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Research Article

EVALUATION OF EFFICACY OF *OOSHAKADI LEKHANA BASTI* IN HYPERLIPIDAEMIA - A SINGLE BLINDED RANDOMIZED CONTROLLED STUDY

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ABSTRACT

Disorders of lipid metabolism and obesity are reported by 30% to 40% with increased prevalence. These conditions are co-related with *Medo-pradoshajavikara* - a condition leading for excess formation of *Meda* (lipids) directly from *Amarasa Dhatu* (improperly formed chyle) and travel all over body through blood circulation. This stage is compared to hyperlipidaemia where it is defined as excess circulation of lipids in blood. The present study highlights the efficacy of *Ooshakadi Lekhana Basti* (type of therapeutic enema) processed by *Ooshakadigana Dravya*s (alkaline substances). *Ooshaka* (alkaline sand) was special drug and used almost for first time which is synonymously known as *Kshara Mrittika*. A single blinded controlled study has been conducted on 45 patients randomized in to three groups each containing 15 patients. The control drug was atrovastin. Average mean reduction of lipids were found statistically significant ($p<0.05$) in the experimental groups over control group in all types of lipids except HDL which has presented increase pattern. Hence the study establishes the efficacy of *Ooshakadi Lekhana Basti* in hyperlipidaemia of obese and non-obese patients.

KEY WORDS: Hyperlipidemia, Obesity, *Medopradoshaja Vikara*, *Ooshakadi Lekhana Basti, Ooshaka, Kshara Mrittika*.

INTRODUCTION

In the present era, sedentary life style, unbalanced diet and stressful mental conditions leading to fatal diseases, resulting in irreversible complications. Disorders of lipid metabolism are increased with incidence of prevalence by 30% to 40%[1] due to gross changes in life style and food habits. It is most relevant to the population as a whole when compared to the other major modifiable coronary risk factors namely smoking and hypertension. Risk is higher at an age of 65 and above due to cumulative effect on cholesterol metabolism. Increased level of cholesterol at the age of 35 increases the risk of heart disease much more significantly than with same level at the age of 65. Framingham heart study reveals that, men are about three times more susceptible to develop heart diseases than women. After menopause women become more prone to develop C.H.D. with high levels of cholesterol. Conditions must be detected early and treated preventing the clogging of the arteries. The impact of a medical intervention should be judged through the top which it influences or ensures the long term wellbeing of a patient. This criterion of long term welfare of patient is being ignored in the present modern system. The practitioners of this system are not really satisfied when they face chronically frustrated patient with serious side effects. Therefore now–a-days global interest is developing towards alternative medicine, especially Ayurveda to face this challenge as it protects patients against such frustration.

NEED AND SIGNIFICANCE

Reports are now available of angio-graphically evaluated trials of lipid lowering strategies and drugs in patient with hyperlipidaemia and known coronary artery disease. These studies have conclusively documented a marked decrease in the progression of coronary atherosclerotic lesions, modest regression and a moderate reduction in coronary events. Several drugs are available for the management of hyperlipidaemia. Most of the drug used in this condition are potentially toxic, costly and are contraindicated in hepatic or renal impairment, gall bladder disease and pregnancy.

Adverse effect of these drugs include reversible myositis, non-specific malaise, impotence, gall stone formation etc., At this juncture Ayurveda can intervene by modifying the risk factors aiming at the prevention of CAD.

Hyperlipidaemia can be correlated to *Medopradoshaja vikara* (disorder of improper lipid metabolism). It is a condition caused by derangement of *Agni* (digestive fire), that leads to formation of *Amaannarasa*(improper formation of chyme). The *Amarasa* with *Madhura Rasa Bhavadhikya* (increased sweet taste) is similar to *Kapha* and *Meda Dhatu* (lipid tissue). This undergoes unique manifestation of *Dhatu Davyamti Kramyam* pathology (direct conversion of *Aama Rasa* in to *Meda Dhatu* avoiding formation of *Rakta* (blood tissue) and *Mamsa* (muscle tissue)). This causes abnormal excess formation of *Meda* which will be sent for circulation[2]. This particular stage is correlated with hyperlipidaemia, which has increased circulated lipids in the blood. In later stages if pathology is not arrested, it is believed that lipids get deposited in the localized areas or all over the body resulting in the formation of adipose tissue and called as *sthoulya*[3]. Many therapeutic measures were mentioned in classics but *basti* (therapeutic enema) has got very prominent role in this pathology. Though it is a prime treatment for *vata* it also acts on *pitta, kapha, rakta* and *sannipataja vyadhis* (combination of all *doshas*)[4] with diversified actions by multiple combinations and permutations.[5]Here the type of *basti* is "*Lekhana Vasti*"[6] with *"OoshakadiGana Dravyas"*[7]*.* Here all the drugs possess qualities opposite to *Meda Dhatu* and *Teekshana* (most potent) in nature, *Tejo Guna Pradhana* (predominant of increasing the ability of digestive fire). This increases the *Jataragni* leading to metabolism of *Snigdhamsha* (unctuous) *Meda* and *Rukshana* (drying) of *Meda*, by *Lekhana* (scraping) and *Chedana* (dissipating / clearing) action because of which the *Meda* in circulation will be decreased.

With this classical background this study is planned to find the role of *Ooshakadilekhana Basti* in the management of *Medopradoshajavikara* w.s.r to hyperlipidaemia.

