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Research Article

A COMPARATIVE CLINICAL STUDY OF *VAMANA* & *VIRECHANA* WITH AND WITHOUT *SHILAJIT YOGA* IN THE MANAGEMENT OF *MADHUMEHA* W.S.R. TO TYPE-2 DIABETES MELLITUS

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KEYWORDS: *Madhumeha*, *Vamana*, *Virechana*, *Shilajit*, *Salasaradi gana*, DM-II.

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ABSTRACT

Diabetes Mellitus, a syndrome of disordered metabolism with multifactorial aetiology is characterized by chronic hyperglycaemia subsequently leading to long-term damage, dysfunction and multiple organ failure. Owing to the importance of disseminating the awareness, first National Ayurveda Day celebrated on 28th Oct. 2016, observed the theme as 'Ayurveda for prevention and control of Diabetes. *Madhumeha* concedes 2 subtypes viz., *Dhatukshayaja* and *Margavarodhaja*. *'Samshodhanam Akurvatam'* forms one of the important aetiological factors of *Madhumeha* which instigated in considering *Panchakarma* procedures of *Vamana* and *Virechana karma* for *Shodhana* particularly in *Margavarodhaja madhumeha* and, for a comprehensive management *Shilajit* Yoga is considered for *Shamana* therapy. **Material and Methods:** The study involved Group A (90 days): *Vamana* & *Virechana* (30 days) + Placebo (60 days). Group B (90 days): *Vamana & Virechana* (30 days) + *Shilajit yoga* (60 days). Dosage: 1 Cap. of 1000mg. Twice daily, Before food. **Results:** In placebo controlled Group-A, 6 (13.63%) got Controlled results, 10 (22.72%) got Marked Improvement, 24 (54.54%) got Moderate Improvement, 4 (9%) got Mild Improvement and in 4 patients there is No Change. In case of Drug trial (*Shilajit* Yoga) Group-B, 24 (50%) got Controlled results, 14 (29.1%) got Marked Improvement and 10 (20.8%) got Moderate Improvement. **Discussion:** *Vamana* acts on the basic pathology of *Bahudravasleshma* and *Bahuabadhameda*. *Vamana* and *Virechana* seems to reduce the insulin resistance, and *Virechana* must be increasing insulin secretion also. In contrast to Group A, '*Shilajit yoga'* intervened in Group B appears to have substantial controlling effect on the blood sugar levels with its Extra pancreatic and Immunomodulatory effects, and probably through Pancreatotrophic action. **Conclusion:** The final result of the study supports the role of *Shilajit* followed by *Shodana* procedures as a safe and complete substitute to allopathic medication in the patients with an excess of about 50-100mg/dl of blood glucose levels above normal levels, in FBS and PPBS values.

INTRODUCTION

Diabetes Mellitus (DM), a silent epidemic and a potentially life threatening life style disorder, has always been invincible. DM, a syndrome of disordered metabolism with multifactorial aetiology is characterized by chronic hyperglycaemia with disturbances in carbohydrate, fat and protein metabolism resulting from the defects in Insulin, subsequently leading to long-term damage, dysfunction and multiple organ failure [1-3]. Of the two variants, DM Type-2 is responsible for 90-95% of Diabetic cases worldwide. Diabetes is one of the major causes of premature deaths worldwide and for every 10 seconds two individuals develop diabetes and one person dies from its complications. According to International Diabetes Federation (IDF) Report & Atlas 2015- there are 415 million people with Diabetes around the world with 69.1 million cases in India and every 6 seconds a person dies from Diabetes. This is estimated to rise to 642 million by 2040 [4].

The whole concept of DM is the reiteration of what is known as *Madhumeha*, a type of *Vataja Prameha* enunciated in Ayurvedic epistemology. *Vataja Prameha* is of 4 types viz., *Majja meha*, *Ojo* or *Madhu meha*, *Vasa meha*, and *Lasika meha,* all of which are *Asadhya* in nature. *Madhumeha* concedes 2 subtypes viz., *Dhatukshayaja* and *Margavarodhaja*. *Dhatukshayaja Madhumeha* is purely *Vataja* and *Asadhya*, which may be construed as the invincible DM Type-1. *Margavarodhaja Madhumeha* is of *Kapha* & *Pitta* related *Vatadosha* and is *Kricchrasadhya*, which is in clinical concordance with the

intractable DM Type-2. *Vataja Pramehas* are *Asadhya*, nevertheless, treatments are mentioned, which should be perceived as the interventions specified for *Margavarodhaja Madhumeha,* an exceptionally *Kricchrasadhyaja Vataja Prameha.*

Charakacharya elucidates the aetiopathogenesis of Madhumeha, where *'Samshodhanam Akurvatam'* forms one of the important aetiological factors and vitiation of *Kapha & Pitta* along with other *Dushyas* form the core pathology of *Margovarodhaja Madhumeha*.[5].

This overview on the disease is the impetus for present research work which considers *Vamana* & *Virechana* procedures to mitigate *Kapha & Pitta* respectively, and *Shilajit Yoga*, as explained in Chakradatta, [6] to subjugate the disease.

As mentioned in the above reference, the intervention with *Shilajit* Yoga is strictly advised only after *Samsodhanam* i.e., *Vamana & Virechana karma*, which forms the principle criteria for planning the study.

MATERIALS AND METHODS

This study was conducted under a strict protocol to prevent bias and to reduce the sources of error in the study. This Randomized Controlled clinical trial was conducted under the following methods:

1. Sample Size:

110 clinically diagnosed *Madhumeha* patients were divided randomly into two groups:

Group A: This is 'Placebo Control Group': 54 patients were registered, 44 patients completed the trial while 10 Patients Left Against Medical Advice (LAMA)

Group B: This is 'Experimental Group': 56 patients were registered, 48 patients completed the trial while 08 patients Left Against Medical Advice (LAMA).

2. Source Of Subjects: Out-Patient Department and In-patient Department of Panchakarma, National Institute of Ayurveda, Jaipur.

3. Informed Consent: The study was explained clearly to the subjects and their signed, written (in patient's language) informed consent was taken before starting the trial.

4. Selection Criteria: A disease specific proforma was prepared and the observations were recorded after performing General, Systemic examinations.

a. Inclusion Criteria:

- Diagnosed Subjects with classical signs and symptoms of DM-Type 2 were included in the trial.
- Subjects who were ready to give written informed consent.
- Patients of age between 20-60 years.

b. Exclusion Criteria:

- Who were not ready to give informed consent.
- Patients of DM- Type 1
- Type-2 Diabetes patients on insulin therapy.
- Genetic defects
- Gestational diabetes
- Diseases of Exocrinopathies.
- Diabetes due to Endocrinopathies – Acromegaly, Cushing's syndrome, Glucogonoma, Pheochromocytoma, Hyperthyroidism etc.
- Drug or Chemical induced DM.
- Diabetes due to infections – Congenital Rubella, CMV etc.
- DM with Retinopathy, Nephropathy & previous H/O Coma..
- DM associated with genetic syndromes- Down's syndrome, Turner's syndrome, Klienfelter's syndrome.

c. Discontinuation Criteria

- Patients who constantly had hypoglycemic levels during *Shodhana karma*.
- Patients who constantly had hyperglycemic levels during *Shodhana karma*.
- Patients who couldn't strictly follow *Purvakarma* (*Snehapana*) or *Paschatkarma* (*Samsarjana krama*).
- Patients who developed complications.

