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Research Article

A CLINICAL EVALUATION OF *GOMUTRA GHANAVATI* IN *MEDOROGA* W.S.R. TO DYSLIPIDAEMIA - A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

In present scenario human lifestyle mainly includes faulty food habits, minimum physical and mental exercise, intellectual exercise with stress and depression resulting into various metabolic disorders in human being. Dyslipidaemia is one of the main metabolic diseases describing disordered lipid metabolism. Dyslipidaemia alone affects approximately 12% of global population. The clinical study was conducted in 60 clinically diagnosed patients of *Medoroga* (dyslipidaemia), divided into two groups (30 patients in each group). In Group A patients were administered 1gm of *Gomutra Ghanavati* orally after meal with lukewarm water twice a day for 60 days. In Group B patients were administered 10mg of Atorvastatin orally after meal with water once a day for 60 days. **Conclusion:** On the basis of their clinical manifestations "*Medoroga"* can be correlated with the clinical entity "Dyslipidaemia". *Gomutra Ghanavati* showed highly significant results in some subjective and objective parameters Thus, it is concluded that *Gomutra Ghanavati* can be used as an effective and safe treatment for dyslipidaemia (*Medoroga*).

INTRODUCTION

The 21st century is an era of tremendous development and innovation in all aspects of life in general, and in this era the field of technology on the one side has made human life much easier but on the other side it cursed many lifestyle disorders to human being. Now days lifestyle mainly includes faulty food habits, minimum physical and mental exercise, intellectual exercise with stress, anxiety and depression resulting into various disorders in human body. Nowadays Cardiovascular Diseases (CVD) are the major cause of morbidity and mortality in our society with dyslipidaemia contributing significantly to atherosclerosis. Dyslipidaemia alone affects approximately 12% of global population. The term dyslipidaemia is used to describe disordered lipid metabolism.

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According to WHO survey done in 2002 almost 1/5th (80%) of global stroke events and about 56% of global heart disease are attributed to dyslipidaemia. This is responsible for about 4.4 million deaths (7.9% of the total) and 2.8% of global disease burden.

Lipids as explained in modern sciences has closely resemblance with *Sneha dravya* in Ayurveda i.e., *Meda, Vasa*, *Majja* etc. In Ayurveda, *Medodushtijanya* sign and symptoms shows closely resemblance with dyslipidaemia explained in modern science. According to Ayurvedic classics, the *Nidan* of *Medo dhatu dushti* are excessive intake of *Shleshma vardhak ahar- Vihar* and reduced physical and mental exercise causes *Agnidushti* which ultimately results in excessive formation *Saam meda* in the body and develop the disease which resents as *"Medoroga or Medodushti".*

Acharya Charak has considered *medoroga* as one of the *Ashtonindit vikara* as explained in *Charak Samhita Sutrasthana 21. Acharya Charaka* with the words *'Medasaavrittat vayu'* explained the *Avarana* of *Saman vayu* with raised level of *Meda* in the pathogenesis of *Medoroga* which further causes *Vata prakopa* in *Koshtha,* again *Agnisandhukshana* which further increases dietary intake leading to formation of

Saam dosha, Saam dhatu again, in the same manner vicious cycle goes on.

Thus, while treating the *Medodushti* as advised by various *Acharyas* in their classics, one should go for *Nidan parivarjana*, *Samshodhana, Deepana, Pachana*, and use of *Guru apatarpana dravyas*. Thus, selection of *Dravya* should have criteria that help to *Lekhana* of excessive *Meda-kapha* without *Vayu-prakopa* and normalising the *Agni* at both level of *Jatharagni* and *Dhatwagni.* Although from decades to till now many studies have been carried out for this burning problem, still there is need of evaluation of certain drugs clinically on various scientific parameters which could be safe, effective, cheap and frequently available for the management of dyslipidaemia, so to fulfil the above purpose this clinical trial has been done.

In present study it has been decided to separately evaluate hypolipidemic effect of *Gomutra* as oral medicine in the form of *Ghanavati* in human being by conducting a clinical trial.

AIMS AND OBJECTIVE

Conceptual and clinical studies on *Medoroga* and dyslipidaemia.

1. To evaluate clinical efficacy of *Gomutra Ghanavati* in the management of a series of patients suffering from *Medoroga (*dyslipidaemia).
2. To compare the efficacy of *Gomutra Ghanavati* and Tablet Atorvastatin in the management of *Medoroga* (dyslipidaemia).

MATERIALS AND METHODS

Following materials and methods were adopted for conducting the present clinical trial.

Selection of Patients

The study was conducted on 60 clinically diagnosed and confirmed patients of *Medodushti* and dyslipidaemia on the basis of subjective, objective and Laboratory parameters. Patients were randomly selected from OPD & IPD of Aarogyashala, P.G. Department of Kaychikitsa NIA, Jaipur and SMS Medical College, Jaipur.

Inclusion criteria

1. Patients between the age group of (20-60) year of either sex.
2. Diagnosed and confirmed cases of dyslipidaemia and *Medodushti* on the basis of investigation.
3. Patients willing to sign the consent form.