AIMS AND OBJECTIVES

- To evaluate the role of *Ooshakadi Lekhana Basti* in the management of *Medopradoshaja Vikara* w.s.r to hyperlipidaemia.
- To ascertain the lowering of lipid levels in obese patients and non-obese patients.
- To compare the efficacy of Ayurvedic *Panchakarma* procedure -*Lekhana Vasti* with an allopathic anti-hyperlipidaemic drug.

MATERIALS AND METHODS

Procurement of Raw materials

1. This includes the collection of raw materials required for the formulation of "*Ooshakadi Lekhana Basti*".
2. Preparation of the *MoorchitaTila Taila* (processed sesame oil, *Triphala Kashaya* (decoction of Triphala), *Ooshaka* (alkaline sand ash), *Yavakshara* (ash of barleyplant), *Shodhana* (purification) of *Aavapadravyas* (metallic substances) and collection of *Gomootra* (cow's urine) required for *Basti*
3. Systematic preparation of the amalgamation of *Nirooha Basti Yoga*[8] called "*Ooshakadi Lekhana Basti*".

1. ***MoorchitaTila Taila :*** Drugs required for *Moorchana* are collected and tila tila is processed according to the classical reference in order to remove bad odour and make devoid of *Amadosha lakshanas* (toxic properties)[9].
2. ***Triphala Kashaya:*** Equal quantity by weight of *Amalaki (Emblica officinalis*), *Haritaki* and *Vibhitaki* (*Terminalia chebula*) were powdered and mixed. 1 part of above powder was taken with 16 parts of water and reduced to ¼th of it to prepare *Triphala Kashaya.*[10]
3. ***Yavakshara& Aavapa Dravya:*** *Yavakshara & Aavapa Dravyas* (except *ooshaka*) were procured directly from Manjeri Pharmacy, Hukkeri. *Aavapa Dravyas* included in the formulation are
   I. *Ooshaka*
   II. *ShuddhaShilajitu*
   III. *Shuddha Kasisa*
   IV. *ShuddhaTutta*
   V. *ShuddhaHingu*
   VI. *Yavakshara & Sarjakshara* (due to unavailability of *Sarjakshara; Yavakshara* was added in the proportion of 2 parts).
4. **Preparation of *Ooshaka:*** *Ooshaka* was considered as *Ooshara Kshara* which is having synonym of *Shilajatu*. But literal meaning of this drug is *Kshara Mritika*. The senile sand was collected which is called *TouduMannu* in local languages. This was processed according to *Ksharavidhi* as specified in the classical text "Rasajalanidhi"[11]
5. Fresh *Gomutra* was collected which passed for first time in the morning from a healthy cow and filtered.
6. **Preparation of *Niroohavasti Yoga*:** The following ingredients were collected and triturated in the same order with uniform direction, pressure and speed[12]

Table 1: Ingredients used for Nirooha Basti

S.No	Name of ingredients	Actual Dose	Altered Dose
1.	*Makshika*(Honey)	*1 pala* = 46 ml	11.5ml
2.	*SaindhavaLavana*(Rock salt)	*1 aksha* = 12 g	6 g
3.	*Sneha =Moorchitatila taila* (Sesame oil)	*6 pala* = 288 ml	72ml
4.	*Kalka = Yavakshara*	*3 pala* = 144 g	36g
5.	*Drava dravya = Triphalakwatha*	*5 pala* = 240 ml	200ml
	Gomutra	*3 pala*=144 ml	50ml
6.	*Aavapa dravya = Ooshakadigana dravyas*	*1pala X 6* = 268 g	6-7 g
7.	Total	*24 palas*	6palas= 300ml

7. ***Anuvasana Basti*** **(retention enema):**

MoorchitaTila Taila was used for the administration of *Anuvasana Basti*.

Materials or tools for therapeutic intervention:

- *Basti yantra* and *Basti putaka* (Devoid of Doshas)
- *Basti yantra* includes enema can and catheter of suitable size for administration of *Nirooha Basti*
- Glycerene enema syringe with catheter was used for administration of *Anuvasana Basti*

METHODOLOGY

Clinical study

Research approach

In the present study, the objective is "Role of *Ooshakadi Lekhana Basti* in management of *Medoprdoshaja Vikara* w.s.r. hyperlipidaemia". The efficacy can be determined by finding out difference between experimental group and control group.

Study design: Randomized Controlled clinical study

Source of Patients: Patients attending O.P.D and I.P.D of Sri Jayachamarajendra Institute of Indian medicine, Bangalore.

Inclusion Criteria

- Patients aged between 18-60 years of both sexes presenting with hyperlipidaemia (increase of all types of lipids).
- Hyperlipidaemia with or without obesity
- Patients who are eligible for *Basti Karma according to classics*.[13]

Exclusion Criteria

- Patients with systemic disorders like diabetes mellitus, diabetes insipidus, coronary artery disorders etc.
- Patients being obese due to other conditions like endocrinal disorders, hormonal therapy etc.
- Patient with any rectal pathology like piles, fistula, fissure, carcinoma.

Consent: Informed consent was obtained from the patient before starting the study.

Grouping:

Patients were selected for the trail studied under three groups, each containing 15 Patients. Group "A" & group "B" are experimental groups and group "C" is Control group.

Group A: Patients with hyperlipidaemia, associated with obesity.

- *Kalabasti* with *6 Nirooha Basti* and 10 *Anuvasana Basti* was administered. *Pariharakala* (Time period to be on rest) was advised for double the duration of administered period of basti i.e. 20 days.

Group B: Patient with hyperlipidaemia and not associated with obesity.

