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EVALUATION OF COMBINED EFFECT OF *UDVARTANA, PANCHATIKTA PANCHAPRASRUTIKA BASTI* AND *NISHAMALAKI YOGA* IN THE MANAGEMENT OF *STHOOLA MADHUMEHA* – A PILOT STUDY

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ABSTRACT

Purpose – *Madhumeha* is one among the *Vataja Prameha* that has been considered as *Mahagada*. *Sthoola Madhumeha* is *Tridoshajanya, Atisantarpanajanya, Keldaudbhajanya Vyadhi*. It is *Yapya vyadhi* because of *Saptadushya* and *Apara ojus* involved.

Sthoola Madhumeha is having extensive etiological factors like improper food habits, genetic, life style etc.. *Sthoola Madhumeha* is of two types viz. *Avaranajanya* and *Dhatu kshayajanya Sthoola Madhumeha*. On the basis of *Nidana Panchaka, Avaranjanya Sthoola Madhumeha* can be corelated to Non Insulin Dependent Diabetes Mellitus (NIDDM)

Type II Diabetes Mellitus is a heterogeneous disorder with varying prevalence among different ethnic groups. The pathophysiology of T2DM is characterized by peripheral insulin resistance, impaired regulation of hepatic glucose production and declining β-cell function, eventually leading to β-cell failure. Hence this study is aimed to Evaluate the Combined Efficacy of *Udvartana, Panchatikta Panchaprasrutika Basti* and

Nishamalaki Yoga in the management of *Sthoola Madhumeha* with special reference to Type II Diabetes Mellitus.

Materials And Methods –

Materials have been collected from classical Ayurvedic texts, and Commentaries. The selection of patients was made from OPD / IPD BVVS Ayurved Medical College and Hospital, Bagalkot, Karnataka.

Conclusion –

The Combined Efficacy of *Udvartana, Panchatikta Panchaprasrutika Basti* and *Nishamalaki Yoga* have shown highly significant on *Sthoola Madhumeha.*

Keywords: *Sthoola Madhumeha, Type II Diabetes Mellitus, Udvartana, Panchatikta Panchaprasrutika Basti* and *Nishamalaki Yoga*

INTRODUCTION

Madhumeha is one among the *Vataja Prameha* that has been considered as *Mahagada[1]*. *Sthoola Madhumeha* is *Tridoshajanya, Atisantarpanajanya, Keldaudbhajanya Vyadhi*. It is *Yapya vyadhi* because of *Saptadushya* and *Apara ojus* involved[2,3,4].

Sthoola Madhumeha is having extensive etiological factors like improper food habits, genetic, life style etc. *Sthoola Madhumeha* is of two types viz.. *Avaranajanya* and *Dhatu kshayajanya Sthoola Madhumeha*[5,6,7]. On the basis of *Nidana Panchaka, Avaranjanya Sthoola Madhumeha* can be corelated to Non Insulin Dependent Diabetes Mellitus (NIDDM)[8,9]

Diabetes Mellitus has emerged as a global health hazard and is having tremendous socio-economic impact to the individual as well as society as awhole.

According to international diabetic federation (IDF) in the year 2014, worldwide about 387 million people were afflicted with Diabetes, the majority of which are aged between 40 and 59, and 80% of them live in low and middle income countries. According to a study carried out in the year 2013 by the Indian council of medical research, India has 62.4 million people with Diabetes, out of which 90% have Type II Diabetes Mellitus[10,11].

Type II Diabetes Mellitus is a heterogeneous disorder with varying prevalence among different ethnic groups. The pathophysiology of T2DM is characterized by peripheral insulin resistance, impaired regulation of hepatic glucose production and declining β-cell function, eventually leading to β-cell failure[12,13].

As *Atisantarpana* is *pradhana*

nidana for *Sthoola Madhumeha, Apatarpana chikitsa* is *pradhana chikitsa siddhanta* which includes *Vamana, Virechana, Basti, Shamanaushadis* and *Rasayana. Udvartana, Abhyanga, Swedana, Seka* and many *Bahirparimarjana chikitsa* are few contemporary treatment modalities for *Sthoola Madhumeha*[14,15,16].

