

## A COMPARATIVE CLINICAL STUDY OF MEDOHARA ARKA AND MEDOHARA ARKA ALONG WITH LEKHANA VASTI ON MEDOVRIDDHI W.S.R. TO HYPERLIPIDAEMIA

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### ABSTRACT:

**Background:** Medovriddhi (hyperlipidaemia) is an alarming health problem of modern society. It is important but modifiable risk factors in atherosclerosis, one of the major causes of hospitalization, death and loss of effective years in middle aged and older adults that affects the cerebro vascular, cardio vascular and peripheral vascular systems. **Objectives:** 1. To evaluate the effect of Medohara Arka on hyperlipidemia. 2. To evaluate the effect of medohara Arka administered after Lekhanavasti. 3. To compare the effect of both. **Method:** In the present clinical study two groups were made. In group – I, 40 patients with Hyperlipidaemia (especially raised values of either Cholesterol or Triglycerides) availing the selection criteria were selected. In this group, Medohara Arka (prepared by distillation of cow's urine only) 40ml. with 10ml. honey has been administered for 30 days. In group- II, 40 patients were selected who were fit for shodhana. In this group Lekhanavasti was administered with oral administration of medohara Arka 40ml. along with honey 10ml for 30 days. **Results:** After completion of 30 days treatment with trial drug – I, the average improvement with respect to different sign and symptoms viz. - weight, BMI, skin fold thickness, total serum cholesterol, LDL cholesterol, HDL cholesterol and Serum triglycerides were 26.6%, 26.6%, 20%, 22.12%, 8.33%, 4.17% and 0% respectively. Whereas in group II cases the average improvements were 88.3%, 65%, 63.33%, 29.41%, 14.03%, 35.55% and 15.55% respectively. **Conclusion:** The clinical assessment of result reveals that after 30 days of treatment 50% of the patients got mild improvement but rest 50% could not get any satisfactory improvement with trial drug-I where as in Group – II, 5% patients got maximum improvement, 75% moderate improvement, 15 % mild improvement and another 5% patients could not get satisfactory improvement.

**Key Words:** Medovriddhi, Hyperlipidaemia, Medohara Arka, Lekhana Vasti.

### INTRODUCTION:

The Ancient Indian Science of health, Ayurveda is now being increasingly accepted by the world at large for its facilities and adaptability even to the modern times.

Maharshi Charaka has described *Sthaulya/Medovriddhi* (Obesity) among the eight most censurable personalities<sup>[1]</sup> and *Samtarpanjanita vyadhi*<sup>[2]</sup>. In the pathogenesis of *Medovriddhi*, *Kapha (Kledaka Kapha)*, *Vata (Samana & Vyana)*, *Meda (fat/lipid)* and *Medodhatvagni Mandyata* are responsible factors<sup>[3]</sup>. The features described in Ayurveda can well be correlated with the features of hyperlipidaemia. Here "Hyper-" means "too much", "-lipid-" means "fat"; and "-aemia" means "blood"; so Hyperlipidaemia is a medical jargon for increased concentration of lipid in the blood<sup>[4]</sup>.

The most common problem with hyperlipidaemia is accelerated arterial disease. Patients with severe, untreated hyperlipidaemia are at higher risk of heart attacks at an early age. Less severe forms will accelerate the development of occlusive arterial diseases. It is important as one of the three main

modifiable risk factors for CVD (the others being smoking and hypertension).

Two large studies "The Scandinavian Simvastatin survival study" by Sheppard et al., 1995 and "The long term Intervention with pravastatin in Ischemic Disease" 1998 concluded that CHD mortality can be reduced by 30% to 40% by reduction of LDL-C. Increase in HDL-C in patients with average LDL-C levels was found to reduce CHD mortality by 20% to 35% (Downs et al 1998; Rubins et al., 1999)<sup>[5]</sup>

Many theories have been postulated with many new hypotheses describing the disease *Medovriddhi* (Hyperlipidaemia) in Ayurveda as well as in modern

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science, still there is enough scope to work out on aetiopathological and management aspect of this disease entity. In modern medical science its management aspect remained symptomatic with troublesome side effects.

Whereas recent studies show that Cow's urine distillate has a potent bio enhancer, activity enhancer and availability facilitator action [6]. All these facts inspired me to choose this drug for clinical trial in one group, which is proved effective after completion of study.