- *Kalabasti* with *6 Nirooha Basti* and 10 *Anuvasana Basti* was administered. *Pariharakala* (Time period to be on rest) was advised for double the duration of administered period of basti i.e. 20 days.

Group C: Patients with hyperlipidaemia with or without obesity were administered with an anti hyperlipidaemic drug called atrovastin. Dose was depended on the lipid levels.

Method of assessment:

- Evaluation of lipid profile for all groups was advised 1 day before and 20 days after the administration of treatment.

Grading of Lipid profile assessment

- All lipid profile in normal limits with increased H.D.L– Good response.
- All lipids profile in normal limits with decreased H.D.L– Moderate response.
- Increase in all lipid parameters with H.D.L increase – Mild response.
- All lipids increased with H.D.L decrease – Poor response.

Table 2: Schedule of Administration of *Basti*

Part of the Day	1	2	3	4	5	6	7	8	9	10
Morning (Empty Stomach)		NB	NB	NB	NB	NB	NB			
After Food	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB

NB = *Nirooha Basti*, AB = *Anuvasana Basti*

Mode of Administration of *Basti*

Anuvasana basti alone was administered on first and last three days. Alternative administration of *Nirooha* and *Anuvasana basti* performed from second day to seventh day. *Nirooha Basti* was administered in empty stomach. After *basti Pratyagamana* (expulsion of *Basti Dravya*), *Laghu Aahara* (light food) was given for consumption and immediately *Anuvasana Basti* was administered.

Method of Administration

***Poorva Karma* (pre-operative)**

- Above mentioned materials were collected.
- Preparation of Enema can and catheter attached without any defects.
- *Aatura Siddha* (Patient concern activities) – Patients visited to hospital with empty stomach. *Sthanika Abhyanga* (local oleation) to *Udara* (abdomen) & *Sphik* (gluteal region) with *Moorchitatila taila* (sesame oil) followed by *SthanikaNadiSweda* (local sudation) with *Dashamoola Siddha Kwatha* (decoction processed by *Dashamoola*).
- *Ooshakadi Lekhana Basti SammelanaVidhi* (preparation of *Nirooha Basti Yoga*)-
- The different components of basti were mixed in the following way. Dose of different drugs were considered according to strength of patient as explained earlier.
  - 1st step – *Madhu* and saindhava lavana were triturated thoroughly in *Khalwa Yantra*.
  - 2nd step – Then *Moorchit Tila Taila* was added mixed slowly and uniformly.
  - 3rd step –*Yavakshara* added little by little and triturated.
  - 4th step – Fresh and clasically prepared *Triphala Kwatha* was added gradually.
  - 5th step –*Gomutra* to be added after proper mixing of *Kwatha*.
  - 6th step – The above mentioned *Aavapa dravyas* are sprinkled in the final amalgamation.

This unique preparation was attained without sedimentation. Triturating was performed in unilateral direction, pressure and speed by same person. The amalgamation was indirectly heated to luke warm temperature.

***Pradhana karma* (operative procedure)**

Position of patient: Patient was advised to lie on the table in *Vama Paarshwa* (left lateral position with right leg flexed) and asked to take deep breath with left hand beneath head. The rectal orifice was anointed with cotton gauge dipped in luke warm oil.

***Basti Yantra* with *Basti Dravya*:** *Sukoshna Basti Dravya* was filled in to the enema can and care was taken for removing air from the catheter. Proper lubrication of catheter was performed.

***Basti Pranidhana* (Administration of *Basti*):** *Sukoshna Vasti Dravya* was administered gradually with uniform speed. Care was taken that medicine was not administered completely at the end. *Vasti Vyapaths* are avoided by taking proper care. The time of administration was noted and checked for any complications during procedure.

***Basti Pratyagamana*:** *Pratyagama Kala* (time of expulsion of administered contents) was recorded. Maximum retention period was 3-4 minute.

***Paschat karma* (post-operative):** Patient was advised to maintain diet regimen in *Vasti Parahara Kala*.

RESULTS

Table 3: Over All Mean Assessment of Lipid Profiles in all Groups

OBJECTIVE	Gropu-A		Group-B		Group-C	
	BEFORE	AFTER	BEFORE	AFTER	BEFORE	AFTER
T.Cholesterol	227.85333	190.806666	242.0666	200.7333	236	209.7
Triglycerides	210.68666	166.95333	187.9333	141.8666	162.4	122.2
HDL	46.83333	48.36	50	52.857	42.9	39.3
L.D.L	138.73333	119.53333	146.4	123.2	156.666	132.866
V.L.D.L	40.3285	31.0000	38.0933	30	33.0333	28.0933
Chol:H.D.L	5.01	4.0333	4.915	4.15	5.341	5.008

Table 4: Showing the individual study of group 1 by using paired t-test

Parameter	Mean	SD	SE	t-value	p-value	Remarks
Total cholesterol	37.4466	33.5609	8.665	4.3215	<0.001	H.S
Triglycerides	60.2660	52.1213	13.457	4.478	<0.001	H.S
H.D.L	4.4733	2.3398	0.6041	7.4048	<0.001	H.S
L.D.L	19.2	23.683	6.11	3.142	<0.001	H.S
V.L.D.L	11.6266	13.5858	3.5078	3.3144	<0.005	H.S

Table 5: Showing the individual study of Group 2 by using paired t-test

Parameter	Mean	SD	SE	t-value	p-value	Remarks
Total cholesterol	47.866	37.3016	9.631	4.97	<0.001	H.S
Triglycerides	47.4	35.192	9.0867	5.2164	<0.001	H.S
H.D.L	7.8666	4.7639	1.23	6.3956	<0.001	H.S
L.D.L	23.2	30.599	7.9	2.936	<0.001	H.S
V.L.D.L	8.36	6.6117	1.7071	4.897s	<0.005	H.S