Assessment Criteria

Subjective Parameters

▪ *Prabhuta Mutrata*	▪ *Sramaswasa*
▪ *Avila Mutrata*	▪ *Mukhamadhurya*
▪ *Nakta Mutrata*	▪ *Vibandha*
▪ *Pipasa*	▪ *Daurbalya*
▪ *Swedaadhikyata*	▪ *Pipilika Sancharati*
▪ *Kshudhadhikya*	▪ *Hasta Pada Tala Daha*
▪ *Atinidra*	▪ *Kara-Pada Suptata*

Subjective Assessment

The Gradational Assessment of Subjective Criteria were considered from -'Gradation of Symptoms: *Medovaha Srotas*, Criteria for Assessment of Results for *Madhumeha'*, a Chapter from the book -'Developing Guidelines for Clinical Research Methodology in Ayurveda', IPGTR&A, Jamnagar, 2011, written by Prof. M.S. Baghel. The following criteria were considered for the present study:

***Prabhuta mutrata* – Frequency of urine**

1.	3 – 6 times per day, rarely at night	0
2.	6 – 9 times per day, 0 – 2 times per night	1
3.	9 – 12 times per day, 2 – 4 times per night	2
4.	More than 12 times per day, more than 4 times per night	3

***Avila mutrata* (Turbidity): News Paper Test**

1.	Crystal clear fluid	0
2.	Faintly cloudy, smoky or hazy with slight turbidity.	1
3.	Turbidity clearly visible but newsprint easily read through test tube	2
4.	Newsprint not easily read through test tube	3
5.	Newsprint cannot be seen through test tube	4

***Naktamutrata* (nocturnal micturation)**

1.	No nocturnal micturation	0
2.	1 – 2 times passing of urine at night	1
3.	2 – 4 times passing of urine at night.	2
4.	more than 4 times passing of urine at night	3

***Pipasadhikya* (Increased Thirst)**

1.	Feeling of thirst (7 – 9 times/24 hours) & relieved by drinking water	0
2.	Feeling of moderate thirst (>9 - 11 times/24 hours) & relieved by drinking water	1
3.	Feeling of excess thirst (>11 – 13 times/24 hours) not relieved by drinking water	2
4.	Feeling of sever thirst (>13 times) not relieved by drinking water	3

***Svedadhikya* (Perspiration)**

1.	Sweating after heavy work and fast movement or in hot weather	0
2.	Profuse sweating after moderate work and movement	1
3.	Sweating after little work and movement (stepping ladder etc.)	2
4.	Profuse sweating after little work and movement	3
5.	Sweating even at rest or in cold weather	4

***Kṣudhadhikya* (Increased Appetite)** (1 meal = about 350gm diet)

1.	As usual / routine	0
2.	Slightly increased (1 meal extra with routine diet)	1
3.	Moderately increased (2 meals extra with routine diet)	2
4.	Markedly increased (3 meals extra with routine diet)	3

***Atinidra / Nidradhikya* (Increased Sleep)**

1.	Normal & sound sleep for 6 – 8 hrs. /24 hrs. with feeling of lightness and relaxation in the body & mind	0
2.	Sleep >8 -9 hrs. /24 hrs. with slight heaviness in the body.	1
3.	Sleep >9 - 10 hrs. /24 hrs. with heaviness in the body associated with *Jrimbha*	2
4.	Sleep >10 hrs. /24 hrs. with heaviness in the body associated with *Jrimbha & Tandra*	3

***Sramasvasa* (Dyspnoea)**

1.	Dyspnoea after heavy work and walking	0
2.	Dyspnoea after moderate work and walking	1
3.	Dyspnoea after mild work	2
4.	Dyspnoea even at resting condition	3

***Mukhamadhurya / Madhurasyata* (Sweetness in mouth)**

1.	Absent	0
2.	Occasional	1
3.	Frequently	2
4.	Continuous	3

***Vibandha / Purishabadhata* (Constipation)**

1.	Stool passes as per normal schedule	0
2.	Passes stool with strain, sometimes takes purgative	1
3.	Passes stool after more than 24 hours, frequently takes purgative	2
4.	Passes stool after gap of one day, normal purgatives does not work	3

***Daurbalya* (Weakness)**

1.	Can do routine exercise/work	0
2.	Can do moderate exercise with hesitancy	1
3.	Can do mild exercise only, with difficulty	2
4.	Cannot do mild exercise too	3

Hasta-Padatala daha

1.	No *Daha*	0
2.	*Hasta-Pada-tala daha* found occasionally, mild, bearable	1
3.	*Hasta-Pada-tala daha* continues but bearable & not severe	2
4.	*Hasta-Pada-tala daha* continues and severe & unbearable	3

Kara-Pada suptata

1.	No *suptata*	0
2.	*Kara-Pada suptata* intermittent	1
3.	*Kara-Pada suptata* continuous but bearable & not severe	2
4.	*Kara-Pada suptata* continuous and severe & Unbearable	3

***Pippalika-Sancharati* (Tingling sensation)**

1.	No tingling sensations	0
2.	Tingling sensation that is not continuous does not disturb routine activity	1
3.	Continuous tingling sensation does not disturb routine activity	2
4.	Severe continuous tingling sensation disturbs routine activity	3

ii. Objective Parameters

- Hematological – TLC, DLC, ESR, Hb%
- Biochemistry – FBS, PPBS, Lipid profile, HbA1c
- Urine examination – Routine, Microscopic, FUS, PPUS

6. Study Type, Design & Duration

The study was an Interventional type and Randomized Placebo Controlled Trial and the total Trial period was 90 days with 30 days for *Shodhana karma* (*Vamana* & *Virechana*) and 60 days for Drug / Placebo administration in both the Groups.

- Group A (90 days): *Vamana & Virechana* (30 days) + Placebo (60 days).
- Group B (90 days): *Vamana & Virechana* (30 days) + *Shilajit yoga* (60 days).
- Any ongoing treatment for T2DM in all the patients was withheld for 3days prior to implementation of the research plan. The blood sugar levels thus achieved were considered for before treatment data.
- *Vamana karma* and *Virechana karma* will be performed once with proper *Purvakarma* and *Paschatkarma*.
- Follow up was done after 15 days of trial period.

7. Drug Review

a. Drugs for *Shodhana Karma*

***Vamana* Drugs**	***Virechana* Drugs**
▪ *Madanaphala* ▪ *Yashtimadhu* ▪ *Vacha* ▪ *Saindhav Lavan* ▪ *Madhu*	▪ *Trivrit* ▪ *Hareetaki* ▪ *Aragwada* ▪ *Sanaya*

b. *Shamana* Drug: *'Shilajit Yoga'* (Ref: Su.Ch / Bh.R / Chakradatta)

***Shilajit* Processing:** *Shuddha Suryatapi Shilajit* was collected and subjected to 7 *Bhavanas* with *Salasaradi gana dravya kashaya.* Then it was dried and powdered.

Dosage: 1 Cap. of 1000mg. Twice daily, Before food.

***Anupana*:** *Salasaradi Gana Kashaya.*

Duration: 60 days.

Table 1: *Salasaradi Gana Dravya*: (S.Su. 38/ 12-13) [7]

Drugs			
1	*Salasara*	13	*Ashana*
2	*Ajakarna*	14	*Dhava*
3	*Khadira*	15	*Arjuna*
4	*Kaalaskanda*	16	*Taala*
5	*Kramuka*	17	*Shaaka*
6	*Bhurja*	18	*Kadara*
7	*Meshashringi*	19	*Naktamaala*
8	*Tinisha*	20	*Puteeka*
9	*Chandana*	21	*Ashwakarna*
10	*Kuchandana*	22	*Aguru*
11	*Shimshapa*	23	*Kaaleeyakam*
12	*Shireesha*		

Out of the above listed drugs of *Salasaradi Gana*, the following drugs which were available in the market were procured and used for the preparation of *Kashaya* to be used for *Bhavana* of *Shilajit* and for dispensing to the trial patients in the form of *Yavakuta churna* to prepare *Anupana*.