Diagnostic Criteria

Patients were diagnosed on the basis of laboratory investigations mainly lipid profile. Patients having alterations in any one or more component of the lipid profile as follows were included in present study-

- Sr. Cholesterol (200mg/dl or more)
- Sr. Triglycerides (150mg/dl or more)
- Sr. LDL (130mg/dl or more)
- Sr. VLDL (40mg/dl or more)
- Sr. HDL (40mg/dl or less) were taken for the study.

Exclusion Criteria

1. Patients suffering from diseases like nephrotic syndrome, hypothyroidism, IDDM, jaundice, hepatitis, chronic infections and other serious diseases.
2. Patients with medical history of -
   - Unstable angina
   - Myocardial infarction
   - Heart failure or stroke within 3 months of study
   - Uncontrolled hypertension (diastolic blood pressure > 100 mmHg)
   - Uncontrolled diabetes mellitus
   - Impaired renal function (creatinine ≥ 2 mg/dl)
   - ALT and AST >2 times of upper limit of normal
3. Pregnancy, lactation and patients having dyslipidaemia due to drugs e.g. glucocorticoids, diuretics.
4. Patient on any Ayurvedic drug in last 15 days.

Method of Preparation of *Gomutra Ghanavati*

80 litres of filtered cow urine was heated in mild flame until it reached to semisolid consistency. After cooling, *Haritaki churna* (Q.S.) was added for making *Vati.* Finally, *Vati* (pills) of 1gm each were prepared and stored in air tight packing.

Mode of administration of the Drugs- All the 60 clinically diagnosed patients are divided into two groups (Group A and Group B) 30 patients in each group.

Group - A	30 patients were administered 1gm of *Gomutra Ghanavati* orally after meal with lukewarm water twice a day for 60 days.
Group - B	30 patients were administered 10mg of Atorvastatin orally after meal with water once a day for 60 days.

Study Design

Randomized, open label, interventional type, controlled trial.

Follow-Up Study

- Follow up of the patient was done fortnightly for a period of 60 days.
- Improvement in the symptoms, if any and other effects were noted down.
- Laboratory investigations were repeated after completion of the treatment i.e., after 60 days.

Criteria for Assessment

Both subjective and objective parameters were employed for assessment of the impact of the treatment.

Subjective Criteria

Ayurveda is a subjective science. To give results, objectively and for statistical analysis, multidimensional scoring pattern to the signs and symptoms of *Medoroga* was adopted. Score was given according to the severity of symptoms. All these symptoms assessment was done by using Symptom Rating Scale as following:

Parameters Score

Absence of symptoms 0

Mild degree of symptoms 1

Moderate degree of symptoms 2

Severe degree of symptoms 3

Objective Criteria

Anthropometric Assessment

- Weight of the patient (in Kg)
- B.M.I.
- Hip Circumference
- Waist Circumference
- Waist – Height Ratio
- Waist - Hip Ratio

Biochemical Parameter Assessment

Routine Blood Investigation

- Haemoglobin (Hb gm%)
- Total Leucocytes Count (TLC)
- ESR (mm/hr)

Lipid profile

- Serum Total Cholesterol (Sr.TC)
- Serum Triglycerides (Sr.TG)
- Serum Low Density Lipoprotein (Sr. LDL)
- Serum Very Low-Density Lipoprotein (Sr. VLDL)
- Serum High Density Lipoprotein (Sr. HDL)

Fasting Blood sugar

C-Reactive Protein Test

OBSERVATION

Observation in Demographic Profile of the Subjects

- The maximum 31 (51.66%) patients were belonging to the age group of 46-60 years followed by 18 (30.00%) patients were belonging to 31-45 year.
- The maximum of 42 (70%) patients were males.
- The maximum numbers of 52 (86.66%) patients were from Hindu community.
- In the present study 47 (78.33%) patients were married.
- The maximum 31 (51.66%) patients were from middle class, 18 (30%) patients.
- The maximum 20 (33.33%) patients were doing government Service, 12 (20%) patients were House wives.
- The maximum 30 (50%) patients were doing table work 18 (30%) patients were related with field work.
- Total of 9 (15%) patients had a family history of obesity, maximum of 18 (30%) patient had family history of hypertension.
- Out of 60 patients of dyslipidaemia 45 (75%) patients were having *Madhyama ahara shakti.*
- Out of 60 registered patients, maximum of 36 (60%) patients showed *Madhyama jarana shakti.*
- The maximum 21 (35%) patients had *Tikshnagni*, 20 (33.33%) patients had *Vishamagni*
- The data shows that maximum 33 (55%) patients had *Madhyama vyayama shakti.*
- Among 60 cases of dyslipidaemia, 27(45%) patients belong to range 25-29.9 Kg/m^2 of BMI.
- Data shows that, among 60 patients of Dyslipidaemia, 81.66% patients had complaint of *Daurbalya,* 65% patients had complaints of *Angachalatva*, 80% patients had complaint of *Angagaurava*, 70% patients had complaint of *Alasya*, 63.33% patients had complaint of *Sandhishool,* 58.33% patients had complaint of *Snigdhangata,* 55% patients had complaint of *Nidradhikya.*
- Among 60 patients of dyslipidaemia, 31 (51.66%) patients had borderline high cholesterol, 19 (31.66%) patients had high cholesterol level. Among 60 patients, 36 (60%) patients had near optimal LDL cholesterol. In HDL level 59 (98.33%) patients showed HDL cholesterol above 40mg/dl. Among 60 patients, 31 (51.66%) patients had triglycerides in Borderline high range, 18 (30%) patients had high triglyceride level.