Table 6: Showing the individual study of Group 3 by using paired t-test

Parameter	Mean	SD	SE	t-value	p-value	Remarks
Total cholesterol	35.766	29.767	7.6859	4.653	<0.001	H.S
Triglycerides	42.466	30.2486	7.810	5.437	<0.001	H.S
H.D.L	8.1	5.676	1.4656	5.526	<0.001	H.S
L.D.L	23.8	29.737	4.911	3.099	<0.001	H.S
V.L.D.L	9.1466	7.897	2.0391	4.485	<0.001	H.S

Table 7: Showing ANOVA table for parameter H.D.L

Source of variation	Degrees of freedom	Sum of squares	Mean sum of squares	F-calculated Value	F-Table Value	P-Value	Remarks
Treatments	2	1503.409	751.7045	5.581	3.23	<0.05	H.S
Error	42	5656.783	134.685				
Total	42	7160.1972					

Table 8: Shows which group is significant for the parameter

Group	Difference from	Difference from	Difference from
2	53.333*	----------	
1	48.36*	4.97	
3	39.366*	13.946*	8.994*

Table 9: Showing ANOVA table for parameter triglycerides

Source of variation	Degrees of freedom	Sum of squares	Mean sum of squares	F-calculated Value	F-Table Value	P-Value	Remarks
Treatments	2	15094.89	7547.445	2.7218	3.23	<0.05	H.S
Error	42	116461.19	2772.88				
Total	44	131556.08					

Table 10: Shows which Group is significant for the parameter

Group	Difference from	Difference from	Difference from
3	122.2	----------	-----
2	141.866	-19.666	------
1	166.953	-44.753	------

Table 11: Showing ANOVA table for parameter V.L.D.L

Source of variation	Degrees of freedom	Sum of squares	Mean sum of squares	F calculated Value	F Table Value	P-Value	Remarks
Treatments	2	328.400	1.642	1.453	3.23	<0.05	H.S
Error	42	4745.54	112.989				
Total	44	5073.94					

Table12: Shows which group is significant for the parameter

Group	Difference from	Difference from	Difference from
3	24.793	----------	-----
2	30.00	-5.207	------
1	30.933	-6.14	------

Statistical analysis

To compare the mean effect of the treatments the statistical analysis was done by using F-test by assuming a completely randomized design and for the analysis purpose the mean effect was same in all the three groups. Further to know which pair of treatment is significant the analysis was done by using Least Significance Different method (L.S.D). To compare control group and experimental groups the statistical analysis was done by using Dunnets's test. To know the effect of the treatment procedure within the control and experimental groups the statistical analysis was done by assuming that the treatment procedure is not responsible for the changes in the observation before and after the treatment. Further to know which group is more effect in treatment procedure comparison of t-values were considered. After thorough analysis of results it was observed that group-A and group-B were indicating better results over group-C. Among the 3 groups, group-B was suggestive of better treatment effect on lipid profile than group-A & C.

DISCUSSION

The present study demonstrates the incidence of age group between 41-50(66.6%) years with sexual distribution of increased female ratio (60%) pertaining to menopausal age. The hormonal imbalance during menopausal age or the diet habits interfere in the women and are more prone to this disease as relation exists between hormones and metabolism of lipids. But it's not possible to conclude the fact because of small sample size and limited type of population attending the out-patient department. Genetic and chromosomal abnormalities in hyperlipidemia are to be considered as the study suggests the positive family history of 17.7% which infers the role of *beeja swabhava*[14] (genetic factor) in concern to *Matrujabhava* (maternal factor) as *Sowmya Dhatu* (soft tissues like lipid tissues) are contributed by them [15]. The predisposing factors like *Snigdha Dravyas* (unctuous substances) (44.4%) followed by *Sheeta* (cold in potency) (31.1%) and *Guru Dravyas* (heavy for digestion) (24.4%)[16, 17] were present abundantly in diet of these patients with typical dietary patterns of *Adhyashana*[18] (excess-eating), *Vishamashana* (uncongenial diet) and *Samashana* (combination of both wholesome and unwholesome diet) type. *Atisampoorana*[19,20] (eating before the digestion of previous food), *Ajeernaaahara* (improperly cooked food) were elicited among the different types of *Adhyashana* in this sample of population as the major causative factors for *Medovriddhi*. The increased occurrence of *Teekshanagni* (increased rate of basal metabolism) presentation with 33.3% defines the role of neuro-transmitters. A number of neurotransmitters afferent and efferent signals plays vital role in energy intake and metabolism. Decreased sympathetic activity, increased level of insulin and disturbed serum leptin concentration causes excessive hunger in *Medovriddhi*. Ayurveda has explained this phenomenon in terms of vitiation of *Vata* by obstruction of its path due to *Meda* leading to *Tikshnagni*. The mentioning of *Madhura Rasa* as important predisposing factor for *Medovriddhi* can be evident by the occurrence of 40% of the study sample indulging in the consumption of this type of *rasa*[21]. Lifestyle and sleep pattern[22, 23](day sleep & excess sleep) are very important causative factors for vitiation of *Meda* that can be well substantiated with the incidence of 33.3% & 22.2% respectively. Here the pathology is due abnormal vitiation of *Kapha* because of day sleep and excess sleep. And also the association of *kapha* as inherent factor in pathogenesis of dyslipidemia is understood from the type of *Prakruti*as presented in the study sample were *kapha-Vata Prakruti* (44.4%), *Vata-kaphaPrakruti* (33.3%), and *Pitta-kaphaPrakruti* (11.11%). Most of them are associated with *Kapha Dosha* as *Pradhana Prakruti* which inherits the *Medopradoshaja Vikara*.