Available Drugs (*Salasaradi Gana*)	**Useful part**
Khadira	Resin
Kramuka	Fruit
Meshasringi	Leaves
Sireesha	Bark
Arjuna	Bark
Karanja	Seeds

8. Follow Up Study

- Patients were followed after 15 days of the trial period.
- Laboratory investigation was repeated after complete treatment.
- Improvement and other side effects were noted.

Assessment of Overall Effect of the Therapy

1) Control of the disease: improvement in FBS and PPBS by > 50 mg/dl or reaching normal range and sign- symptoms relieving completely.
2) Marked Improvement: Relieved signs / symptoms and improved FBS and PPBS 26-50 mg/dl.
3) Moderate Improvement: Moderately improved signs / symptoms with an improvement of 10-25 mg/dl in FBS and PPBS.
4) Mild Improvement: Nominal reduction in signs/symptoms, Improvement of <10 mg/dl in FBS and PPBS.
5) Nil / Unchanged: no change in the status of signs or symptoms or in the blood glucose levels.

OBSERVATIONS AND RESULTS

A total of 110 patients were registered under the trial, out of which 92 patients were completely studied upon in the research. Hence, the Observational Data of Distribution was presented for 110 patients while Result Data of statistical analysis was presented for 92 patients.

Age wise distribution of patients

Age: In the Present study maximum (48.18%) patients were in the age group of 41-50 yrs which indicates the incidence of disease is above 40yrs of age which is in concordant with the recent statistical data on the onset of type – DM after the age of 40yrs.

Occupation: Data shows that in present study the incidence of *Madhumeha* is maximum in Housewives (31.82%). This occurrence could be because of sedentary life-style of most of the house wives and lack of awareness on the life-style disorders.

Family history: Majority of the patients (60%) were having positive family history of diabetes. This clearly supports the factor of genetic predisposition, an important etiology in Type 2 DM.

Treatment history: In the present study 28.18% of patients were using Oral Hypoglycemic Agents (OHA) and 23.63% were using Ayurveda treatment while 32.72% were taking both and 15.45% patients were without any treatment.

This observation confirms that the primary preference of general population is usually allopathic management. As the awareness of Ayurvedic and other natural healing approaches is increasing people are opting these modalities after either failing or dissatisfied with the allopathic management.

Chronicity: Chronicity wise distribution of patients shows that maximum patients (46.36%) were suffering from 1-5 years, while 6.36% had a chronicity of more than 10 years. The intractability of the disease directly depends on its chronicity and in this study most of the subjects are with less chronicity rendering more possibility for the research.

Physical activity: Maximum no. of patients (56.36) were leading a sedentary life, indicating a direct etiology to *Madhumeha*.

Diet pattern: Maximum patients (70%) were vegetarians. This criterion is of no significance to the study.

***Dominant rasa*:** Maximum numbers of patients (91.82%) have habit of taking *Madhura rasa* dominant diet. This indicates dietary etiology where excessive intake of *Madhura rasa* leads to *Kapha* and *Medo vriddhi*, thereby *Agnimandya*, *Ama* and *Kleda utpatti* and ultimately *Margavarodhaja madhumeha.*

Agni: In this study *Viṣamagni* was observed in majority of subjects (37.27%). This indicates the vitiated state of *Agni* leading to improper digestion, assimilation and metabolism at organ and cellular level, one of the main causes of the disease.

***Sarira prakriti*:** In 110 patients, maximum (46.36%) belongs to *Vata- Kaphaja* (VK) *Prakriti*. The main pathological factors in *Madhumeha* being *Vata* and *Kapha*, this observation confirms the type of body constitution responsible for the vulnerability to the disease.

***Manasa prakriti*:** Maximum patients (56.36%) were of *Rajasa- Tamasa Prakriti*. This observation was important in the form of temperament laying the foundation for the disease.

Sara: Maximum patients (45.45%) were of *Meda-Sara*. This suggests that *Meda sara* individuals are more prone to *Madhumeha*.

***Abhyavaharana & Jarana Sakti*:** In the present study, the majority of patients 62.73% had *Madhyama Abhyavaharana-sakti* and maximum patients (56.36%) have *Madhyama Jaraṇasakti*. Though the significance of this observation is less it indicates the possibility of digestive disturbances leading to *Ama* formation and then to the disease.

Body weight & BMI: Maximum number of patients (33.64%) were having body weight in the range of 61-70Kg and 4.55% were having >90 Kgs weight and, 48.18% patients had BMI in between 25-29.9, 40 and 3.64% patients had BMI >35. These observations though are not significant, indicate the direct relation of overweight and *Madhumeha*.

***Nidana sevana*:** Most of the patients (88.18%) gave the history of *Ghrita* consumption, followed by those who consume *Ati-snigdha Ahara* (82.73%), Milk Products (81.82%) *Guḍa vaikrita* (sugarcane) (80.00%), *Ati-Dadhi sevana* (77.27%), *Ati-madhura rasa* (73.64%), *Navannapana* (68.18), *Ati-sita* (60.91), *Madhya* (Alcohol) (35.45) and *Mamsa sevana* (30.00).

According to *Viharaja nidana* most of the patients gave the history of *Avyayama* (80%), *Asyasukha* (76.36%), *Swapnasukha* (74.55%), *Alasya* (69.09%) and *Divaswapna* (33.64%).

The diet and life-style aspects in this observation highlighted all the factors responsible for the insidious development of *Madhumeha*.

***Rupa*:** In this study the following symptoms were found predominantly: *Prabhuta-mutrata* (92.73%), *Daurbalya* (78.18%), *Avila-mutrata* (76.36%), *Kaṇṭha-talu- sosa* (*pipasadhikya*) (70.00%), *Alasya* (69.09%) *Svedatipravritti* (68.18%), *Kṣudhadhikya* (58.18%) and *Hasta-pada-tala daha* (58.18%).

The typical symptomatology of *Madhumeha* is observed in more than half of the subjects. *Prabhuta mutrata* (excess and frequent urination) being present in almost all the patients indicates the vitiation of *Drava dhatu,* which is also represented by the symptom *Avila mutrata* (turbid urine). Following these are the other symptoms like *Pipasadhikya, Kantha-talu-sosa, Daurbalya* etc., which represent the deficiency of proper metabolism in the body.

***Upadrava*:** Most common *Upadrava* was Neuropathy (58.18%) and *Daha* (58.18) followed by Hypertension (50%). Retinopathy was found in 16.36%. Hypoglycemic attack and *Prameha piḍika* have the same incidence i.e.

10%. Incidence of Nephropathy was in 6.36% and that of gangrene was in 0.09%.

Altered sensations like polyneuropathy followed by burning sensation in peripheries and hypertension were observed to be the common complications of *Madhumeha*. The chronic condition of the disease resulted in micro-vascular pathologies like retinopathy, nephropathy etc.