Similarly, *Lekhanavasti* is well accepted procedure for the management of *Medovridhi*. However, many research works have already been conducted on the various types of *Lekhanavastis* with positive results. Hence, in the present study, I have administered *gomutraarka* (Cow's Urine distillate) along with *lekhanavasti* in the second Group and the result obtained after completion of trial is quite encouraging.

#### OBJECTIVES:

1. Therapeutic evaluation of *Medohara Arka* on Hyperlipidaemia.
2. Therapeutic evaluation of *Medohara Arka* along with *Lekhanavasti* on hyperlipidaemia
3. To compare the effect of both the groups.

#### MATERIALS AND METHODS:

**Study Design:** Randomized uncontrolled comparative clinical study

**Study sample:** Patients belonging to the Puri district

**Sample size:** 95

**Selection of Patients:** Out of 95 cases screened total 80 cases were registered for the study (selected from O.P.D. and I.P.D. of Gopabandhu Ayurveda Mahavidhyalaya, Puri) availing selection criteria. All the patients were divided into two groups G (1)& G (2) maintaining parity depending on age, sex and severity as mentioned below.

Group	Number of cases	Drugs
G <sub>(1)</sub>	40	<i>Medohara Arka</i> 30ml. with honey 10ml.
G <sub>(2)</sub>	40	<i>Lekhanavasti</i> (8 Vastis) along with <i>Meddohara Arka</i> 30mi. and honey 10ml.

**Method of Preparation:** Trial drug 1 (*Medohara arka* prepared from *gomutra* only)<sup>[7],[8]</sup>

Distillation method (*Arka Kalpana Vidhi*)

#### LekhanaVasti:<sup>[9]</sup>

##### Ingredients:

- Madhu(Honey) - 80ml.
- SaindhavaLavana(Rock salt) - 15gm.
- Tila tail (sesame oil) - 120ml.
- Gomutra(Cow's urine) - 160ml.

Kwath (decoction) 160 ml. prepared from following ingredients,

- Haritaki (*Terminaliachebula*)
- Amalaki (*Emblicaofficinalis*)
- Vibhitaki(*Terminalliabellerica*)
- Vacha (*Acoruscalamuslinn*)

**Preparation:** Prepared following the sequence of *Asthapana Vasti*

##### Inclusion Criteria

1. Age- 16-60 yrs.
2. Sex - Both the sexes
3. Body mass index (B.M.I.): Weight (kg)/ Height (Mt)<sup>2</sup>
  - a. Male - 25 or more
  - b. Female - 23 or more
4. Lipid profile consistent with Fredrickson type hyperlipidemia: total cholesterol greater than or equal to 200 mg%, LDL-C greater than or equal to 100 mg/dl; triglycerides more than 150 mg/dl; HDL less than 40mg/dl

##### Exclusion Criteria

1. Any concomitant condition which preclude the patient from successfully participating in the study;
2. Pregnant or breast feeding;
3. Participation in another clinical trial within 30 days from initiation of the study;
4. Known cardiac disease including: congestive heart failure, cardiac arrhythmias, unstable angina, myocardial infarction within the last 6 months, or uncontrolled malignant hypertension;
5. High risk of developing coronary artery disease;

6. Any condition affecting a major organ system, such as liver or kidney disease or malignancy;
7. Uncontrolled diabetes mellitus or newly diagnosed patients (within 3 months) or recent change in anti-diabetic pharmacotherapy within 3 months of screening;
8. Evidence of active renal disease indicated by serum creatinine > 2.0 mg/dL;
9. Known HIV or Hepatitis B or C positive patient;
10. Concurrent use of corticosteroids; Allergy or intolerance.

**Type of study** - Single blind clinical trial.

**Assessment Criteria**<sup>[10]</sup>

Assessment was made on the basis of a progress in cardinal clinical features and other biochemical parameters as mentioned below.

- Total serum cholesterol
- LDL cholesterol

- HDL cholesterol
- Total serum triglycerides

**Assessment of Result:**

The assessment of progress was noted at 15<sup>th</sup> day and 30<sup>th</sup> day after treatment.

The result in view of percentage of improvement was classified as follows.

- a) Maximum improvement : 75% or more improvement.
- b) Moderate improvement : 50 to 75% improvement.
- c) Mild improvement : 25 to 50% improvement.
- d) Unsatisfactory : No or less than 25% improvement.