The mean %age of improvement in the Total Cholesterol (20.58%), Triglycerides (32.47%), H.D.L (5.89%) and L.D.L (18.33%) is more in the Group 2 (hyperlipidemia without obesity) where as V.L.D.L. (33.53%) in Group 1 (hyperlipidemia with obesity). From the analysis the parameters H.D.L. shows high significance i.e. the mean treatment effect of three groups is not same (as $p<0.05$ from table – 7 & table - 8). All the treatment effects are not same. The highest mean effect of 53.33 in Group-B, if among choice is to be made in three groups then group-B is best and most effective in H.D.L. parameter as mean value is more than L.S.D value. From the table 9 and 10, of all the three groups mean value of first group exceeds control mean value significantly; treatment of group-A is good for significant effect on Triglycerides. From table 11 & 12 of all the three groups mean value of first group exceeds group-C mean value significantly; treatment of group-A was effective and significant effect on V.L.D.L. Rest of the parameter not significant as $p>0.05$.

Student's paired t-test demonstrates that all parameters of group-A shows highly significance from table 4 (as $p<0.05$). Among Lipid profiles the parameter H.D.L is highly significant than the other parameters (by

comparing t values). From table 5 all parameters of group-B show high significance than the other with less variation (by comparing t and SD values), where as the parameter of total cholesterol shows more net mean effect. From table 4 H.D.L parameters of group-C shows less variation and total cholesterol indicates net mean effect. Further to know which group was more effect in treatment procedure comparison of t-values from tables-4 was considered. Among the parameters of lipid profile total cholesterol was more significant in group-B, triglycerides in group-C, H.D.L in group-A, L.D.L in group-B and V.L.D.L was highly significant in group-B. With above treatment results it is evident that *Ooshakadi Lekhana Vasti* is efficient in management of *Medopradhoshaja Vikara* w.s.r to hyperlipadeamia.

Probable mode of action of *OoshakadiLekhana Vasti*

Basti Karmukata (mode of action) understood at different levels of the body like *Dosha, Dhatu, Mala* and in different *Roga-margas*[24] (different routes involved in diseases). The multidimensional actions[25]exerted by the *Basti* are due to the usage of various combinations of drugs[25]. The specific formulation called "*Ooshakadigana*" *dravya* mainly possesses *Katu*, *Tikta, Kashaya Rasa* (different inherent tastes of the drugs). *Ushna, Teekshana, Laghu, Rooksha Gunas* are the inherent qualities with *Ushna Veerya* (potency) and *Katu Vipaka* (taste exerted at the end of digestion). These properties are *Tejo Guna Prahana* and are understood to act at the level of *Jataragni* (digestive fire) enhancing the *Dhatvagni* (metabolism). Thus the formation of *Ama Rasa* is avoided and sequential formation of *Rasa, rakta* is achieved resulting in decreased production of *Medadhatu*. Further it will not cause the occlusion (*Aavarana*) of *Vata* which will not cause increased appetite which is usually set-in due to *Jataragni deepti.* Hence avoiding the patient in indulging in the causative factors. The *Tila Taila* administered, in obese persons enters minute channels and does *Kshapana* of *Meda* by the *Sukshama, Teekshana*, *Ushna Gunas* and also has ability to acquire the properties of the other drugs by *Samskara*. The *Moorchita Tila Taila* has the *Vyavayi Guna* (fast spreading nature) along with the above specified qualities where the absorption is facilitated, carried all over the body performing the required function of *Lekhana* (scraping) and *Rookshana* (drying) leading to *Nasha* of *Meda* (cleansing the accumulated lipids).The *Kshara Guna* (alkaline property) effect of *Gomutra, Yavakshara* is increased by the synergistic effect of *Ooshakadi Gana* drugs as they also possess similar properties. The complete and final product of *Nirooha Basti* is a hyper tonic solution. After entering in the large intestine it creates the osmotic pressure gradient, favoring the body fluids transfer from hypotonic to hyper tonic solutions along with toxic materials like LDL cholesterol. This phenomenon preferably helps to drag the toxins (unwanted metabolites) from inter intra cellular levels to large intestine and are eliminated out of body. This LDL cholesterol has the affinity for toxins and thus becomes harmful in the body.

Rectum being rich in vasculature and the unique preparations of *Nirooha Yoga,* the drugs are absorbed and cross the rectal mucosa through selective permeability. The major active principles present in the above formulation are of alkaline nature. This normalizes physiological P^H of rectal mucosa facilitating for growth of bacterial flora which results in the stimulation of enzymes for the proper metabolism of cholesterol in to corpasterol. Most of the ingredients used in the formulation have been screened for anti-hyperlipidaemic activities. Honey was tested for anti-hyperlipidaemic activity by pre-clinical trials on rats and proven efficacious.[27,28]. Sesame protein isolated from *Sesamum indicum* found to be producing the anti-hyperlipidaemic activity in normal and high cholesterol diet fed rats[29]. A study established hypolipidaemic activity of *Triphala* in an experimentally induced hypercholesteremic rats on all the lipids and free fatty acids[30]. As mentioned above it is proposed that the drugs absorbed either reaches portal circulation through superior haemorohoidal veins from upper rectal mucosa or directly enters into the systemic circulation through middle and inferior rectal veins from lower rectal mucosa. These active principles that reaches liver, stimulates production of bile salts resulting in regularization of emulsification of fats thus avoiding fatty accumulation in liver and in blood cells. The active principles directly entering in to circulation reduces the density of blood (*Sandrata*) by scraping the lipids in blood vessels with their alkaline property. Thus avoids the narrowing of arteries (atherosclerosis) which is major risk factor of CHD.