RESULTS

Analysis of Subjective Parameters

Clinical improvement in *Prabhuta-mutrata*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	2.21	0.91	1.30	58.95	0.67	0.10	820	<0.0001 (ES)
B	48	2.18	0.41	1.78	81.31	0.85	0.12	1081	< 0.0001 (ES)

	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	1.30	1.78	58.95	81.31	0.97	0.15	707.5	0.0036 (VS)

Clinical improvement in *Avila mutrata*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	1.53	1.19	0.35	22.73	0.92	0.14	285	0.0196 (S)
B	48	2.12	0.78	1.35	63.46	0.69	0.10	1035	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.35	1.35	22.73	63.46	1.12	0.17	473.5	< 0.0001 (ES)

Clinical improvement in *Naktamutrata*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	2.02	0.91	1.12	55.17	0.66	0.10	703	< 0.0001 (ES)
B	48	2.37	0.53	1.84	77.59	0.80	0.11	1128	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	1.12	1.84	55.17	77.59	1.02	0.16	540	< 0.0001 (ES)

Clinical improvement in *Pipasadhikya*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	2.02	0.72	1.30	64.37	0.60	0.09	820	< 0.0001 (ES)
B	48	1.88	0.53	1.35	71.74	0.63	0.09	1128	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	1.30	1.35	64.37	71.74	0.89	0.14	1043	0.9285 (NS)

Clinical improvement in *Swedadhikya*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	2.23	1.21	1.02	45.83	0.41	0.06	820	< 0.0001 (ES)
B	48	2.08	0.67	1.41	67.65	0.73	0.10	1081	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	1.02	1.14	45.83	67.65	0.77	0.12	732.5	0.0024 (VS)

Clinical improvement in *Daurbalya*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	1.40	1.23	0.16	11.67	0.97	0.15	119	0.2798 (NS)
B	48	1.41	0.90	0.51	36.23	1.00	0.14	535	0.0014 (VS)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.16	0.51	11.67	36.23	1.36	0.21	847	0.0775 (NS)

Clinical improvement in *Ksudhadhikya*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	1.53	0.90	0.63	41.33	1.24	0.18	574	< 0.001 (VS)
B	48	1.60	0.70	0.90	56.52	0.61	0.09	634	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.90	0.63	56.52	41.33	1.46	0.22	986	0.5668 (NS)

Clinical improvement in *Atinidra / Nidradhikya*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	1.44	1.02	0.42	29.03	1.01	0.15	321	0.0108 (S)
B	48	1.33	0.84	0.49	36.92	1.00	0.14	502	0.0019 (VS)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.42	0.49	29.03	36.92	1.48	0.23	1010	0.7114 (NS)

Clinical improvement in *Sramasvasa*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	1.16	0.84	0.33	28.00	0.97	0.15	234	0.0348 (S)
B	48	1.33	0.88	0.45	33.85	1.00	0.14	479	0.0039 (VS)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.33	0.45	28.00	33.85	1.31	0.20	969	0.4715 (NS)

Clinical improvement in *Mukhamadhurya*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	1.53	0.60	0.93	60.61	0.46	0.07	703	< 0.0001 (ES)
B	48	1.20	0.27	0.94	77.97	0.52	0.07	861	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.93	0.94	60.61	77.97	0.73	0.11	1047	0.9539 (NS)

Clinical improvement in *Vibandha*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	1.20	0.67	0.53	44.07	1.00	0.14	470	< 0.0011 (VS)
B	48	1.72	0.77	0.95	55.41	0.72	0.11	528	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.95	0.53	55.41	44.07	1.39	0.21	812	0.0422 (S)

Clinical improvement in *Hasta-Pada-tala daha*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	1.53	0.70	0.83	54.55	0.53	0.08	561	< 0.0001 (ES)
B	48	1.63	0.31	1.32	81.25	0.83	0.12	861	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.83	1.32	54.55	81.25	0.96	0.15	691	0.0018 (VS)

Clinical improvement in *Kara-Pada suptata*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	1.42	0.60	0.81	57.38	0.59	0.09	496	< 0.0001 (ES)
B	48	1.14	0.35	0.80	69.64	0.79	0.11	435	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.81	0.80	57.38	69.64	1.11	0.17	1001	0.6537 (NS)

Clinical improvement in *Pipilika-Sancharati*

Group	N	Mean		Diff.	% of Change	SD	SE	W	P
		BT	AT						
A	44	1.42	0.58	0.84	59.02	0.57	0.09	528	< 0.0001 (ES)
B	48	1.45	0.49	0.96	66.20	0.54	0.08	861	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	U	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.84	0.96	59.02	66.20	0.80	0.12	942	0.2882 (NS)

Subjective Parameters

The effect of therapy on the variable *Prabhuta mutrata* is statistically extremely significant (p<0.0001) in both Groups, while clinically Group A showed 58.95% relief and Group B showed 81.31% relief. When the two Groups A & B were compared the difference was very significant (p=0.0036) between the two groups indicating a better therapeutic effect in Group B than in Group A.

In the variable *Avila mutrata* Group A showed 22.73% relief with p-value of 0.0196, which was a significant result, Group B showed 63.46% relief with p value of <0.0001 which was an Extremely significant result. When both groups are compared, two tailed p value is <0.0001, which is an extremely significant result, indicating a better result in Group B than in Group A.

The effect of therapy on the variable *Naktamutrata* is statistically extremely significant (p<0.0001) in both Groups, while clinically Group A showed 55.17% relief and Group B showed 77.59% relief. When two groups A & B were compared, the difference was extremely significant (p<0.0001), indicating a better therapeutic effect in Group B than in Group A.

The effect of therapy on the variable *Pipasadhikya* is statistically extremely significant (p<0.0001) in both Groups, while clinically Group A showed 64.37% relief and Group B showed 71.74% relief. When two groups A & B were compared, two tailed p value is 0.9285, where the difference is though statistically Non-significant, clinically Group B was more effective than Group A.

The effect of therapy on the variable *Swedadhikya* is statistically extremely significant (p<0.0001) in both Groups, while Group A showed 45.83% relief and Group B showed 67.65% relief. When the two groups A & B were compared, the two tailed p value is 0.0024 where the difference is very significant indicating a clinically better result in Group B than in Group A.

In the variable *Daurbalya*, Group A showed 11.67% relief with p-value 0.2798 which is not significant and Group B showed 36.23% relief with p-value 0.0014 which is very significant. When the two Groups are compared the two tail p value is 0.0775, which is though not a significant difference indicates a better clinical effect in Group B than in Group A due to the % relief.

In the variable *Ksudhadhikya* statistically p-value is <0.001 in Group A which is Extremely significant and p-value is <0.0001 in Group B which is a very significant result; Clinically Group B showed 56.52% relief and Group A showed 41.33% relief. While both groups are compared p=0.5668 which suggests that Clinically Group B has a better effect than Group A.

In the variable *Atinidra / Nidradhikya*, Group B showed 36.92% relief with p-value 0.0019 which was very significant result and Group A showed 29.03% relief with p-value 0.0108 which was also a significant result. When the two groups A & B were compared, there was no significant difference (p=0.7114) between the two groups which implies that clinically Group B is better than Group A.

In the variable *Sramasvasa*, Group B showed 33.85% relief with p-value 0.0039, which was very significant result and Group A showed 28.00% relief with p-value 0.0348 which was also a significant result. When the two groups A & B were compared, there was no significant difference (p=0.4715) between the two groups, which implies that clinically Group B is better than Group A.

The effect of therapy on the variable *Mukhamadhurya* is statistically extremely significant (p<0.0001) in both Groups, while clinically Group B showed 77.97% relief and Group A showed 60.60% relief. When the two groups A & B were compared, there was no significant difference (p=0.9539) between the groups suggesting that clinically Group B yielded better result than Group A.

