SD)		Z-value	p-value	Significance
		Group A	Group B			
1	Weight in kg	43.51±26.1	29.36±21.3	2.45	<0.014	HS
2	Body Mass	0.13±3.34	-1.52±3.29	2.000	<0.0449	HS

	Index(B.M.I)					
3	Waist Circumference(WC)	3.67±6.88	3.33±7.44	1.202	<0.308	NS

In case of Body weight(in kgs), the control treatment was more effective than that of the study, as there was a highly significant difference observed in the mean change in the cholesterol in both the groups. Similarly, comparing the mean change in the B.M.I values, we found that control group was more effective than the study group as the mean change was highly significant. However, in case of waist circumference, Comparing both the groups, indicated that both the treatments were equally effective.

Discussion:-

Dyslipidemia is considered to be a major risk factor for cardiac disorders both in a developed and developing world. In modern science, the most commonly used drugs for treating dyslipidemia or cardiovascular disorders have a lot of side effects than benefits. Looking at the ayurvedic aspect of dyslipidemia, Agni, Kapha and Meda are the major factors vitiated in the pathogenesis of the disease. By correcting this with probable mode of action of these drugs like Deepan, Pachan Kapha-kleda nashak, Agnivruddhikara etc, we may help to manage these kinds of metabolic diseases in the earlier stage itself. Taking all the above view in consideration, it was thought in mind to evaluate the effect of this drug as a dietary supplement to achieve the goal of treating dyslipidemia as a Cardio-vascular risk factor. The study was carried out in the dept. of Swasthyarakshan of our institute. Patients of Dyslipidemia with Cardio-0vascular risk were selected as per the Framingham Heart score sheet, irrespective of their sex, religion, socio-econom/ic and educational status in group A and B. All the patients were clinically examined by using modern as well as Ayurvedic parameters like Samanya Parikshan, AshtavidhaParikshan and Dashavidha Parikshan, Srotas Parikshan etc.Physical characters with respect to the disease like Weight, BMI and Waist circumference was also evaluated.

Discussion on Principal Findings

1. **Discussion on Physical Parameters:(Body weight, B.M.I, Waist circumference)**

The effect of therapy after treatment in both the Groups A and B was evaluated statistically, with the help of paired‘t’ test and it was found that effects onthese characters were significantly favourable to the patient in both groups. Ultimate goal of the management of Dyslipidemia is to reduce increased weight and Cholesterol levels respectively. The extremely significant reduction in Weight, BMI in both groups, was evident in this study. (table no.3.7,3.8 &3.9)

2. **Discussion on Objective Criteria (Framingham Heart Score)**

a). Effect on Total Cholesterol

The mean score of the total cholesterol before treatment in group A was 218.3±18.25 which was reduced to 174.8±25.24. which was statistically found to be very highly significant because t=9.124 at P<0.0001(table-3.4). Whereas in group B, the mean total Cholesterol before treatment was 217.4±23.18 which was reduced to 188.0±21.47 after treatment within duration of three months(table 3.5). This data statistically analysed and found to be highly significant because t= 7.539 at P<0.0001.It means that both the drugs showed highly significant effect on the total cholesterol levels. Comparing the difference of mean change in the total cholesterol levels between the two groups by applying Mann Whitney test showed remarkable difference (at p<0.014) which shows that experimental group is considered to be significant (table no.3.6).

b) **Effect on High Density Profile (HDL):**

The mean values of HDL before treatment was 41.63 which was reduced to 41.50.which is found to be statistically non-significant because t=0.223 at p<0.824. Whereas for group B, the initial mean value of HDL was 40.37 which got reduced to 40.89,which was found to be very highly significant because t=2.529 at p<0.824 for group A and t<0.017. The above data proves that the effect of dietary formulation showed a very non-significant effect on the HDL levels in the experimental group. However, it showed a highly significant effect in control group.. Comparing the change in the mean HDL levels of group A and Group B, by applying ….test, the z value was 2.005 at p<0.0449, which indicates that the difference in the mean change of HDL values was significant(table no 3.6)

c) **Effect on Systolic Blood Pressure (SBP)**
The mean score of SBP observed before treatment was 136.3 which was reduced to 132.6 after treatment. Similarly, For group B, the mean SBP Value before treatment was 135.6 which was reduced to 132.3 after 3 months. The Statistical analysis of the data was done for both the groups which was significant where t=2.67 at p<0.012(table no.21) for group A and t=2.45 at p<0.02 respectively.It indicates that the dietary formulation is effective in lowering the systolic Blood Pressure in both the groups. Comparing the change in the mean SBP values of both the groups by applying unpaired t-test showed that difference in mean for group A was 3.67 and for group B was 3.33, which was statistically not significant where z=1.018 at p<0.308.