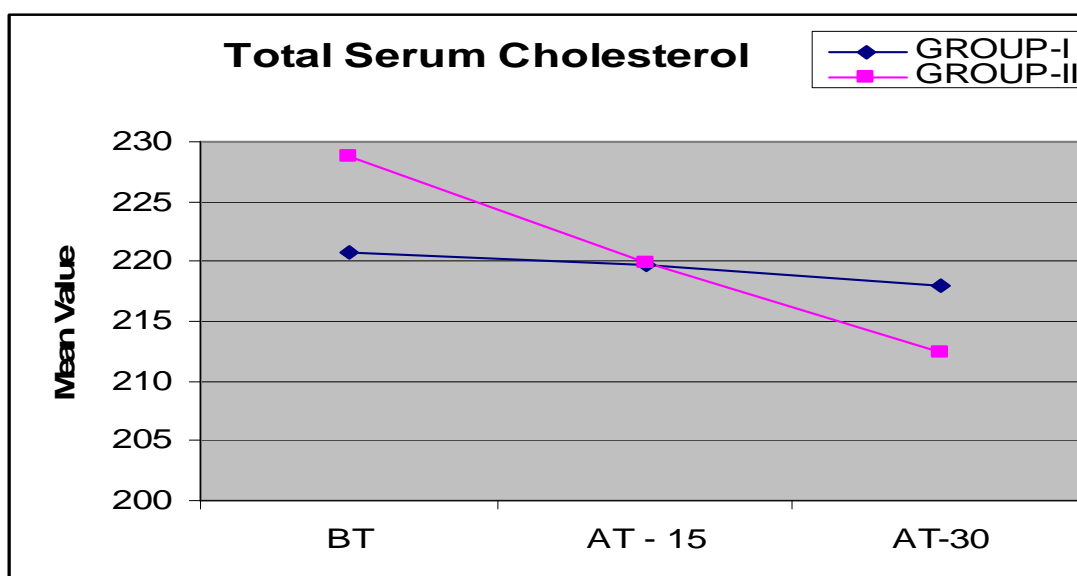
**OBSERVATIONS AND RESULTS:**

In the present observational study 80 individuals were registered to evaluate the efficacy of *Medohara Arkaas* well as *Medohara Arka* along with *Lekhanavasti* the details of which are as follows,

**Table No. 1. Statistical analysis showing the effectiveness of Group - I & Group - II treatment on serum cholesterol**

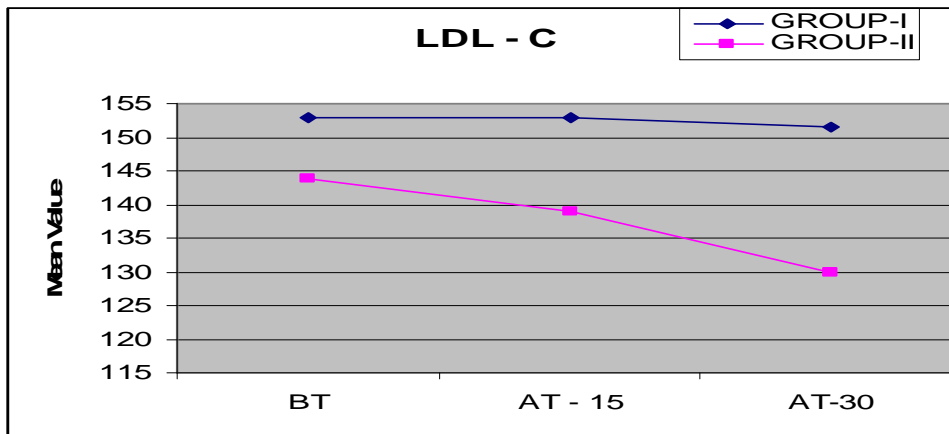
Treatment Group	Duration of treatment	Mean ± S.D.	Mean Diff. ± S.E	d.f (n - 1)	t - value	p- value
Group - I	BT	220.7±26.82		39		
	A.T(15)	219.7±27.03	0.98±0.41	39	2.39	*<0.05
	AT(30)	218.0±27.58	2.68±0.85	39	3.15	*<0.05
Group - II	BT	228.73±46.57		39		
	A.T(15)	219.85±30.999	10.28±1.81	39	5.68	**<0.001
	AT(30)	212.35±29.16	18.88±2.47	39	7.64	**<0.001

\* Significant, \*\* Highly Significant, # Insignificant, θ = just significant, S.D. = Standard Deviation, S.E. = Standard Error, d.f. = Degree of freedom, t = Test of significance, p = Probability, < = Less than, > = More than