RESULTS

- All the results calculated by using software: In Stat Graph Pad 3.
- For non-parametric data Wilcoxon matched-pairs signed ranks test is used while for parametric data paired "t" test is used and results calculated in each group.
- For calculating the inter group comparison, Mann-Whitney Test and unpaired 't' test was used.

Table 1: Effect of Therapy in Subjective Parameters (Wilcoxon matched paired single ranked test)

Variable	Group	Mean		Mean Diff.	% Relief	SD±	SE±	P	S
		BT	AT						
Kshudhadhikya	A	0.60	0.16	0..44	71.66%	0.62	0.11	<0.001	HS
	B	0.60	0.13	0.47	76.66%	0.68	0.12	<0.001	HS
Pipasadhikya	A	0.53	0.26	0.27	49.05%	0.44	0.08	<0.001	HS
	B	0.56	0.36	0.20	35.71%	0.48	0.09	>0.05	NS
Angasaada	A	0.33	0.06	0.27	78.78%	0.44	0.08	<0.001	HS
	B	0.36	0.16	0.20	55.55%	0.40	0.07	<0.05	S
Swedadhikya	A	0.76	0.30	0.46	60.52%	0.68	0.12	<0.001	HS
	B	0.53	0.16	0.37	67.92%	0.67	0.12	<0.001	HS
Atinidra	A	0.73	0.46	0.27	35.61%	0.52	0.09	<0.05	S
	B	0.76	0.36	0.40	52.63%	0.72	0.13	<0.05	S
Kshudrashwasa	A	0.46	0.23	0.23	50.00%	0.43	0.07	<0.05	S
	B	0.43	0.33	0.10	21.73%	0.30	0.06	>0.05	NS
Moha	A	0.13	0.03	0.10	76.92%	0.30	0.06	>0.05	NS
	B	0.20	0.06	0.14	65.00%	0.34	0.06	>0.05	NS
Krucchvyavayata	A	0.43	0.30	0.13	30.23%	0.43	0.08	>0.05	NS
	B	0.26	0.13	0.13	61.53%	0.38	0.06	>0.05	NS
Daurgandhya	A	0.30	0.16	0.14	65.00%	0.34	0.06	>0.05	NS
	B	0.20	0.03	0.17	80.00%	0.37	0.06	>0.05	NS
Krathana	A	0.40	0.20	0.20	50.00%	0.40	0.07	<0.05	S
	B	0.33	0.20	0.13	39.39%	0.34	0.06	>0.05	NS
Alpaprana	A	0.26	0.06	0.20	76.92%	0.40	0.07	<0.05	S
	B	0.53	0.40	0.13	24.53%	0.34	0.06	>0.05	NS

Results in patients of Group A

In Group A, patients were treated with *Gomutra Ghanavati* showed statistically highly significant results (i.e., P value<0.001), in subjective parameters- *Kshudhadhikya, Pipasadhikya, Angasaada* and *Swedadhikya* whereas statistically significant (i.e., P value <0.05) in case of subjective parameters *Atinidra*, *Alpaprana, Kshudrashwasa* and *Krathana*. While in *Moha*, *Krucchvyavayata* and *Daurgandhya* there were non-significant results (i.e., P value >0.05).

Results in patients of Group B

In Group B, patients were treated with Atorvastatin tablet, showed statistically highly significant results (p value <0.001) in subjective parameters –*Kshudhadhikya* and *Swedaadhikya.* Whereas in case of other subjective parameters i.e., *Atinidra and Anghasaada* there were statistically significant results (p value <0.05). While in other subjective parameter there were non-significant results (P value >0.05).

Table 2: Intergroup Comparison of Group A & Group B for Subjective Parameters (Mann-Whitney Test)

Variable	Groups	Mean diff.	SD±	SE±	P	S
Kshudhadhikya	A	0.83	0.74	0.13	< 0.001	HS
	B	0.30	0.59	0.10		
Pipasadhikya	A	0.06	0.72	0.13	< 0.05	S
	B	0.02	0.48	0.08		
Angasada	A	0.63	0.71	0.13	< 0.001	HS
	B	0.20	0.40	0.07		