d)**Effect on Diastolic Blood Pressure(DBP)**
The mean score of DBP observed before treatment was 89.7 which was reduced to 89.6 after treatment. Similarly, For group B, the mean DBP Value before treatment was 89.6 which was reduced to 89.0 after 3 months. The Statistical analysis of the data was done for both the groups which was not significant where z=1.222 at p<0.231 for group A and z=0.941 at p<0.354 respectively(table no 19 & 20).It indicates that the dietary formulation is not much effective in lowering the diastolic blood pressure in both the groups. Comparing the change in the mean DBP values of both the groups by applying Mann Whitney-test showed that difference in mean for group A was 1.67 and for group B was 1.33, which was statistically not significant where z=0.170 at p<0.865(table no 3.6)

e) **Effect of Therapy on General Symptom Score by Wilcoxon Ranked Sign Test:**
According to Wilcoxans Ranked Sign test, the graded symptoms such as Kshudrashwaas,Shotha, Urahshoola, Palpitations, Kasa, Daurbalya etc was recorded. and it was observed that in both the groups, a very highly significant change in the score of the symptoms beore and after the treatment was noted. The drug in group A as well as in group B has sufficiently reduced the status of these ,which was decided by percentage of relief in the symptoms. Also, Wilcoxon ranked sign test showed a very highly significant reduction in the symptom score. Hence further comaprision is done by using **Mann-Whitney U test and** it was found that both the groups had better results on all symptoms score of subjective parameter. Hence, it can be clarified that both the dietary supplements were equally effective in reducing the symptoms of dyslipidemia.

Pharmacological Action Of Drugs:
This study was conducted to find the solution for normalizing the lipid functions & treating dyslipidemia, without any therapeutic medicines and ultimately to reduce the risk of cardio-vascular diseases In this present study, patient was given a traditional combination of condiments in the form of dietary supplement called as Chaturushan with the primary outcome of achieving normal lipid levels along with secondary outcomes such as reduction in weight, waist circumference, BMI etc.The Traditional Combination of Chaturushan as a dietary supplement consists of formulation of four dietary herbs namely, Shunthi(Zinziber Officinale), Marich(pipper nigrum), Pippali(Pipper longum) and Pippali Moola(Pipper longum Radix.)

Shunthi, being katu ,ushna and specifically vibandhaanaah&shoolhar, it is useful is all types of kapha related ailments & improves appatite.

Marich: It is Deepan, Paachan And Shleshmaprasekiand thus is useful in dissolving the thrombosed blood and clearing the channels of blood vessels for normal passage of blood.

Pippali: Pippali, being Rasayana is a very beneficial herb. It is known as "Meda-kapha vinashini" and acts as Aamdoshahar, Kaphaavilayankar. It helps in proper functioning of Digestive System and Respiratory System (Pranvahastrotas) Also.

Pippali Moola: The herb suppresses symptoms like Shwaas (Dyspnea),Kshudhamaandya (Loss Of Appatite).Gaurav,Daurbalya etc. It avoids accumulation of toxins in the body boosting the immunity system.

All the four drugs used in the formulation are selected on the basis of their homogenous Rasa, veerya and vipaak properties also considering their Hypolipidemic activity.As mentioned earlier in the introductory part, dyslipidemia can be condsidered as the shleshma-medojvikaar and hence, the management recommended is Deepan, Paachan and Agnivruddhikar. All the four ingredients used in the study are well established and contains various distinct characteristics which are quite beneficial in shleshma- medajanyavikaar (i.e Dyslipidemia).

Conclusion:-

1. Chaturushan a dietary supplement is quite effective in lowering the Total cholesterol levels.
2. Although, individually both supplements showed highly significant effect on the Total cholesterol levels, on comparison study group was more effective in reducing the total cholesterol level than that of the control.
3. In case of High density Cholesterol (HDL), study group was not found to show significant results. But, control group showed moderate effect on the Level of HDL
4. It was revealed that both the groups were highly effective in reducing the Systolic Blood Pressure.
5. However, Comparing both the groups for Systolic Blood Pressure, it was signified by table no. 3.6 that both the groups were equally effective in lowering the Systolic Blood Pressure.
6. Effect on Diastolic blood pressure was found to be non significant in both groups. It means, both the groups were sufficiently not effective in reducing the diastolic Blood Pressure.
7. It can be concluded that both the groups were capable to reduce the physical parameters, (body weight, B.M.I and waist circumference)
8. On comparing the effects of the two groups on subjective parameters, it can be concluded that both the supplements are equally effective in reducing the subjective scores of the disease.