Large intestine contains maximum number of nerve plexuses and lumbo sacral plexus that spread all over the body. *Vata Dosha* is considered to be the entity of functions performed by the above plexuses in the present context. Here by the virtue of *Basti* treatment *Vata* is channelized, causing stimulation of particular endocrine glands to release their enzymes like pancreatic lipase, acetyl-a coenzyme which are responsible for metabolism of lipids. *Basti Dravyas* are absorbed into *Sira* or *Rasayani* (channels) that generally carries *Rasa* along with *Rakta*. The increased *Meda Dhatu* also goes to *Deha Sanchari* (travel all over the body) through these *Sira* and *Rasayini*. It is perceived as increased lipids circulating through *Rasa* and *Rakta*. Hence the drugs administered in the form of *Basti* have effect even on *Rakta Dhatu* which is having the increased circulating lipids. Contributions in genetic factors - The gene responsible for familial hyperlipidaemia produces defective L.D. L receptors the cell to catch hold of the

LDL cholesterol. Thus results in the accumulation of LDL cholesterol and rapid buildup of fatty deposits in the arteries. Genes are mainly made up of protein molecules; even the *Basti* formulation administered was rich in protein. So it may alter the genetic code and development of proper receptors resistant lipase etc., that might have occurred which is yet to be tested for significances.

Alteration of Dose: The *Yoga* possesses *Teekshana Dravyas* (most strong and potent). The doses of ingredients are altered to *Avara Pramana* (lower dose) as the actual classical dose was not tolerable by the patients in the pilot study. The altered dose is according to the *Avara Pramana* specified for *Basti* in *Avara Bala* patients which suits for present generations.[31]

ADVERSE EVENTS

Mild abdominal pain was observed which was spontaneously resolved after intake of food or after administration of *Anuvasana Basti*. Few females were presented with pre-ponement of the menstrual cycles followed by the course of *Basti* treatment.

CONCLUSION

This study concludes that, *Ooshakadi Lekhana Basti* to be effective in hyperlipidaemia and found to be more efficacious in the group of non-obese hyperlipidaemia patients. HDL was found to be increased along with the reduction of other lipids. The *Ooshaka* drug was found to be safe though it was highly alkaline in nature.

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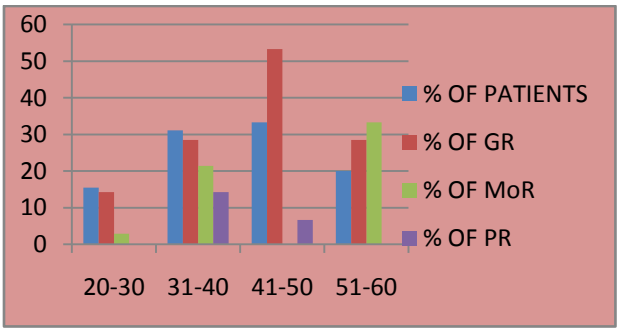
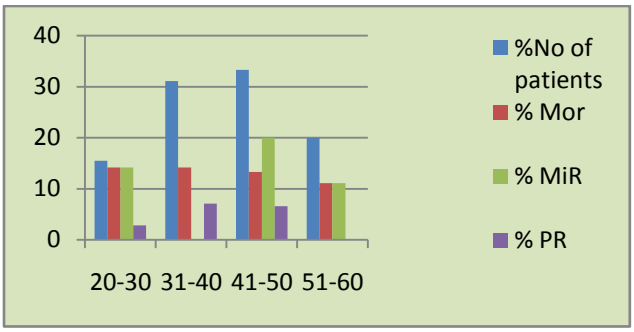
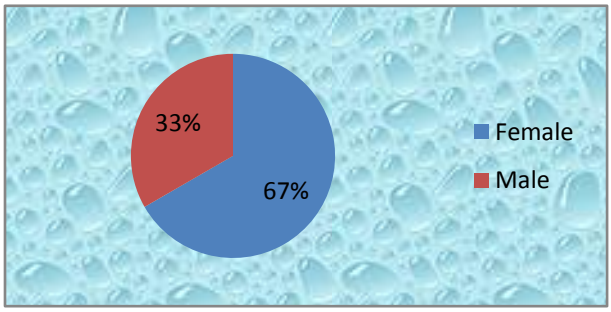
Graph-1: Showing the incidence and overall response in age of group 1 & 2