Swedadhikya	A	0. 66	0.84	0.15	< 0.001	HS
	B	0.13	0.43	0.07		
Atinidra	A	0.63	0.76	0.13	<0.05	S
	B	0.20	0.56	0.10		
Kshudrashwasa	A	0.40	0.25	0.10	< 0.001	HS
	B	0.06	0.25	0.04		
Moha	A	0.23	0.43	0.07	>0.05	NS
	B	0.13	0.34	0.06		
Krichchyavyavayata	A	1.16	3.81	0.69	<0.05	S
	B	0.16	0. 37	0.06		
Daurgandhya	A	0.53	0.73	0.13	<0.05	S
	B	0.13	0.34	0.06		
Alpaprana	A	0.30	0.46	0.08	**>0.05**	NS
	B	0.26	044	0.08		
Krathana	A	0.20	0.40	0.07	**>0.05**	NS
	B	0.13	0.34	0.06		

- ***Kshudhadhikya***: The p value is < 0.001 which is statistically highly significant which shows that there is statistical difference in efficacy of both treatments on *Kshudhadhikya.*
- ***Pipasadhikya***: The p value is 0.04 i.e. < 0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments on *Pipasadhikya.*
- ***Angasada***: The p value is <0.001 which is statistically highly significant which shows that there is statistical difference in efficacy of both treatments on *Angasada.*
- ***Swedadhikya***: The p value is <0.001 which is statistically highly significant which shows that there is statistical difference in efficacy of both treatments on *Swedadhikya.*
- ***Atinidra***: The p value is <0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments on *Atinidra.*
- ***Kshudrashwasa***: The p value is <0.001 which is statistically highly significant which shows that there is statistical difference in efficacy of both treatments on *Kshudrashwasa.*
- ***Moha***: The p value is >0.05 which is statistically non-significant which shows that there is no statistical difference in efficacy of both treatments on *Moha.*
- ***Kruchchyavyavayata***: The p value is <0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments on *Kruchchyavyavayata.*
- ***Daurgandhya:*** The p value is <0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments on *Daurgandhya.*
- ***Alpaprana:*** The p value is >0.05 which is statistically non-significant which shows that there is no statistical difference in efficacy of both treatments on *Alpaprana.*
- ***Krathana***: The p value is >0.05 which is statistically non-significant which shows that there is no statistical difference in efficacy of both treatments on *Krathana.*

Table 3: Effect of Therapy in Anthropometric Parameters (Paired 't' Test)

Parameters	Gp	Mean		Diff	% Relief	SD±	SE±	T	P	S
		BT	AT							
Body Weight (kg)	A	70.83	68.13	2.70	3.84%	1.60	0.29	9.2	<0.001	HS
	B	74.30	71.43	2.86	3.84%	1.89	0.34	8.31	<0.001	HS
B.M.I. (kg/m^2)	A	27.06	26.15	0.91	3.36%	0.69	0.13	7.23	<0.001	HS
	B	25.76	24.90	0.85	3.29%	0.61	0.11	7.51	<0.001	HS
Waist Circum(cm)	A	111.2	110.9	0.26	0.23%	0.63	0.11	2.28	<0.05	S
	B	110.2	106.1	4.15	3.76%	2.89	0.52	7.85	<0.001	HS

Hip Circum(cm)	A	116.5	116.3	0.2	0.17%	0.61	0.11	1.79	>0.05	NS
	B	116.1	107.6	8.43	7.26%	7.54	1.37	6.12	<0.001	HS
Waist-Hip Ratio	A	0.91	0.92	-0.01	1.09%	0.16	0.03	0.24	>0.05	NS
	B	0.94	0.92	0.02	1.75%	0.72	0.02	9.13	<0.001	HS
Waist-Height Ratio (cm)	A	0.59	0.55	0.03	5.08%	0.76	0.14	2.60	<0.05	S
	B	0.59	0.46	0.13	22.0%	0.08	0.01	8.50	<0.001	HS

Result In Patients of Group A

In case of objective parameters, all parameters (body weight, BMI, waist circumference, hip circumference, waist-hip ratio and waist-height ratio) it has shown highly significant result (p value <0.001). Body weight had shown reduction by 3.84%, BMI reduced by 3.29%, waist circumference reduced by 3.76%, hip circumference reduced by 7.26%, waist-height ratio reduced by 7.04% and waist-hip ratio reduced by 1.75%.

Result In Patients of Group B

In case of objective parameters, all parameters (body weight, BMI, waist circumference, hip circumference, waist-hip ratio and waist-height ratio) it has shown highly significant result (p value <0.001). Body weight had shown reduction by 3.84%, BMI reduced by 3.29%, waist circumference reduced by 3.76%, hip circumference reduced by 7.26%, waist-height ratio reduced by 22% and waist-hip ratio reduced by 1.75%.