Udvartana having qualities like *Rukshana, Lekhana, Kledahara*, hence it is considered as best line of treatment for *Sthoola Madhumeha*[17,18].

Panchatikta Panchaprasrutika Basti helps to manage impaired metabolic condition by impacting equilibrium state of *dosha,* nourishing the *dhatu* and maintain thereby blood sugar level[19,20,21].

Nishamalaki Yoga with its *gunas laghu, ruksha, tikta rasa, Usna veerya* as well as *Rasayana* effect helps to treat *Sthoola Madhumeha*[22,23].

Keeping the above protocol in mind, here in an effort is made for holistic approach towards Sthoola Madhumeha by evaluating the combined effect of *shodhana karma, Bahirparimarjana chikitsa* with *Shamanaushadi yoga.*

Hence this study is aimed to Evaluate the Combined Efficacy of *Udvartana, Panchatikta Panchaprasrutika Basti* and *Nishamalaki Yoga* in the management of *Sthoola Madhumeha* with special reference to Type II Diabetes Mellitus.

AIMS AND OBJECTIVES:

Aim: A holistic approach towards *Sthoola Madhumeha* by evaluating the combined effect of *Shodhana karma, Bahirparimarjana chikitsa* with *Shamanaushadi yoga.*

The specific objectives are:

1. To evaluate the combined effect of *Udvartana, Panchatikta Panchaprasrutika Basti* and *Nishamalaki Yoga* in the management of *Sthoola Madhumeha.*

MATERIALS AND METHODS:

- Source of Data: Literary Source: The Literary data has been collected from Central library as well as Panchakarma departmental library of Parul Institute of Ayurveda, Vadodara and BVVS Ayurved Medical College and Hospital, Bagalkot. The data also collected from journals, periodicals and other published works and even from internet source.

- Clinical Source: Around 10 diagnosed cases of *Sthoola Madhumeha* (Type II Diabetes Mellitus) was collected from OPD of BVVS Ayurved Medical College and Hospital, Bagalkot on the basis of Inclusion & Exclusion criteria.

- Drug Source: The respective Medicine was percurred from NKCA Pharmacy,

Mysore under the guidance of *Rasashastra and Bhaishajya Kalpana* department.

Method of collection of data:

In this Pilot Study, 10 diagnosed cases of *Sthoola Madhumeha* (Type II Diabetes Mellitus) has been selected on the basis of following selection criteria.

SELECTION CRITERIA:

1. Diagnostic Criteria:

1. Classical sign & symptoms of *Sthoola Madhumeha* (Type II Diabetes Mellitus) such as
   1. *Prabhoota Mootra Pravritti* (Polyuria)
   2. *Avila Mootratha* (Albumin)
   3. *Pipasa* (Polydipsia)
   4. *Kshuda* (Appetite)
   5. *Atiswedata* (Prespiration)
   6. *Alasya* (General debility)
   7. *Karapadadaha* (Neuropathy)
   8. *Karapadadaha Suptata* (Neuropathy)
   9. *Daurbalya* (Weakness)
   10. *Galatalushosha* (Dryness of mouth)

2. Investigations –
   1. FBS
   2. PPBS
   3. HBA1C

2. Inclusion Criteria:

1. Patients present with classical signs & symptoms of *Sthoola Madhumeha* (Type II Diabetes Mellitus) of 6 month and FBS ranging between 120mg/dl to 180mg/dl and PPBS ranging between 160mg/dl to 300mg/dl.

2. Patients between the age group of 40 to 60 years.

3. Patients having *Sthoola Madhumeha* and BMI > $30kg/m^2$

4. Patients irrespective of religion, sex, socio-economic status, occupation etc.

5. Patients who are fit for *Udvartana* and *Basti.*

6. Patients who are willing to sign the informed consent.

3. Exclusion Criteria:

1. Patients with diagnosed cases of *Sahaja* and *Dhatukshayajanya Sthoola Madhumeha.*

2. Patients of Type II Diabetes Mellitus under Insulin treatment and anti diabetic medicines.

3. Patients associated with any Endocrine metabolic disorders and complications.

4. Pregnancy and Lactation.

B. ASSESSMENT PARAMETERS:

I. Subjective Parameters :

1. *Prabhoota Mootra Pravritti*

2. *Avila Mootratha*

3. *Pipasa*

4. *Kshuda*

5. *Atiswedata*

6. *Alasya*

7. *Karapadadaha*

8. *Karapada Suptata*

9. *Daurbalya*

10. *Galatalushosha*

II. Objective Parameters :

1. FBS

2. PPBS

3. HBA1C

C. STATISTICAL ANALYSIS:

The collected data and observations was analyzed critically and scientifically by paired and unpaired 't' test.