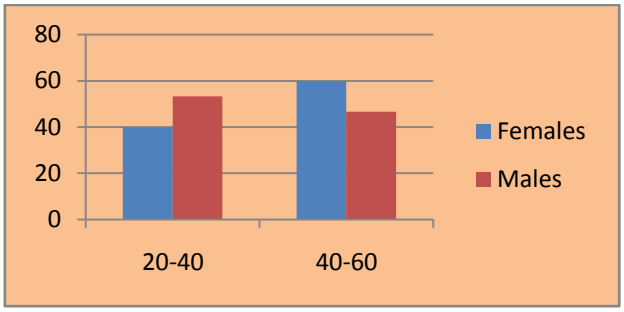
Graph-2: For group 3



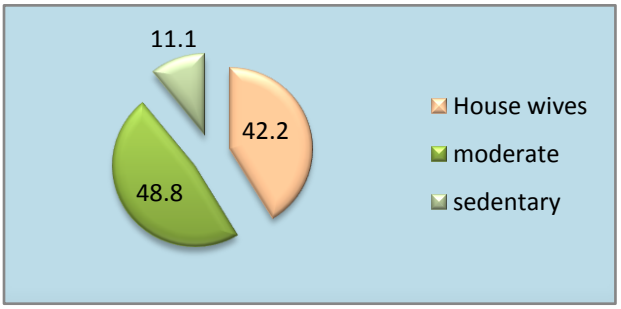
Graph-3: Showing the incidence in sex



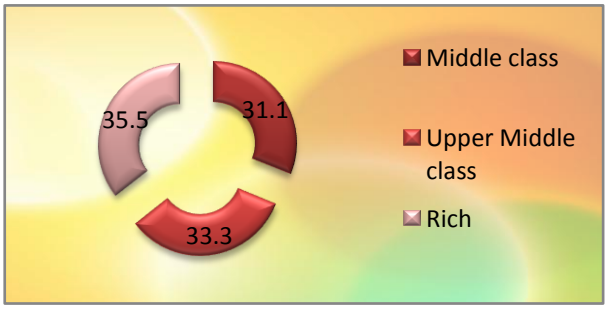
Graph-4: Showing the incidence in sex and age



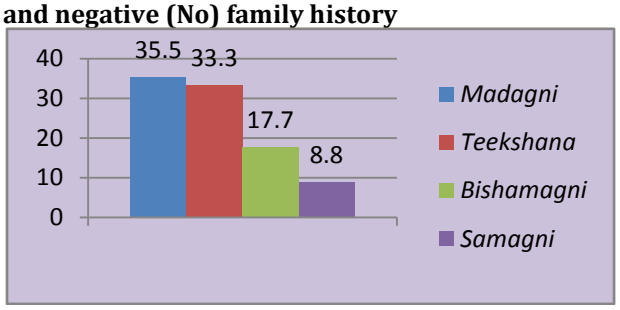
Graph-5: Showing the incidence and Over all response in occupational status



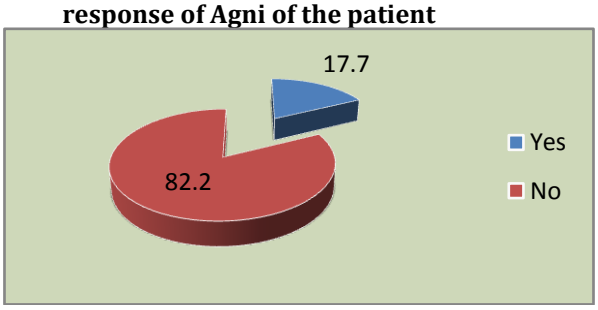
Graph-6: Showing the incidence and overall response in socio-economic status



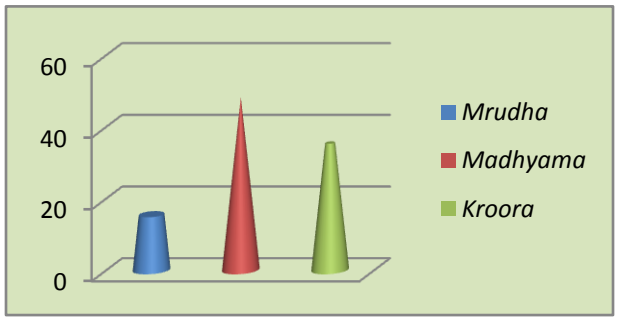
Graph-7: Showing the incidence of Positive (Yes) and negative (No) family history



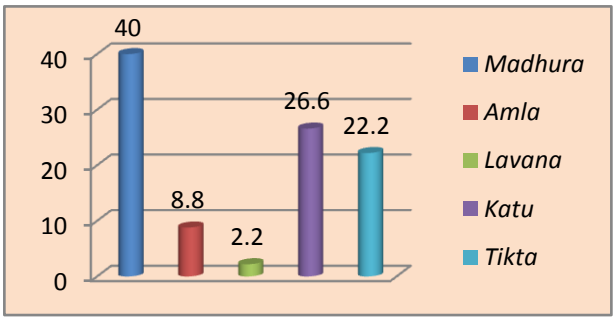
Graph-8: Showing the incidence and overall response of Agni of the patient



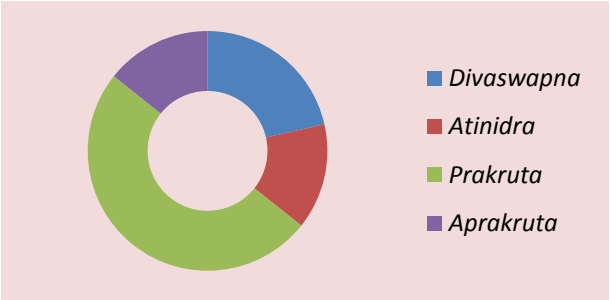
Graph-9: Showing the incidence and Overall response of Koshta of the patient



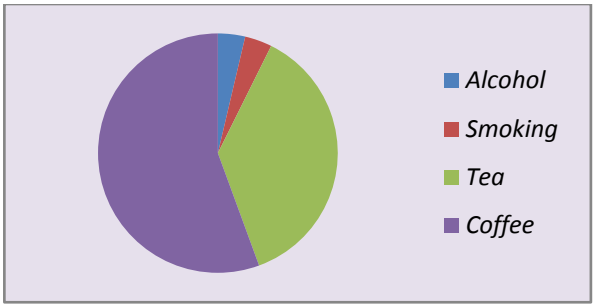
Graph-10: Showing the incidence of Predominant Rasa