Table 4: Intergroup Comparison of Group A & Group B for Anthropometric Parameters: (Unpaired t Test)

Variable	Groups	Mean diff.	SD±	SE±	t value	P	S
Body Weight	A	2.70	1.60	0.29	0.36	<0.05	S
	B	2.86	1.88	0.34			
BMI	A	0.91	0.69	0.12	0.39	<0.05	S
	B	0.84	0.61	0.11			
Waist Circumference	A	0.2660	0.6396	0.1167	7.181	<0.001	HS
	B	4.1500	2.8921	0.5280			
Hip Circumference	A	0.2000	0.6100	0.1114	5.960	<0.05	S
	B	8.4300	7.5410	1.3760			
Waist-Hip ratio	A	0.007	0.16	0.03	0.94	>0.05	NS
	B	0.02	0.01	0.002			
Waist-Hight ratio	A	0.05	0.12	0.02	1.14	>0.05	NS
	B	0.07	0.34	0.05			

(HS: Highly Significant S: Significant NS: Non-Significant)

- **Body weight:** The p value is <0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments on body weight.
- **BMI:** The p value is <0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments in BMI.
- **Waist Circumference:** The p value is <0.001 which is statistically highly significant which shows that there is statistical difference in efficacy of both treatments on waist Circumference.
- **Hip Circumference:** The p value is <0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments on hip circumference.
- **Waist-Hip Ratio:** The p value is >0.05 which is statistically non-significant which shows that there is no statistical difference in efficacy of both treatments on waist-hip ratio.
- **Waist-Hight Ratio:** The p value is >0.05 which is statistically non-significant which shows that there is no statistical difference in efficacy of both treatments on waist-hip ratio.

Table 5: Effect of Therapy on Lipid profile (Paired 't' Test)

Variable	Group	Mean		Mean Diff.	% Relief	SD±	SE±	T	P	S
		BT	AT							
Sr.TC (mg/dl)	A	222.1	186.3	35.76	16.10%	27.1	4.94	7.23	<0.0001	HS
	B	228.9	179.3	49.63	21.65%	37.0	6.75	7.34	<0.0001	HS
Sr.TG (mg/dl)	A	182.5	144.9	37.56	19.48%	33.4	6.10	6.15	<0.0001	HS
	B	183.8	140.3	43.52	23.67%	46.6	8.52	5.10	<0.0001	HS
Sr. LDL (mg/dl)	A	122.0	112.0	10.00	8.19%	24.5	4.47	2.24	<0.05	S
	B	118.7	76.1	42.59	35.88%	34.3	6.27	6.79	<0.001	HS
Sr. VLDL (%)	A	33.2	32.3	0.83	2.50%	5.35	0.97	0.85	>0.05	NS
	B	34.4	39.3	-4.90	14.24%	12.5	2.28	2.14	<0.05	S
Sr. HDL (mg/dl)	A	51.0	51.3	-0.23	0.45%	2.37	0.43	0.53	>0.05	NS
	B	39.1	50.1	11.0	28.13%	19.0	3.48	4.07	<0.0001	HS

Results of Patients in Group A

In lipid profile parameters – Sr. total cholesterol and Sr. TG showed statistically highly significant results (i.e. P value< 0.001). While Sr. LDL showed statistically significant results (i.e. P value <0.05), whereas in Sr. HDL and Sr. VLDL there were statistically non-significant results (i.e. P value >0.05).

Results of Patients in Group B

In lipid profile parameters - Sr. total cholesterol (TC), Sr. TG, Sr. LDL, and Sr. HDL statistically highly significant results were found (P value < 0.001). While in Sr. VLDL there were statistically significant result found.

Table 6: Intergroup Comparison of Group A & Group B for Lipid Profile (Unpaired t Test)

Variable	Groups	Mean diff.	SD±	SE±	t value	P	S
Sr. TC	A	35.76	27.08	4.94	2.11	<0.05	S
	B	22.60	20.66	3.77			
Sr.TG	A	38.77	32.85	5.55	2.99	<0.001	HS
	B	16.07	30.62	5.17			
Sr.LDL	A	19.27	25.77	4.42	2.87	<0.0001	HS
	B	39.99	33.16	5.68			
Sr.VLDL	A	7.40	14.89	2.55	2.59	<0.05	S
	B	1.91	14.74	2.52			
Sr.HDL	A	0.25	0.98	0.18	0.95	>0.05	NS
	B	0.64	1.85	0.34			

- **Serum Total Cholesterol:** The p value is <0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments on serum total cholesterol.
- **Serum Triglycerides:** The p value is <0.001 which is statistically highly significant which shows that there is statistical difference in efficacy of both treatments on serum triglycerides.
- **Serum Low Density Lipoproteins:** The p value is <0.0001 which is statistically highly significant which shows that there is statistical difference in efficacy of both treatments on Sr. LDL.
- **Serum Very Low-Density Lipoproteins:** The p value is <0.05 which is statistically significant which shows that there is statistical difference in efficacy of both treatments on Sr. VLDL.
- **Serum High Density Lipoproteins:** The p value is >0.05 which is statistically non-significant which shows that there is no statistical difference in efficacy of both treatments on Sr. HDL.