Follow Up: On 24th day and On 50th day

Total Duration: 50 days

STATISTICAL RESULTS

S. No.	Parameters	BT Mean	FU Mean		Diff 'd'	% of Relief	Paired t test			
							SD	SE	't'	P
1.	Quantity of Urine	2.70	16th	2.40	0.30	11.11	0.52	0.16	1.9640	=0.0811
			30th	1.60	1.10	40.74	0.52	0.16	11.000	<0.0001
			50th	1.30	1.40	51.85	0.48	0.15	8.5732	<0.0001
2.	Frequency of Urine	2.00	16th	-	-	-	-	-	-	-
			30th	1.50	0.50	25	0.53	0.17	3.0000	=0.0150
			50th	1.10	0.90	45	0.32	0.10	2.4495	=0.0368
3.	Kshudha	2.80	16th	2.40	0.40	14.285	0.52	0.16	2.4495	=0.0368
			30th	1.50	1.30	46.428	0.71	0.22	8.5105	<0.0001
			50th	1.50	1.30	46.428	0.71	0.22	8.5105	<0.0001
4.	Pipasa	2.80	16th	2.40	0.40	14.285	0.52	0.16	2.4495	=0.0368
			30th	1.50	1.30	46.428	0.71	0.22	8.5105	<0.0001
			50th	1.50	1.30	46.428	0.71	0.22	8.5105	<0.0001
5.	Swedadhikya	2.40	16th	2.10	0.30	12.5	0.57	0.18	1.9640	=0.0811
			30th	1.10	1.30	54.166	0.57	0.18	6.0908	=0.0002
			50th	0.90	1.50	62.5	0.32	0.10	9.0000	<0.0001
6.	Alasya	2.60	16th	2.30	0.30	11.53	0.67	0.21	1.9640	=0.0811
			30th	1.50	1.10	42.307	0.71	0.22	11.0000	<0.0001
			50th	0.90	1.70	65.384	0.32	0.10	11.1291	<0.0001
7.	Karapada daha	1.10	16th	-	-	-	-	-	-	-
			30th	0.20	0.90	81.81	0.42	0.13	9.0000	<0.0001
			50th	0.20	0.90	81.81	0.42	0.13	9.0000	<0.0001
8.	Dourbalya	1.80	16th	1.70	0.10	5.55	0.42	0.13	1.0000	=0.3434
			30th	0.90	0.90	50	0.32	0.10	9.0000	<0.0001
			50th	0.90	0.90	50	0.32	0.10	9.0000	<0.0001
9.	Gala Talu Shosha	2.70	16th	2.40	0.30	11.11	0.48	0.15	1.9640	=0.0811
			30th	1.10	1.60	59.25	0.32	0.10	9.7980	<0.0001
			50th	1.00	1.70	62.96	0.47	0.15	11.1291	<0.0001
10.	FBS	2.10	16th	1.90	0.20	9.523	0.32	0.10	1.5000	=0.1679
			30th	1.20	0.90	42.85	0.42	0.13	9.0000	<0.0001
			50th	1.20	0.90	42.85	0.42	0.13	9.0000	<0.0001
11.	PPBS	2.20	16th	2.00	0.20	9.090	0.47	0.15	1.5000	=0.1679
			30th	1.10	1.10	50	0.32	0.10	11.0000	<0.0001
			50th	1.10	1.10	50	0.32	0.10	11.0000	<0.0001
12.	HBA1C	2.00	16th	-	-	-	-	-	-	-
			30th	1.50	0.50	25	0.53	0.17	3.0000	=0.0150
			50th	1.10	0.90	45	0.32	0.10	2.4495	=0.0368

DISCUSSION

Discussion on Results:

Effect on Quantity of Urine:

The statistical analysis revealed that the mean score of Quantity of urine which was 2.70 before the treatment was reduced to 2.40 on 16th day, 1.60 on 30th day and 1.30 on 50th day. This change is statistically not significant at 16th day, extremely significant on 30th and 50th day.