In the variable *Vibandha*, Group B showed 55.41% relief with p-value < 0.0001, which was an Extremely significant result and Group A showed 44.07% relief with p-value< 0.0011 which was a very significant result. When the two groups A & B were compared, the difference was significant (p=0.0422) suggesting that clinically Group B has a better effect than Group A.

The effect of therapy on the variable *Hasta-Pada-tala* is statistically extremely significant (p<0.0001) in both Groups, while Group A showed 54.55% relief and Group B showed 81.25% relief. When both the groups are compared the p value is 0.0018 indicating a very significant difference suggesting that clinically Group B has a better effect than Group A.

The effect of therapy on the variable *Kara-Pada suptata* is statistically extremely significant (p<0.0001) in both Groups, while Group A showed 57.38% relief and Group B showed 69.64% relief. When the two groups A & B were compared, there was no significant difference (p=0.6537) between the groups, suggesting clinically more efficacy in Group B than in Group A.

The effect of therapy on the *variable Pipilika-Sancharati* is statistically extremely significant (p<0.0001) in both Groups, while Group B showed 66.20% relief and Group A showed 59.02% relief. When the two groups A & B were compared, there was no significant difference (p=0.2882), suggesting clinically more efficacy in Group B than in Group A.

ANALYSIS OF OBJECTIVE PARAMETERS

Pattern of improvement in FBS

Group	N	Mean		Diff.	% of Change	SD	SE	t	P
		BT	AT						
A	44	191.43	131.27	60.16	31.43	36.52	5.22	11.53	< 0.0001 (ES)
B	48	195.37	130.79	64.58	33.05	31.30	4.77	13.53	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	t	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	60.16	64.58	31.43	33.05	59.01	9.00	0.49	0.5380 (NS)

Pattern of improvement in PPBS

Group	N	Mean		Diff.	% of Change	SD	SE	t	P
		BT	AT						
A	44	269.53	193.00	76.53	28.39	41.53	6.33	12.08	< 0.0001 (ES)
B	48	265.69	189.71	75.98	28.60	45.65	6.52	11.65	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	t	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	76.53	75.98	28.39	28.60	70.52	10.75	0.05	0.9525 (NS)

Pattern of improvement in GHb (HbA_1C)

Group	N	Mean		Diff.	% of Change	SD	SE	t	P
		BT	AT						
A	44	7.75	6.62	1.13	14.55	0.68	0.10	10.82	< 0.0001 (ES)
B	48	7.42	6.27	1.14	15.43	0.89	0.13	9.05	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	t	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	1.13	1.14	14.55	15.43	1.26	0.19	0.09	0.9191 (NS)

Pattern of improvement in Se. Cholesterol

Group	N	Mean		Diff.	% of Change	SD	SE	t	P
		BT	AT						
A	44	206.49	183.35	23.14	11.21	23.90	3.64	6.35	< 0.0001 (ES)
B	48	219.40	179.43	39.97	18.22	27.30	3.90	10.25	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	t	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	23.14	39.97	11.21	18.22	36.76	5.61	3.51	0.0024 (VS)

Pattern of improvement in Se. Triglycerides

Group	N	Mean		Diff.	% of Change	SD	SE	t	P
		BT	AT						
A	44	182.37	159.23	23.14	12.69	30.30	4.62	5.01	< 0.0001 (ES)
B	48	190.08	151.69	38.39	20.20	29.76	4.25	9.03	< 0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	t	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	23.14	38.39	12.69	20.20	36.72	5.60	3.23	0.0170 (S)

Pattern of improvement in Se. HDL Cholesterol

Group	N	Mean		Diff.	% of Change	SD	SE	t	P
		BT	AT						
A	44	59.88	59.56	0.33	0.54	7.37	1.12	0.29	0.7735 (NS)
B	48	60.16	57.78	2.38	3.96	7.04	1.01	2.37	0.0220 (S)

Group	Mean diff.		% of Change		SD	SE	t	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.33	2.38	0.54	3.96	8.46	1.29	1.59	0.1753 (NS)

Pattern of improvement in Se. LDL Cholesterol

Group	N	Mean		Diff.	% of Change	SD	SE	t	P
		BT	AT						
A	44	109.86	92.61	17.25	15.70	19.96	3.04	5.67	<0.0001 (ES)
B	48	121.61	89.24	32.37	26.61	27.25	3.89	8.31	<0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	t	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	17.25	32.37	15.70	26.61	35.64	5.43	3.17	0.0035 (VS)

Showing pattern of improvement in Se. VLDL

Group	N	Mean		Diff.	% of Change	SD	SE	t	P
		BT	AT						
A	44	36.20	31.72	4.48	12.38	6.78	1.03	4.34	<0.0001 (ES)
B	48	37.85	29.82	8.03	21.22	6.69	0.96	8.40	<0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	t	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	4.48	8.03	12.38	21.22	8.31	1.27	2.80	0.0134 (S)

Pattern of improvement in Specific Gravity

Group	N	Mean		Diff.	% of Change	SD	SE	t	P
		BT	AT						
A	44	1.03	1.02	0.01	0.56	0.01	0.001	5.54	0.0003 (ES)
B	48	1.03	1.02	0.01	0.86	0.005	0.0007	12.63	<0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	t	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.01	0.01	0.56	0.86	0.01	0.001	2.96	0.0695 (NS)

Pattern of improvement in FUS (Fasting Urine Sugar)

Group	N	Mean		Diff.	% of Change	SD	SE	t	P
		BT	AT						
A	44	2.55	0.94	1.61	63.13	0.79	0.11	14.36	<0.0001 (ES)
B	48	2.12	0.67	1.45	68.39	0.59	0.09	16.03	<0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	t	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	1.61	1.45	63.20	68.13	1.11	0.17	2.05	0.2479 (NS)

Pattern of improvement in Body weight

Group	N	Mean		Diff.	% of Change	SD	SE	t	P
		BT	AT						
A	44	70.55	69.29	1.27	1.79	1.09	0.16	8.09	<0.0001 (ES)
B	48	69.37	66.56	2.81	4.06	0.70	0.11	26.40	<0.0001 (ES)

Group	Mean diff.		% of Change		SD	SE	t	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	1.27	2.81	1.79	4.06	1.62	0.25	6.27	<0.0001 (ES)