Table 7: effect of Therapy on Lab Investigations (Paired 't' Test)

Variable	Gp	Mean		Mean Diff.	% Relief	SD±	SE±	T	P	S
		BT	AT							
FBS (mg %)	A	99.30	90.3	9.0	9.06%	11.05	2.01	4.45	<0.001	HS
	B	94.30	87.76	6.53	6.92%	13.38	2.44	2.67	<0.05	S
Hb% (gm %)	A	12.98	13.39	0.40	3.08%	1.83	0.33	1.20	>0.05	NS
	B	12.50	12.95	0.45	3.20%	2.36	0.43	2.08	>0.05	NS
TLC	A	7309	7280	29.0	0.39%	2060	376.1	0.077	>0.05	NS
	B	7233	6860	372.6	4.53%	1477	269.7	1.38	>0.05	NS
ESR	A	22.2	16.53	5.66	25.38%	12.39	2.26	2.50	>0.05	NS
	B	16.10	21.10	5.00	31.05%	16.35	2.98	1.67	>0.05	NS
CRP (Grade)	A	0.5	0.40	0.10	25.00%	0.42	0.13	-	>0.05	NS
	B	0.4	0.25	0.15	37.50%	0.67	0.31	-	>0.05	NS
Urine Sugar	A	1.15	1.02	0.13	11.3%	0.30	0.07	1.32	>0.05	NS
	B	1.06	1.03	0.03	2.83%	0.10	0.02	1.21	>0.05	NS
Urine Protein	A	0.34	0.30	0.04	11.76%	0.24	0.05	0.66	>0.05	NS
	B	0.26	0.26	0.00	0.00%	0.47	0.10	0.00	>0.05	NS

In **FBS** there was statistically highly significant result in Group A while in Group B statistically non-significant result was found. In Hb% there was statistically non-significant result in Group A and in Group B statistically significant result was found.

In other laboratory parameters like i.e., TLC, ESR CRP, urine sugar and urine protein had not shown any significant change hence these parameters in both Groups showed statistically non-significant.

Table 8: The % Relief in Both the Groups in Subjective Parameters

Parameters	% Relief in Group A	% Relief in Group B
Kshudhadhikya	71.66%	76.66%
Pipaasadhikya	49.05%	35.71%
Angasada	78.78%	55.55%
Swedadhikya	60.52%	67.92%
Atinidra	35.61%	52.73%
Kshudrashwasa	50.0%	21.73%
Moha	76.92%	65.0%
Krucchyavyavayata	30.23%	61.53%
Daurgandhya	65.0%	80.0%
Krathana	50.0 %	39.39 %
Alpaprana	76.92 %	24.53 %

Table 9: The % Relief in Both the Groups in Anthropometric parameters

Parameters	% Relief in Group A	% Relief in Group B
Body Weight	3.84%	3.84%
BMI	3.36%	3.29%
Waist Circumference	0.23%	3.76%
Hip Circumference	0.17%	7.26%
Waist-Hip Ratio	1.09%	1.75%
Waist-Height Ratio	5.08%	22.0%

Table 10: The % Relief in Both the Groups in Lipid Profile

Parameters	% Relief in Group A	% Relief in Group B
Sr.TC (mg/dl)	16.10%	21.65%
Sr.TG(mg/dl)	19.65%	23.67%
Sr. LDL (mg/dl)	8.19%	35.88%
Sr. VLDL (%)	2.50%	14.24%
Sr. HDL (mg/dl)	0.45%	28.13%

DISCUSSION

Discussion on Intergroup Comparison

Effect on Subjective Parameters

Percentage of Improvement

Group A (*Gomutra Ghanavati*) showed better result than Group B (Atorvastatin) on subjective parameters i.e., *Angasaada* (78.78%) and *Alpapraan* (76.92%) and *krathana* (50%) and *Moha* (76.92%) and *Kshudrashwasa* (50%) and *Pipasadhikya* (49.05%).

Group B (Atorvastatin) showed better result than Group A (*Gomutra Ghanavati*) on subjective parameters i.e., *Kshudhadhikya* (71.66%), *Swedadhikya* (67.92%), *Atinidra* (52.73%), *Krucchyavyavayata* (61.53%) *Daurgandhya* (80%).

Effect on Objective Parameters

Percentage of Improvement in Lipid Profile

Group A (*Gomutra Ghanvati*) was seen to cause a decrease on total cholesterol (16.10%), serum triglyceride (19.65%), LDL (8.19%), VLDL (2.50%) and slightly increase of HDL (0.23%).

Group B (Atorvastatin) was seen to cause a decrease on total cholesterol (21.65%), serum triglyceride (23.67%), LDL (35.88%), VLDL (14.24%) and increase in HDL (28.13%).

From the available result it is evident that both drugs are efficient enough to partially inhibit fat absorption in obese subjects so can produce weight loss. The long-term use of the trial drug with following of strict diet and exercise regimen can bring good results in obese and overweight individuals. Weight gain is mainly due to *Guru guna adhikya ahara-vihara* and increased *Apachita dhatu*. The *Ruksha, Ushna, Lekhana* and *Medo Hara* property of drugs helps in reducing the excessive deposition of *Meda* in various depots of the body. This can be considered as cause for significant positive result obtained in case weight reduction in the trail drug Group A.

Probable Mode of Action of the Therapy

It is very difficult to know the exact mode of action of drug in the human body. But on the basis of certain principles and theories an attempt has been made here to describe the probable mode of action of the drug under trial.