Effect on Frequency of Urine:

The statistical analysis revealed that the mean score of Frequency of urine which was 2.00 before the treatment was reduced to 1.50 on 30th day and 1.10 on 50th day. This change is statistically not significant at 16th day, significant on 30th and extremely significant on 50th day.

Effect on Kshudha:

The statistical analysis revealed that the mean score of Kshudha which was 2.80 before the treatment was reduced to 2.40 on 16th day, 1.50 on 30th day and 50th day. This change is statistically significant at 16th day, extremely significant on 30th and 50th day.

Effect on Pipasa:

The statistical analysis revealed that the mean score of Pipasa which was 2.80 before the treatment was reduced to 2.40 on 16th day, 1.50 on 30th day and 50th day. This change is statistically significant at 16th day, extremely significant on 30th and 50th day.

Effect on Swedadhikya:

The statistical analysis revealed that the mean score of Swedadhikya which was 2.40 before the treatment was reduced to 2.10 on 16th day, 1.10 on 30th day and 0.90 on 50th day. This change is statistically not significant at 16th day, extremely significant on 30th and 50th day.

Effect on Alasya:

The statistical analysis revealed that the mean score of Alasya which was 2.60 before the treatment was reduced to 2.30 on 16th day, 1.50 on 30th day and 0.90 on 50th day. This change is statistically not significant at 16th day, extremely significant on 30th and 50th day.

Effect on Karapada Daha:

The statistical analysis revealed that the mean score of Karapadadaha which was 1.10 before the treatment was reduced to 0.20 on 30th day and 50th day. This change is statistically not significant at 16th day, extremely significant on 30th and 50th day.

Effect on Dourbalya:

The statistical analysis revealed that the mean score of Dourbalya which was 1.80 before the treatment was reduced to 1.70 on 16th day, 0.90 on 30th day and 50th day. This change is statistically not significant at 16th day, extremely significant on 30th and 50th day.

Effect on Galatalu Shosha:

The statistical analysis revealed that the mean score of Galatalu Shosha which

was 2.70 before the treatment was reduced to 2.40 on 16th day, 1.10 on 30th day and 1.00 on 50th day. This change is statistically not significant at 16th day, extremely significant on 30th and 50th day.

Effect on FBS:

The statistical analysis revealed that the mean score of FBS which was 2.10 before the treatment was reduced to 1.90 on 16th day, 1.20 on 30th day and 50th day. This change is statistically not significant at 16th day, extremely significant on 30th and 50th day.

Effect on PPBS:

The statistical analysis revealed that the mean score of PPBS which was 2.20 before the treatment was reduced to 2.00 on 16th day, 1.10 on 30th day and 50th day. This change is statistically not significant at 16th day, extremely significant on 30th and 50th day.

Effect on HBA1C:

The statistical analysis revealed that the mean score of HBA1C which was 2.00 before the treatment was reduced to 1.50 on 30th day and 1.10 on 50th day. This change is statistically not significant at 16th day, significant on 30th and extremely significant on 50th day.

DISCUSSION ON MODE OF ACTION

Udvartana:

In *the manifestation of Madhumeha there will be* dominancy of *kaphadosha,*

meda and kleda[24] is noted. *Rookshana dravya* have the gunas like *tikta, katu, kashaya rasa, ruksha, laghu, ushna, vishada guna* which are opposite to *Nidana* of *Madhumeha. These gunas* helps for *Samprapti vighatana* of Sthoola Madhumeha. *Triphala churna*[25] posses all the qualities of *rookshana. Acharya Sushruta has* described the usage of *triphalachurna* in the management of Sthoola Madhumeha[26]. *Udvartana karma* helps to reduce the aggravated kapha *dosha* and also *meda* by its qualities like *Shoshana* and *lekhana* karma. Acharya Charaka and Acharya Vagbhata have explained Udvartana as the prime line of treatment in Sthoola Pramehi in Prameha chikitsa prakarana[27, 28] because of its qualities like Rukshana, Lekhana, Kledahara.