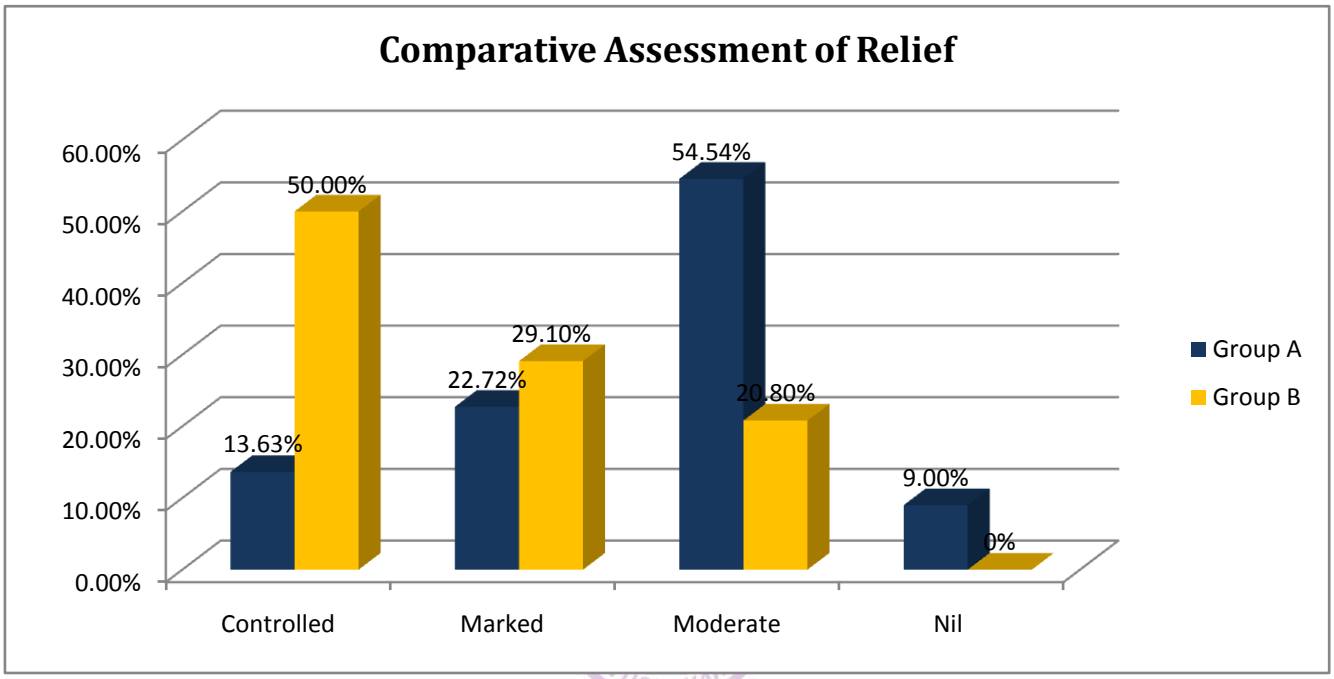
Pattern of improvement in BMI (Body mass Index)

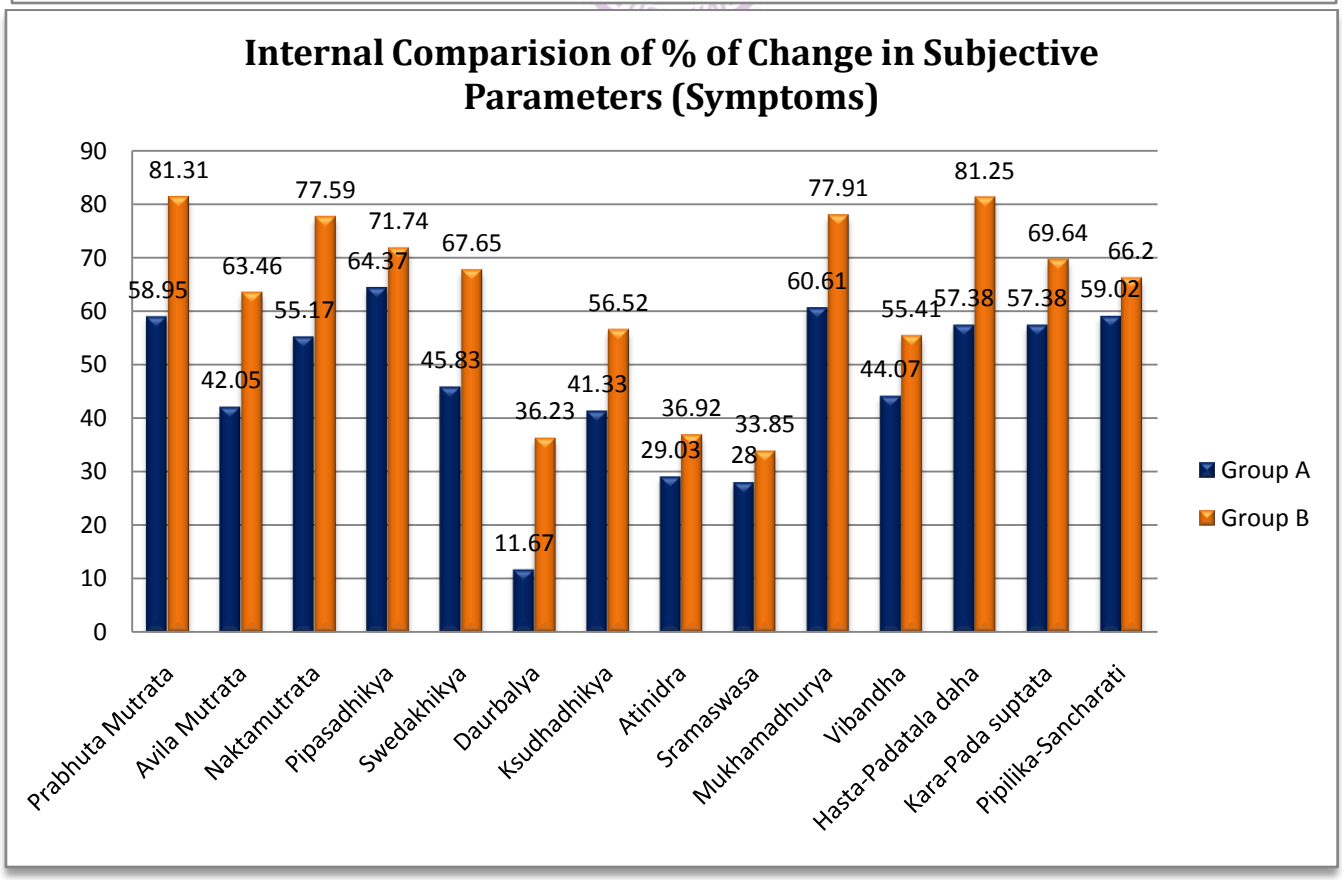
Group	N	Mean		Diff.	% of Change	SD	SE	t	P
		BT	AT						
A	44	25.59	25.19	0.40	1.57	0.98	0.14	2.86	0.0062 (VS)
B	48	26.41	25.34	1.07	4.06	0.26	0.04	26.80	<0.0001 (ES)