References:-

1.SEVAMED ISSN 0972-5903 Vol 14 No.1, January 2015
2.www.ncbi.nih.gov,pmc3665099, lifestyle disorders
3..K.Park;Preventive and Social Medicine; cardiovascular disorders,risk factors,23rd Edition Reprint 2003, M/S Banarasidas Bhanot Page no.365-366
4.K.Park;Preventive and Social Medicine; cardiovascular disorders, 23rd Edition Reprint 2003, M/S Banarasidas Bhanot Page no.368
5.Lucy B Adams, Hyperlipidemia, National Cholesterol Education Programme(NCEP) ReportNIH publication no. 91-2732
6.Indrayan A. Forecasting vascular disease cases and associated mortality in India.Reports of the National Commission on Macroeconomics and Health. Ministry of Health and Family Welfare, India 2005. Available at http//www.whoindia.org/EN section102/Section201-888.htm
7.Yeshrum D.Gotto AM Jr.Hyperlipedimia:Perspective in diagnosis and treatment.Med J. 1995:88-379-91
8.Framingham Risk Score-http/en.m.wikipedia.org.
9.Vd.Kashinath Shastri;Agnivesha Charak Samhita, Sutrasthana 17/30,32,33,34,36,37/Kriynta shirasiya adhyaya;Chaukhamba Prakashan,Varanasi.
10.Vd.Kashinath Shastri;Agnivesha Charak Samhita, Chikitsa-sthana 78-80/Kriynta shirasiya adhyaya;Chaukhamba Prakashan,Varanasi.
11. Vd Yadunandan Upadhyay; Madhav Nidan;Hridrog 31/6; Chaukhambha Sanskrit Sansthan, Varanasi.
12The lipid research clinics coronary primary prevention trial results.reduction in incidence of coronary heart disease JaMA 1984;251;351-64
13.Dr.PriyavattaSharma,Bhavprakash of Bhavmishra,reprint 2012,Varanasi Chaukhamba Orientalia,2006,Purvakhanda,Haritkyadi Varga,8,18
14.Dr.PriyavattaSharma,Bhavprakash of Bhavmishra,reprint 2012,Varanasi Chaukhamba Orientalia,2006,Purvakhanda,Haritkyadi Varga,28,29
15.Dr.PriyavattaSharma,Bhavprakash of Bhavmishra,reprint 2012,VaranasiChaukhambaOrientalia,2006,Purvakhanda,Pippalyaadi Varga,30,31,32page-140.
16. Vd.Kashinath Shastri; Agniveshkrita charak Samhita;Vimanasthana reprint 2013,vol 1/16; Rasavimaan adhyay; Chaukhambha Prakashan, Varanasi
17.Ritesh A Gujrathi,Rambabu dwivedi,An observational study on effect of gomutraharitaki, diet in management of sthaulya.Ayu.ncbi.nim.nih.gov.pmc articles/PMVA479317
18.V.Maruthappan K,Hypolipidemic activity of Harithaki in atherogenic diet induced hyperlipidemic Rats,journal of advanced pharmaceutical technology and research ,2010,apr-june
19. Hyperlipidemia primary care (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High T.cholesterol in Adults (Adult Treatment Panel III). JAMA 2001 May 16;285(19):2486-97. See the related National Guideline Clearinghouse (NGC) summary.
20.Vd.Kashinath Shastri; Agniveshkrita charak Samhita;Sutraasthana reprint 2013,vol 27/297; Annapaan vidhi adhyay; Chaukhambha Prakashan, Varanasi

21..Vd.Kashinath Shastri; Agniveshkrita charak Samhita;Vimanasthana reprint 2013,vol 1/16; Rasavimaan adhyay; Chaukhambha Prakashan, Varanasi
22.The lipid research clinics coronary primary prevention trial results.reduction in incidence of coronary heart disease JAMA 1984;251;351-64
23.Arthur C gyton and john E Hall textbook of medical physiology ,11th edition,Elsevier saunders, page-848.
24..Tablers cyclopaedic medical dictionary, edition 20th,illustrated in full colour, editor-donald venus, page-819.
25.The ayurvedic Pharmacopoeia of india, part –I, volume-II, government of india,ministry of health and Family welfare, department of ayush, pg-62.http/www.ayurveda.hu/API-Vol-1.pdf.