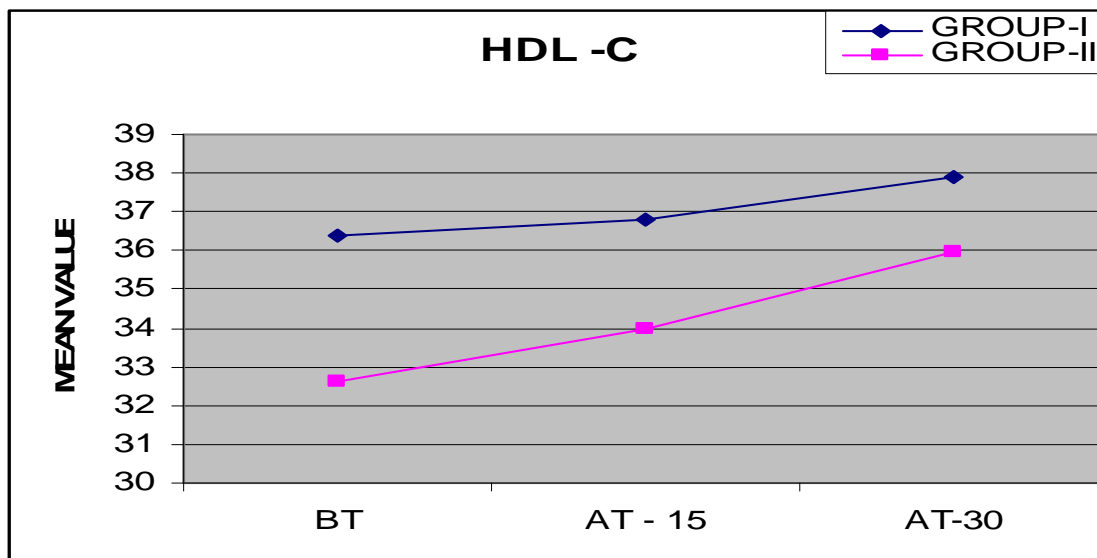
**Table No. 2. Statistical analysis showing the effectiveness of Group - I & Group - II treatment on LDL**

Treatment Group	Duration of Treatment	Mean ± S.D.	Mean Diff. ± S.E	d.f (n - 1)	t - value	p- value
Group - I	BT	152.96±19.28		39		
	A.T(15)	152.96±19.28	1.11±0.67	39	1.65	# > 0.05
	AT(30)	151.4±18.78	2.81±0.90	39	3.12	*<0.05
Group - II	BT	143.9±26.28		39		
	A.T(15)	138.85±21.75	6.5±1.26	39	5.15	**<0.001
	AT(30)	129.95±17.85	15.51±2.3	39	6.74	**<0.001



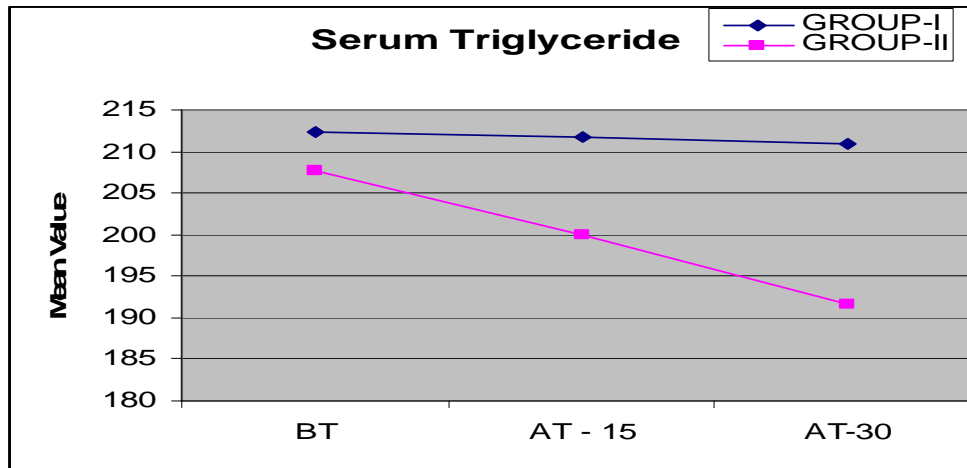
**Table No. 3. Statistical analysis showing the effectiveness of Group - I & Group - II treatment on HDL**

Treatment Group	Duration of Treatment	Mean ± S.D.	Mean Diff. ± S.E	d.f (n - 1)	t value	p- value
Group - I	BT	36.4±9.37		39		
	A.T(15)	36.8±9.33	0.4±0.22	39	1.8	# >0.05
	AT(30)	37.9±9.16	1.9±0.57	39	3.33	*<0.01
Group - II	BT	32.64±9.37		39		
	A.T(15)	34.0±8.18	1.36±0.24	39	5.67	**<0.001
	AT(30)	35.95±8.41	3.31±0.36	39	9.10	**<0.001