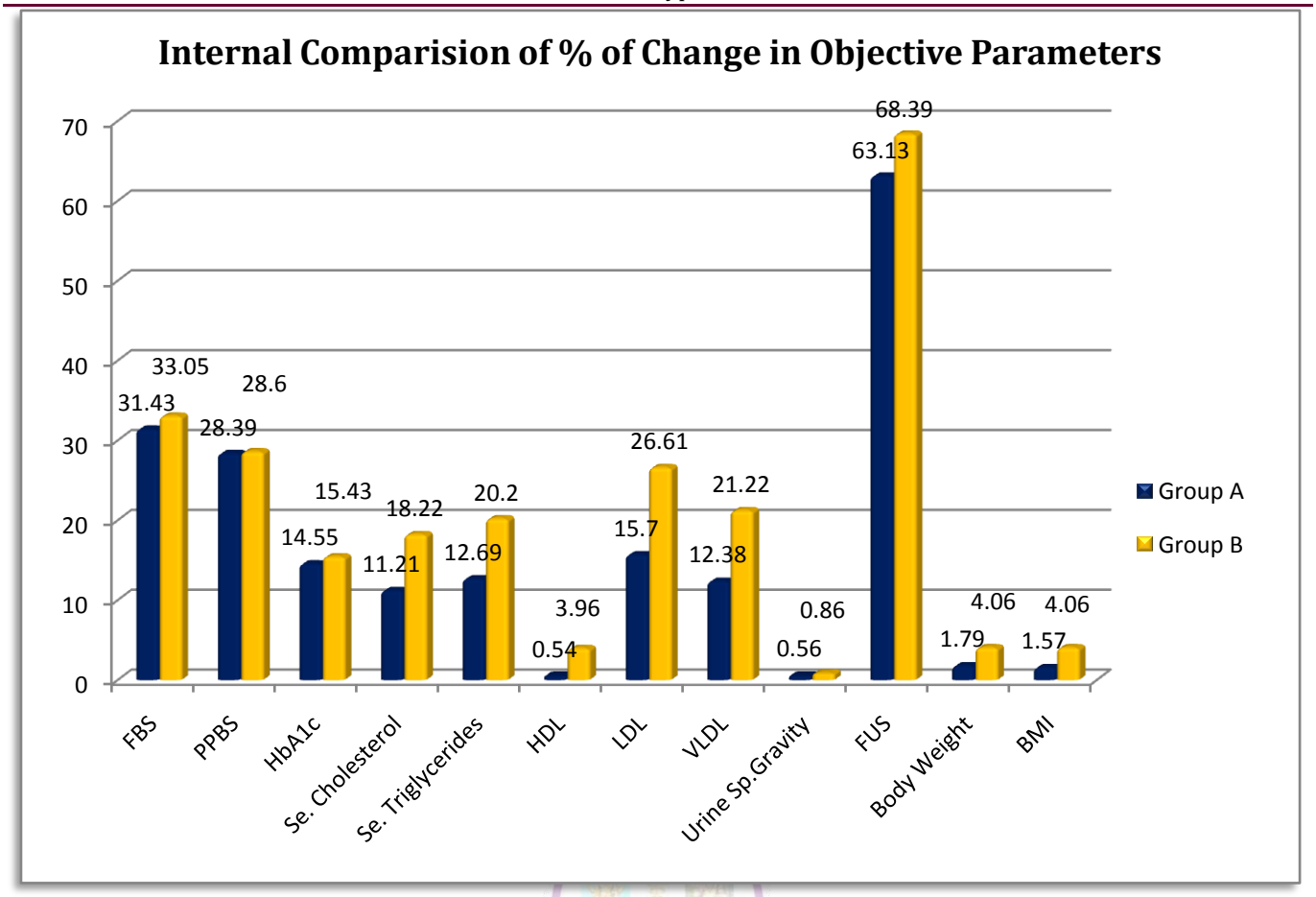
Group	Mean diff.		% of Change		SD	SE	t	P
	Grp. A	Grp. B	Grp. A	Grp. B				
A vs B	0.40	1.07	1.57	4.06	1.04	0.16	4.21	<0.0001 (ES)

Overall comparison of effect of the therapy in 92 patients of *Madhumeha*

S. No.	Total effect of therapy	Group-A (N= 44)		Group-B (N= 48)		Total (N= 92)	
		No. of Pts.	%	No. of Pts.	%	No. of Pts.	%
1	Controlled	6	13.63%	24	50%	30	32.60%
2	Marked Improvement	10	22.72%	14	29.1%	24	26.08%
3	Moderate Improvement	24	54.54%	10	20.8%	34	36.95%
4	Nil / Unchanged	4	9.0%	0	0%	4	4.34%







The effect of therapy on Fasting Blood Sugar is statistically extremely significant (p<0.0001) in both Group A & B. On comparison between the groups, though the difference is not statistically significant (p=0.5380), clinically Group B with 33.05% change was more effective in reducing Fasting Blood sugar than Group A with 31.43% change.

The effect of therapy on PPBS is statistically extremely significant (p<0.0001) in Both Groups A & B. On comparison between the groups though the difference is not statistically significant (p=0.9525), clinically Group B with 28.60% change was more effective in reducing Post Prandial Blood Sugar than Group A with 28.39% change.

The effect of therapy on Glycosylated Haemoglobin (GHb/HbA_1C) is statistically extremely significant (p<0.0001) in Both Group A & B. On comparison between the groups though the difference is not statistically significant (p= 0.9191), clinically Group B with 15.43% change was more effective on Glycosylated haemoglobin than Group A with 14.55% change.

The effect of therapy on Se. Cholesterol is statistically extremely significant (p<0.0001) in both Group A & B. Inter group comparison showed very significant difference (p=0.0024) between two groups suggesting that clinically Group B (18.22%) was more effective than Group A (11.21%).

The effect of therapy on Se. Triglyceride is statistically extremely significant (p<0.0001) in Group A & B. Intergroup comparison showed significant difference (p=0.017) between two groups suggesting that clinically Group B (20.20%) was more effective than Group A (12.60%).

In the variable Se. HDL Cholesterol, Group B showed 3.96% of change with p-value 0.0220 which is statistically significant and Group A showed 0.54% of change with p-value 0.7735 which is not a significant result. Inter group comparison yielded non- significant (p=0.1753) difference, conferring that clinically Group B was more effective than group A.

The effect of therapy on Se. LDL was extremely significant (p<0.0001) in Group A & B. When the two groups were compared, there was very significant difference (p=0.0035) between two groups indicating that clinically Group B was more effective with a change of 26.61% than Group A with 15.70% change.

The effect of therapy on Serum VLDL Cholesterol was statistically extremely significant (p<0.0001) in Group A & B. When the two groups were compared, there was significant difference (p=0.013) between the groups indicating that clinically Group B with 21.22 % change was more effective than Group A with 12.38 % change.

The effect of therapy in urine Specific Gravity is statistically extremely significant with p-values 0.0003 & <0.0001 in Group A & B respectively. When the Groups A & B were compared, there is no significant difference (p=0.0695) between Groups, suggesting that clinically

Group B with 0.86% change was more effective than Group A with 0.56% change.

The effect of therapy in FUS (Fasting Urine Sugar) is statistically extremely significant with p-values <0.0001 in both Group A & B. Inter group comparison showed no significant difference (p=0.2479) between the groups indicating that clinically Group B showed better effect with 68.13% of change than Group A with 63.20% of change.

In minimizing body weight both the Groups A & B were extremely significant with p-value <0.0001 and the inter-group comparison showed extremely significant difference in between the groups indicating that clinically Group B was very effective with a change of 4.06% when compared to 1.79% in Group A.

In BMI, Statistical evaluation of studied groups showed extremely significant (P<0.0001) result in Group B and very significant (p=0.0062) result in Group A. The inter-group comparison showed extremely significant difference (p<0.0001) in between group A & B and clinically Group B with 4.06% of change was more effective than Group A with 1.57% of change.

Over all comparison of effect of therapy

In case of placebo controlled Group-A, 6 patients (13.63%) got Controlled results, 10 (22.72%) patients got Marked Improvement, 24 (54.54%) patients got Moderate Improvement, 4 (9%) patients got Mild Improvement and in 4 patients there is No Change at the end of the study.

In case of Drug trial (*Shilajit Yoga*) Group-B, 24 (50%) patients got Controlled results, 14 (29.1%) patients got Marked Improvement and 10 (20.8%) patients got Moderate Improvement.

DISCUSSION ON PHARMACO- KINETICS:

- Type‑2 diabetes occurs due to impaired insulin secretion, peripheral Insulin Resistance and Excessive Hepatic Glucose production. Insulin resistance impairs glucose utilization by insulin sensitive tissues and increase hepatic glucose output, both these effects contribute to the hyperglycemia.
- Increased hepatic glucose output predominantly accounts for increased fasting hyperglycemia, whereas decreased peripheral glucose uptake results in postprandial hyperglycemia [8].
- *Bahudravasleshma* and *Bahuabaddhameda* [9] are the basic pathological factors for *Prameha*. *Bahudravasleshma* could be because of tissue defect, whereas *Bahu‑abaddhameda* can be correlated with free fatty acids, which are released from intra abdominal central adipose tissues. Free fatty acid is the main etio-pathological factor for Insulin Resistance.
- Also, the derangement of glucose, fat and protein metabolism during Diabetes results in the development of hyperlipidaemia [10] [11] [12].