Gomutra have *Lekhana* property. The commentators have used the term like *Karshana* (Yogindranath Sen), *patalikaran*a (Dalhan on Su.Su.40/5), *Vishodhana, Brimhaniya viparyaya, Apakarshana* etc to indicate the *Lekhana karma*. So, to break the pathogenesis of disease, *Dravya* having properties opposite to *Meda-kapha* and those which are having *Srotovishodhana, Karshana, Lekhana* properties are used. According to *Acharya Vagbhatta*, a drug acts by its *Rasa*, *Guna, Virya*, *Vipaka* and *Prabhava*. (*A.H. Su.*9/22-23) The probable mode of action of a substance can be evaluated through its *Rasapanchaka* and *Panchabhautika* constitution.

Both the drugs; *Gomutra* and *Haritaki* have *Katu, Tikta, Kashaya rasa.*

Action due to *Katu rasa-* *Katu rasa* has *Medonashak* property. (Su.Su.42/15) It is constituted of predominantly *Agni* and *Vayu mahabhoot* (*Ch.Su.* 26/40). It augments the *Pachakagni* (*Ch.Su.*26/42.4) subsequently to *Medodhatwagni* thereby resulting in proper quantity and quality of both *Sthayi* and *Asthayi Medo dhatu*. It also leads to proper absorption of the ingested food. It also depletes the *Sneha*, *Sweda*, *Kleda* and also decreases the *Mamsa* and *Medo dhatu* (*A.H.Su.*10/17). It also relieves the obstructions to the channels in the body due is *Marganvivranauti* property. (*Ch.Su.*26/42.4) It removes *Sanga* pathology and leading to proper formation of the *Dhatu* as well as their proper nutrition.

Action due to *Tikta rasa-* *Tikta rasa has Medoshoshana* property. (Su.Su.42/16) It is constituted of *Akasha* and *Vayu mahabhuta* (*Ch.Su.*26/40) and it have *Deepana*, *Pachana*, *Lekhana*, *Upashoshana*, and *Sthirikarana* property (*Ch.Su.*26/ 42.5). By its *Deepana* property, it augments *Jatharagni* leading to subsequent increase in the *Medodhatwagni* thus formation of optimal *Meda dhatu*. It has *Pachana* property which leads to digestion of *Ama* and *Srotoshodhana* that relieves the *Sanga* pathology and at the *Jatharagni* level produces optimal *Rasadi dhatu*. The *Lekhana* property and *Ruksha guna* of *Tikta rasa* leads to depletion of *Kapha*, *Meda*, *Sweda* and *Kleda*. (*A.H.Su.*10/15) *Sthirikarana* (*Ch.Su.*26/42.5) property leads to formation of *Mamsa* and *Meda* having a proper

Samhanana (compactness). *Tikta* is the most *Laghu* amongst the six *Rasa* (*A.H.Su* 10/37) thereby relieving the symptom *Gaurava*.

Action due to *Kashaya rasa-* *Kashaya rasa* is the most *Ruksha* amongst the six *Rasas* (*A.H. Su.*10/38). By the virtue of its *Shoshana* property, it absorbs the *Medo dhatu*, *Kleda*, *Sweda*, *Kapha dosha* (*A.H. Sutra* 10/20) thus relieving the *Atiprivitti* Pathology. It also aids in removing excess *Kleda* present in the body thus performing *Kledaharana* (*Ch.Su.*26/42.6). It also augments the digestive fire leading to subsequent optimal *Medo dhatu* formation.

- *Gomutra* has *Tikshna, Ushna* and *Laghu guna* while *Haritaki* has *Ruksha guna.*

Action due to *Ruksha guna-* *Rukshna guna* is the opposite to *Snigdha guna* which is the dominant *Guna* of *Medo dhatu*. It causes *Stambhana* (obstruction) and *Kharatva* (roughness) (*Su.Su.*46/523) thereby bringing about a reduction in the excessively produced *Medo dhatu*. It causes absorption of excess *Kapha dosha*. It is dominant in *Vayu* and *Agni mahabhuta* (*Ch.Su.*26/11) which results in alleviation of the vitiated *Kapha* which is the main *Dosha* responsible for the pathogenesis of *Medo roga*.

Action due to *Laghu guna-* It is constituted of *Akasha*, *Agni* and *Vayu mahabhuta* in *Panchbhautika* composition. (*Ch.Su.*5/6). *Laghu guna* has *Laghavakara* (lightness), *Kaphaghna* (alleviating *Kapha dosha*), and *Shighrapakitva* (quickly digestible (*Bh.Pu.Miasra Prakarana 202*) property. *Laghu guna* also causes *Lekhana* (removes corpulence) and *Ropana* (it heals the scars) (*Su.Su.*46/526). Due to these properties, it alleviates the aggravated *Kapha* and augmentation of *Vata*, thereby reducing *Gaurava* (heaviness). It also causes *Apatarpana* (depletes the *Sharira dhatu*), *Karshana* (brings about leanness), *Lekhana* (causes lightness in the body) (*Dalhana S. Su* 46/256). It also aids in *Deepana* (augmentation of the digestive fire), *Pachana* (digestion), *Rukshana* (dryness) and *Vaishadya* (it cleanses the body) (*C.Su.*26/11). It may hasten the metabolism and absorption of the drug at cellular level.