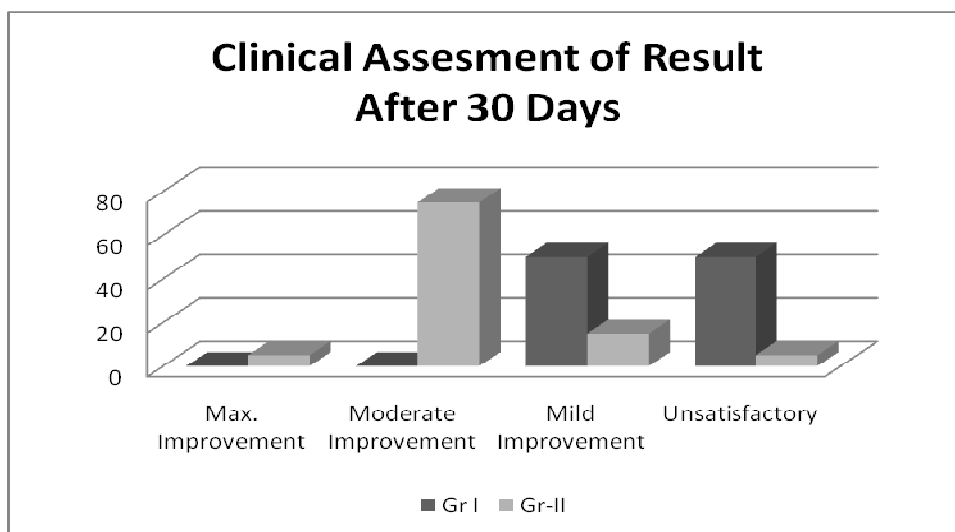
**Table No. 4. Statistical analysis showing the effectiveness of Group - I & Group - II treatment on Serum Triglyceride**

Treatment Group	Duration of Treatment	Mean ± S.D.	Mean Diff. ± S.E	d.f (n - 1)	t value	p- value
Group - I	BT	212.3±60.75		39		
	A.T(15)	211.8±60.92	0.5±0.27	39	1.85	# >0.05
	AT(30)	211.0±60.89	1.3±0.56	39	2.32	*<0.05
Group - II	BT	207.7±117.84		39		
	A.T(15)	199.9±104.43	7.8±3.45	39	2.26	θ =0.05
	AT(30)	191.55±91.94	23.2±7.44	39	3.11	*<0.05



**Table No. 5. Showing the clinical assessment of result after treatment in different Groups.**

Sl No.	Clinical Assessment	After 15 Days Of Treatment		After 30 Days Of Treatment	
		GROUP - I f (%)	GROUP - II f (%)	GROUP - I f (%)	GROUP - II f (%)
1	Max. Improvement	-	-	--	2 (5%)
2	Moderate Improvement	-	-	--	30 (75%)
3	Mild Improvement	12 (30%)	38 (95%)	20 (50%)	6(15%)
4	Unsatisfactory	28 (70%)	2 (5%)	20(50%)	2 (5%)



## DISCUSSION:

In the present work, attempt has been made to evaluate the effect of *Medohara Arka* (cow's urine distillate) compared to the effect of *Medohara Arka* along with *Lekhanavasti* on *Medovridhhi* (Hyperlipidaemia) cases. After completion of trial period of 30 days it is observed that, As regards BMI. Among trial (Group-I) cases mean reduction in BMI. is 0.11 & 0.3 after 15 and 30 days of treatment respectively.

Similarly mean improvement of 0.61 & 1.36 after 15 and 30 days of treatment respectively was recorded among the trail (Group – II) patients.

On the same issue there was an improvement about 36.6 and 65 percent after 15 and 30 days of treatment respectively in trial (Group – II), which was 16.6 & 26.6 percent among the Group - I cases.

Statistically it was highly significant in Group – I & II cases after 30 days treatment. BMI estimation depends on the ratio of weight and square of height in meter.

The implemented treatment has benefited the patients by reducing medadhatu only but it has no action on height. So improvement couldn't be elicited as seen in body weight, though BMI. is proportionate with body weight.

### Serum cholesterol

Among the Group – I patients, there was an improvement with a mean difference of 0.98 & 2.68mg% after 15 & 30 days respectively which is statistically significant.