➢ As far as *Vamana* is concerned it alleviates primarily *Kapha* and to some extent *Pitta*. Here *Vamana* seems to reduce the peripheral insulin resistance in muscles by alleviating *Bahudravasleshma* and so helping to increase the glucose uptake. As *Vamana* also reduces the *Meda*, it must be promoting the function of insulin by reducing the circulating free fatty acids in the body.

As the effect of *Virechana* is at the site of *Pitta* it can be hypothesized that by acting primarily on liver and pancreas it may help to reduce hepatic glucose production and increase insulin production by overcoming the impaired insulin secretion condition.

Both of these procedures justify their role in reducing both FBS and PPBS considerably. *Vamana* acts on the basic pathology of *Bahudravasleshma* and *Bahuabadhameda*. It is clear that both *Vamana* and *Virechana* are reducing the insulin resistance and *Virechana* must be increasing insulin secretion also.

➢ There were some patients in both groups who could maintain their FBS and PPBS well in control even during the follow up with the antidiabetic diet regimen and life style changes. However, this trend could not be maintained for long where increase in both FBS and PPBS was noted, suggesting the fact that only *Vamana* or *Virechana* is not capable enough to maintain the sugar levels.

Prameha is an *Anushangivyadhi* - disease having relapsing nature. Hence, for better control of blood sugar levels, along with this *Shodana* therapy *Rasayana chikitsa* (rejuvenation therapy) is needed.

DISCUSSION ON MODE OF ACTION

In *Prameha*, the predominant *Dosha* (causative factors) and *Dushya* (effected tissue) are *Kapha* and *Meda* (fat). *Panchakola churna* selected for *Deepana ‑paachana* increases Agni and alleviates *Kapha* and *Meda*. Its indication in Prameha is probably due to its therapeutic effect in breaking the pathogenesis of *Prameha*.

Ghrita (ghee) has been mentioned as best *Sneha* in Ayurveda because of its specific qualities of *Yogavahitva* (substance which acquires the property of another substance when combined together and acts as catalyst) and *Samsakaranuvartana* (property to assimilate effectively the properties of other substances). Hence, *Ghrita* was chosen for *Abhyantara snehana* purpose. (It may help to reduce the insulin resistance at cellular level as well as the circulating free fatty acids in the blood).

Apart from *Kapha* and *Medas* for which *Vamana* karma is advised, Patients with *Madhumeha* (DM) commonly have the condition of *Malabaddhata* and *Pitta* participation, in whom *Virechana karma* will be of substantial use.

Hence, It can be inferred that both *Vamana* and *Virechana* cause marked reduction in FBS and PPBS levels. In early course of disease *Samshodhana* must be the choice of treatment; as at this stage, patient has dominance of *Kapha* and *Pitta*.

It can be hypothesized that *Vamana*- by reducing *Kapha* and *Meda* helps to minimize insulin resistance, whereas *Virechana*- probably by lowering down the

hepatic glucose production and probably by promoting insulin secretion helps to control blood sugar. Nevertheless, as *Prameha* is *Anushangivyadhi*, neither *Vamana* nor *Virechana* alone can act as complete treatment for it. Hence, in the present study the DM-II patients in both the Groups were first subjected to *Shodhana karma* (which included both *Vamana karma* and *Virechana karma*) followed by conservative therapy, wherein Group B was intervened with *Shilajit Yog* and Group A with Placebo.

Shilajit considered for the present study was processed and potentiated through 7 *Bhavanas* with *Salasaradi gana dravya kashaya*. The processed and powdered *Shilajit* is dispensed to patients (Gr-B) in Capsule (1000mg capacity) form to be consumed twice in a day before food with *Salasaradi gana kashaya* as *Anupana*.

The Organoleptic properties of *Shilajit* in Ayurvedic terms are *Anamlam, Katu- Tikta- Kashaya-rasa, Soshana-Chedana guna, Ushna virya* and *Katu vipaka*. Researches revealed that *Shilajit*, along with extra pancreatic, immunomodulatory[13] and antioxidant effects [14][15] increases the number of β-cells of pancreas, i.e. pancreatotrophic action, which may result in better sensitivity of pancreatic β- cells with prompt secretion of a large quantity of insulin in response to hyperglycemia [16]. Along with proved anti-diabetic activity [17] [14] *Shilajit* is also clinically tested for its anti-hyperlipidaemic activity [18].

In *Salasaradi gana* there are 23 drugs out of which 6 drugs viz., *Khadira, Kramuka, Meshasringi, Sirisha, Arjuna* and *Karanja* were procured as per the availability in the market. The organoleptic properties of all these drugs consists of *Katu- Tikta- Kashaya- rasa, Laghu-Ruksha guna, Katu vipaka* and have the pharmacotherapeutic effects of *Kapha-Pitta samana* and *Prameha hara.*

Out of the 6 drugs- *Khadira, Kramuka, Arjuna* shows *Sita virya* and *Meshasringi, Sirisha, Karanja* shows *Ushna virya*. In addition to the *Pramehahara* property *Khadira* possess *Medohara* property and *Sirisha* posses *Sothahara* property. The scientific studies of these drugs revealed potential Anti-Hyperglycemic and Anti-Hyperlipidaemic properties in alloxan and streptozotocin induced diabetic rats. These 6 drugs were used for the preparation of *Kashaya* to be used as *Bhavana dravya* for *Shilajit* and the same drugs were dispensed to the patients in coarse powder form for preparing *Kashaya* to be used as *Anupana* to *Shilajit yog* capsules. The cumulative effect of all these properties must have resulted in *Samprapti vighatana* of *Madhumeha vyadhi.*

In contrast to Group A (placebo), *Salasaradi gana dravya bhavita Shilajit- 'Shilajit yoga'* intervened in Group B appears to have substantial controlling effect on the blood sugar levels, following *Shodhana karma* through *Vamana* and *Virechana*.

CONCLUSION

- Both *Vamana* and *Virechana* justify their role in reducing both FBS and PPBS considerably. *Vamana* acts on the basic pathology of *Bahudravasleshma* and *Bahuabadhameda*. *Vamana* and *Virechana* are reducing the insulin resistance and *Virechana* must be increasing insulin secretion also.
- *Prameha* is an *Anushangivyadhi* - disease having relapsing nature. Hence, for better control of blood sugar levels, along with this *Shodana* therapy *Rasayana chikitsa* (rejuvenation therapy) is administered.
- Both the Groups were first subjected to *Shodhana* karma (which included both *Vamana karma* and *Virechana karma*) followed by conservative therapy, wherein Group B was intervened with *Shilajit Y*og and Group A with Placebo.

In contrast to Group A, *Salasaradi gana dravya bhavita Shilajit- 'Shilajit yoga'* intervened in Group B appears to have substantial controlling effect on the blood sugar levels with its Extra pancreatic and Immunomodulatory effects, and probably through Pancreatotrophic action. The final result of the study supports the role of *Shilajit* followed by *Shodana* procedures as substitute for the allopathic medication in the patients with an excess of about 50-100mg/dl of blood glucose levels above normal levels, in FBS and PPBS values.

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