Basti:

Basti helps in treating all the diseases wherein two, three or all of the *Vata, Pitta, Kapha* and *Rakta dosha are involved in the manifestation of the disease.* Basti karma helps in tretating the disese by cleansing the *Srotas,* by increasing the *Oja, Teja, Shukra*, *Agni and Medha*. In Sthoola *Madhumeha* there will be involvement of *Kapha*, this vitiated *Kapha* affects the *Jathragni* and *Dhatwagni* and interrupts the metabolism and thereby increases the *Rasa, Meda, Kleda, Vasa, Lasika, Mamsa* etc. All

this vitiated *Dushyas* obstructs the route of *Vata dosha* and later *Vata dosha* get aggravate and changes its path and carries vital *Dhatus* towards *Basti* excretes them out there by causing depletion.

Acharya Charaka has mentioned that Basti dravya reaches the Nabhi, Kati, Parshva and Kukshi and thereby expels out the Pureesha and vitiated Doshas[29]. Acharya Sushruta has mentioned that the active principles of Basti dravya spreads all over the body through the minute Srotas just as how water reaches to all parts of the plant from its root[30]. Honey has quality called ambiphilic which helps to dissolve both water as well as lipids in it. Rock salt reduces the surface tension and converts gel form of honey to solution form. So that added oil can be easily dissolve into mixture. Kalka helps to dissolve easily and will give good potency to Basti formulation. Kwatha dravya helps to increase surface area for absorption along with its other actions.

Absorption of basti dravya through the gastro intestinal mucosa occurs through the active transport and diffusion process. So when a hyper osmotic solution is present in the lumen secretion towards it from the membrane and in presence of hypo-osmotic solution absorption from the solution occurs. It may be considered that Niruha Basti is hyper osmotic which

facilitates elimination of morbid factors i.e. endo toxins into the solution and produces detoxification during elimination whereas the Sneha Basti and other nourishing Basti contain hypo osmotic solution facilitating absorption of active principles into the blood.

Enteric nervous system (ENS) communicate with the central nervous system through the parasympathetic (via the Vagus nerve) and sympathetic (via the Prevertebral ganglia) nervous system. Sensory neurons of the ENS monitors the chemical changes within the GIT. Enteric motor neurons helps for the contraction of GI tract smooth muscle and activity of GI tract endocrine cells. Enteric motor neurons makes use of more than thirty neurotransmitters, most of which are identical to the ones found in CNS such as acetylcholine, dopamine, serotonine etc. The enteric nervous system has the role to alter its response depending on factors like bulk and nutrient composition. As the total nervous system is interrelated so this regular stimulation to ENS may have some positive effect over the CNS also and in this way the neuro- endocrine regulation may take place.[31]

Basti corrects the Vata Dosha and by virtue of the lekhana property of the drugs used in Panchatikta Panchaprasrutika Basti cleanses the channels removes the

Medasa Avarana and regulates the movement of Vata. Panchatikta Panchaprasrutika Basti helps to manage impaired metabolic condition by impacting equilibrium state of dosha, nourishing the dhatu and maintain thereby blood sugar level.

Nishamalaki Churna :

Nishamalaki Yoga with its gunas laghu, ruksha, tikta rasa, Usna veerya as well as Rasayana effect helps to treat Sthoola Madhumeha. *Nishamalaki* is found effective in the clinical management as well as prevention of complications of Sthoola *Madhumeha.*

CONCLUSION

1. Sthoola Madhumeha a type of Prameha can be correlated to type 2 Diabetes mellitus based on sign and symptoms.
2. Bahudosha, Agnimandhya particularly Dhatwagnimandhya, Medasavruta Marga, Margavarana Janya Vata Prakopa are important factors involved in pathogenesis of Sthoola Madhumeha.
3. The combined effect of Udvartana, Panchatikta Panchaprasrutika Basti and Nishamalaki Yoga has showed significant result after 1st follow-up and highly significant result after 2nd follow-up.
4. The combined effect of Shodhana

Karma, Bahirparimarjana Chikitsa and Shamanaushadi yoga is found to be the perfect protocol in the management of Sthoola Madhumeha.

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