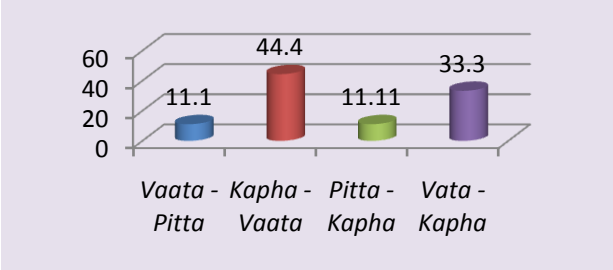
Graph – 11: Showing the incidence of in *Nidra*



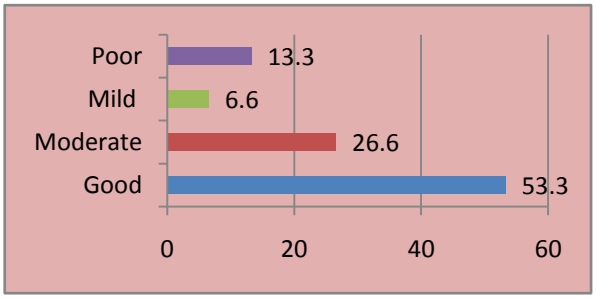
Graph -12: Showing the incidence of *Vyasana*



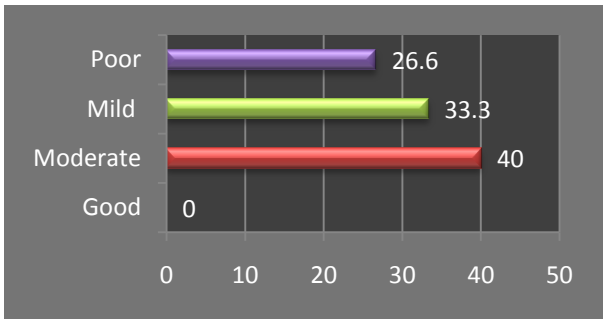
Graph -13: Showing the incidence and overall response of Prakruti of the patient



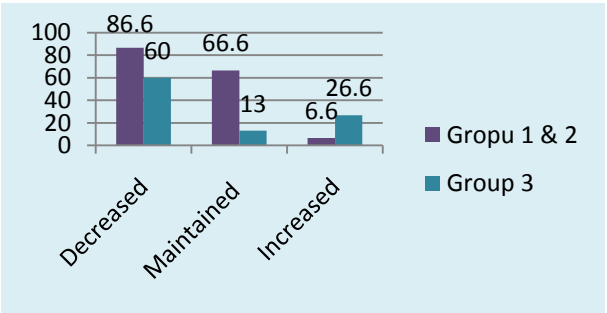
Graph-14: Showing Response of lipids in group 1&2



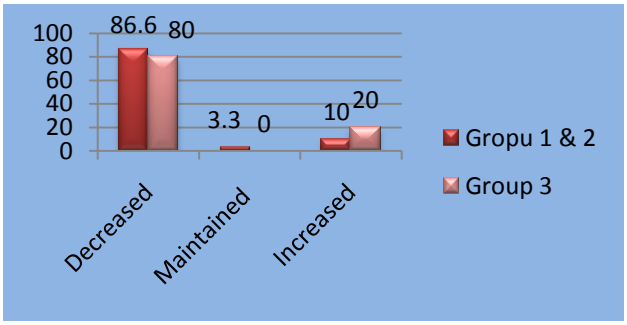
Graph-15: Showing Response of lipids in group 3



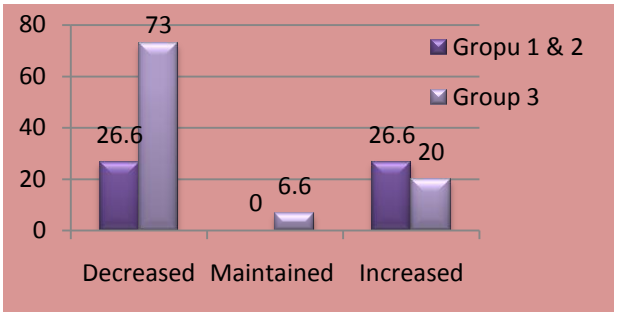
Graph-16: Showing response of cholesterol in group 1 & 2 & Group 3



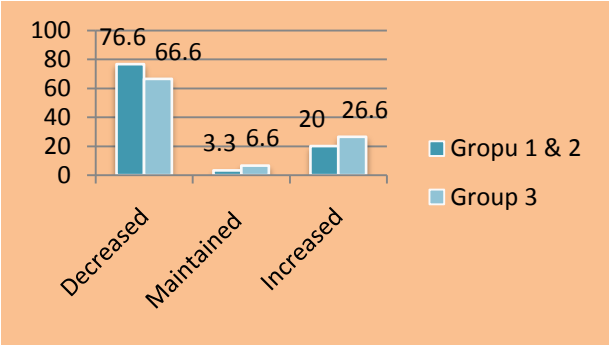
Graph-17: Showing response of triglycerides in group 3



Graph-18: Showingresponse of H.D.L group 1 & 2 and in group 1 & 2 and group 3



Graph-19: Showing response of L.D.L In group 1 & 2 and group 3



Graph-20: Showing response of V. L.D.L in group 1 & 2 and group 3