- In *Gomutra Ghanavati* both *Gomutra* as well as *Haritaki* have *Ushna virya.*

Action due to *Ushna virya-* *Ushna virya* is *Ashupaki*, pacifies *Kapha* and *Vata dosha* and promotes *Sweda* and *Daha* (*A.H.Su* 9/18-19), thus helps in digestion of *Ama*, acts as exothermic, and increases basal metabolic rate. All these properties are opposite to properties and composition of *Medo dhatu* which is *Parthiva* and *Jala mahabhuta pradhana* owing to which it functions for *Samprapti vighatana* of *Medo dusti* precipitated by *Dhatwagnimandhyata*.

In the trial medicine *Gomutra* have *Katu vipaka*

Action due to *Vipaka* of *Gomutra-* The *Katu vipaka* is *Laghu* in nature being composed of *Akash*, *Vayu* and *Agni mahabhuta* (*S.Su.*41/13). It increases in the *Vata dosha* and decreases *Mamsadi dhatu* (*C.Su.*26/61) thereby showing catabolic effects.

Action due to *Vipaka* of *Haritaki-* *Haritaki* has *Madhura vipaka,* which is *Guru* in nature and increases *Kapha* and *Mamsadi dhatu* (*C.Su.*26/61-62) thereby showing anabolic effects. So, this drug has equal balance of anabolic and catabolic effects and prevents the vitiation of *Vata*.

The total effect of the *Gomutra Ghanavati* is *Tridosha Shamaka* especially *Kapha vata shamaka*. It pacifies the vitiated *Kapha dosha* which is dominant in the pathogenesis of dyslipidaemia as well as depletes the excessively produced *Rasa*, *Mamsa*, *Meda*, *Vasa*, *Sweda*, and *Kleda* which are all similar in attributes to *Kapha dosha*. Thus, the drug appeared successful in breaking the *Dosha-dushya sammurchana*. *Dipana* and *Pachana* effect of *Katu* and *Tikta rasa* would have acted upon *Dhatwagnimandya* and helped in normalising the body metabolism.

General Observation Made During the Trial

Considering all these activities, it can be proposed that *Gomutra Ghanavati* have hypolipidaemic action and may play a crucial role in the management to slow down the progress of dyslipidaemia. 2 patients in Group A of *Gomutra Ghanavati* complained of restlessness and burning sensation in abdomen during the trial which may be due to they were taking *Pittaj Prakriti* of the patient or may be due to *Ushn*a and *Teekshna guna* of *Gomutra*. These patients were advised to reduce the dose of 1 *Vati* (500mg) twice in a day: with this intervention his problem was controlled. No other side effect of trial medicine was noticed in any of the patients of dyslipidaemia, registered for the present study.

CONCLUSION

Following conclusions can be drawn from the present clinical trial which was conducted on 60 patients of dyslipidaemia in two divided groups each of 30:

- Dyslipidaemia is very prevalent in today's society and the risk factor for cardiovascular disorders mostly seen associated with diabetes mellitus and hypertension.
- On the basis of their clinical manifestations the clinical entity "Dyslipidaemia" can be correlated with the term "*Medoroga*".
- In dyslipidaemia there is disequilibrium of *Agni* (especially *Jatharagni* and *Medo dhatwagni*) resulting in the formation of *Dushtameda*.

- Restoration of *Agni* to normal physiological states, removal of *Amadosha* and accumulated *Sama meda* from the body are main principles of management of dyslipidaemia.
- *Gomutra Ghanavati*, showed statistically highly significant results in *Kshudhadhikya, Pipasadhikya, Angasada, Swedadhikya, Daurgandya,* while showed significant result in *Atinidra, Kshudrashwasa, Krathana* and *Alpaprana.*
- Highly significant results in reducing serum cholesterol, serum triglycerides and significant result in Sr. LDL along with these it showed highly significant results in anthropometric parameters i.e. reduction in body weight and B.M.I. and significant result in waist-height ratio was observed in this trial.
- There was non-significant result in subjective parameters i.e., *Moha, Krucchavyavayata* and *Daurgandhya*.
- So, from the result of present study it can be concluded that *Gomutra Ghanavati* responded very well to dyslipidaemia and is safe for the patients.
- All the patients registered for the present clinical trial tolerated *Gomutra Ghanavati* very well except only two patients of Group A complained of restlessness and burning sensation in abdomen which might be due to the reason that they were taking *Gomutra Ghanavati* empty stomach or due to *Pittaja prakriti* of the patients or may be due to due to *Ushna, Tikshna* and *Ruksha guna* of *Gomutra.* These patients were advised to reduce the dose of 1 *Vati* (500mg) after meal twice in a day. With this intervention their problem was controlled. No other side effect of trial drug was noticed in any patients of dyslipidaemia.
- Thus, it is concluded that *Gomutra Ghanavati* can be used as an effective and safe treatment for dyslipidaemia (*Medoroga*).

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