Among Group – II patients mean difference of 10.28 & 18.88 in Serum Cholesterol has been recorded after 15 & 30 days treatment respectively. Both are highly significant statistically.

Percentage of efficacy being 4.17 & 22.12% respectively after 15 & 30 days in Group-I cases and 17.64 & 29.41% in group-II cases.

This is compared with the out come of others which is demonstrated as 16% after 32 days (Panda Satish-*et.al.*) against 29.41% received through our trial.

As it is known cholesterol and its fractions are the derivative of lipid vis-à-vis medadhatu. Since both the trial drugs have an impact on medadhatu. There is a fall in cholesterol level. This corroborates the textual references in Ayurveda.

### LDL Cholesterol

As regards LDL Cholesterol, among the Group – I patients, there was an improvement with a mean difference of 1.11 & 2.81mg% after 15 & 30 days

respectively which is statistically insignificant after 15 days but significant after 30 days of treatment.

Among Group – II patients mean difference of 6.5 & 15.51 in LDL Cholesterol has been recorded after 15 & 30 days treatment respectively. Both are highly significant statistically.

Percentage of efficacy being 0 & 8.33% respectively after 15 & 30 days in Group-I cases and 10.52 & 14.03% in group-II cases. This seems to be justifying as explained above.

### HDL cholesterol

Among the Group – I patients, there was an improvement with mean difference of 0.4 & 1.9mg% after 15 & 30 days respectively which is statistically insignificant after 15 days but significant after 30 days of treatment.

Among Group – II patients mean difference of 1.36 & 3.31 in HDL Cholesterol has been recorded after 15 & 30 days treatment respectively. Both are highly significant statistically.

Percentage of efficacy being 0 & 4.17 % respectively after 15 & 30 days in Group-I cases and 26.66 & 35.55% in group-II cases.

### Serum triglycerides

As regards Serum Triglycerides, among the Group – I patients, there was an improvement with mean difference of 0.5 & 1.3 % after 15 & 30 days respectively which is statistically insignificant after 15 days but significant after 30 days of treatment.

Among Group – II patients mean difference of 7.8 & 23.3mg% in Serum Triglycerides has been recorded after 15 & 30 days treatment respectively which is just significant after 15 days and highly significant after 30 days statistically.

Percentage of efficacy being 4.17 & 22.62% respectively after 15 & 30 days in Group-I cases and 17.64 & 29.41% in group-II cases.

### Overall Assessment of result

As regards assessment of result in the Ayurvedic stream of management, no cure can be possible that has been reflected throughout the trial. Thus improvement in various grade have been taken up as follows:

the result obtained after 15 days is not complementary, while 30 days treatment has elicited maximum, moderate, mild and unsatisfactory result amounting 5, 75, 15 & 5% respectively among group – II patients where as in group – I only 50% patients got mild improvement.

### Probable action of *Gomutraarka*

Modern research papers reveal that cow's urine distillate is a potent bio enhancer, activity enhancer as well as availability facilitator. All these characteristics help in lipolysis, ultimately responsible for less deposition of lipid/fat in the body.

More over the hypothesis may be it increases the metabolic rate, so that due to the fat metabolism or lipolysis there is reduction of weight as well as skin fold thickness and decrease in lipid profiles.

### Probable action of *lekhanvasti*

In the field of medical management *Vasti* (enema)therapy is supposed to be half of the treatment. It is such a complex phenomenon which is difficult to pin point exactly the probable mechanism of action of *Vasti* therapy. In fact it is presumed that various factors work in collaboration with each other to produce the beneficial effect.

The classical *lekhan vasti* contain NaCl whose molecular weight is 58.5. Therefore molecular solution containing 58.5 of NaCl/ltr. has strength of 2 osmomol/ltr. Normally human plasma has a strength of about 290m osmomol/Ltr i.e. 0.29 osmomol<sup>[11]</sup>. As a fact *Vastidravya* accommodating NaCl content a strength of 2 osmomol/Ltr. This phenomenon facilitate movement of plasma fluid from lower concentration to higher concentration but there is no loss of protein since it maintain the colloid osmotic pressure and work like a retention force. Thus complete cleansing of *mahasrotas* enables the patients to show increased absorption of drug, long lasting beneficial effects in case of *Medovridhi vis-a vis Hyperlipidaemia*.

### CONCLUSION:

*Medohara Arka* administered after *Lekhana Basti* provided better result in almost all the parameters because it eliminates *Doshas* from the body and simultaneously helps in better drug absorption and

perform their action of *samprapti vighatana* at cellular level.

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