



Validation Of An Integrated Ayurveda-Yoga Module For Residential Treatment Of Patients With Type 2 Diabetes Mellitus - A Compilation From Traditional Literature

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Background:

Treatment regimens for type 2 diabetes mellitus (DM2) vary from one school of ayurveda to another. The regimens used round the country fall under Kerala ayurveda, Banaras School and Himalayan ayurveda. Given the fact that Ayurvedic literature is elaborate and specific, there is a need to critically validate and develop treatment regimens strictly based on traditional literature.

Aim: *To compile treatment regimen for the management of DM2.*

Methods: *The steps for development of the residential treatment regimen were:*

1. *Exhaustive literary search for concepts of prameha; zooming to Madhumeha from 18 scriptural texts of Ayurveda, to tabulate their common and unique features.*
2. *Development of a flow chart under two channels i.e. for those with Sthaulya madhumeha and Krisha madhumeha with 4 phases of management i.e. Purvakarma, Pradhana karma, Paschat karma and Sanshaman chikitsa.*
3. *Development of 6 assessment tools to define the eligibility for four phases of treatment.*
4. *Preparation of exhaustive list of medications for the Samshamana phase.*
5. *Addition of Nidanaparivarjana, ahara & vihara based on dinacharya with added integrated yoga therapy.*
6. *A final document of the treatment manual validated by external experts- Ayurveda academic staff of teaching institutions.*

1.0 Introduction

Awareness about 'Health' and approach of community towards complementary and alternative medicine in quest of 'Healthy Life' is increasing.¹ Among CAM, ayurvedic medicine is making its good name. Its holistic approach, its natural and safe methods, its potential for taking care of present day health needs, are getting recognized globally. It has placed a new challenge in front of Ayurvedic society. The challenge of ayurveda medical practice today is to present the knowledge base in modern medical language to make it acceptable to the medical community at large through validated techniques.

1.1 Prevalence of DM2

According to data presented by WHO, in year 2000, 171 million people were suffering from Diabetes (2.8% of the population). Of these 31.7 million were Indians. The global prevalence of diabetes among adults (aged 20–79 years) by 2010 was estimated to be 6.4%, affecting 285 million adults, and projected to be 7.7% of (439 million) adults by 2030.² Over 60% of health care costs are used in inpatient settings, suggesting that treating complications of diabetes was a major cost factor in developed countries.^{3,4,5}

Various oral hypoglycemic agents, Insulin formulations, life style modification plans consisting of dietary management and exercise, are some of the important efforts towards the management of Diabetes.^{6,7,8} In spite of fascinating advances in pharmaco-therapeutic agents, world is seeking for safer and effective remedies. Increased side effects, lack of effective treatment for complications, high cost of new drugs and resistance to the drugs are some reasons for renewed public interest in ayurvedic medicines.^{9,10,11}

Sanskrit literature from the time of 'Vedas' provides descriptions of diabetes mellitus under the Madhumeha which is one form of Prameha.^{12,13} Ancient ayurvedic classics by Charaka, Sushruta, and Vagbhata contain ample literature about Prameha and its treatment. Prameha is a metabolic disorder and is diagnosed mainly with the help of signs and symptoms related to 'Mutra' (Urine). Genetic predisposition with sedentary life style, injudicious intake of food, and stress are recognized as some of the important etiological factors of Prameha,^{14,15} There are several studies that have

documented the beneficial effects of different herbal preparations in reducing blood glucose levels through phase 2 and 3 trials.^{16,17} Some of these include Phalatrikadi kwatha,¹⁸ Gokshuradi guggulu,¹⁹ Haridramlaki churna and Devdarvadi ghan vati.²⁰

Ayurveda being a holistic science, it has to be practiced as a whole science including several steps of management and cannot be given only as one capsule of a proven herbal preparation. Hence it is necessary to review the classical texts and compile the literature and present a holistic management protocol with a flow chart of different steps to be followed. Also it is essential to provide validated check lists of the criteria of entry into each step in the management. The present study was aimed at developing such a treatment protocol for the treatment of type 2 diabetes (Madhumeha) as per the classical texts of ayurveda.

2.0 Objectives:

1. To compile all available knowledge about madhumeha in vedas (Atharva veda), puranas (Garuda purana, Kautilya arth-Shastra) and samhitas (Charaka samhita, Sushruta samhita, bhel samhita etc).
2. To compile the literature from the ayurveda commentaries (Gayadasa, chakrapani etc) & research studies (done in ayurveda research institutes like- BHU, IPGT) on the management of madhumeha (DM2).
3. To check the content validity of the protocol by senior consulting ayurveda physicians/professors from leading institutions of ayurveda.

3.0 Methodology

3.1 Inclusion criteria:

1. For objective 1 and 2: The classical texts of ayurveda which has the descriptions of madhumeha as a part of prameha.
2. For objective 3: Ayurveda academic staff of teaching institutions with a master's degree and > 5 years' experience as clinical practitioners and academic staff of ayurveda medical college.
3. Inclusion criteria for subjects for whom this protocol can be followed:
 - 3.1. Women and men between 30-60 years (married or single) who satisfy ADA criteria for diagnosis of DM2.
 - 3.2. Those, who have not undergone ayurveda treatment in the past six months.

3.2 Exclusion criteria:

1. Patients with complications of DM2 such as CAD, nephropathy, proliferative retinopathy, cannot undergo this treatment protocol.
2. Patients who are suffering from duodenal or peptic ulcers cannot undergo this treatment protocol.
3. Those who are diabetic from childhood and have low BMI (Dhatu kshaya madhumehi) are excluded for this protocol.

3.3 Steps:

Different acharyas in ayurveda talk about different ways for the treatment of madhumeha. Some talk about samshodhana and samshamana, but some talk about only sanshamana. In the same way, the studies done in various research institutes of ayurveda are either drug trials or on a single procedure of the treatment of madhumeha. Therefore, to develop an overall protocol, we followed the following steps-

3.3.1 Step-1: Exhaustive literary search from the vedas, puranas, samhitas and research thesis available in ayurveda was done for the concept of prameha, zooming into madhumeha as the most probable description of diabetes mellitus. The vedas reviewed included the Kaushika sutra of Atharva Veda, the puranas included- Agni purana, apart from all the Laghutrayis and Bruhatrayis of ayurveda.

All the features mentioned in the classical texts for madhumeha were used to develop a four phase residential management protocol. The four phases of treatment are-

- a. Sanshodhana (Purvakarma, Pradhana karma & Paschat karma)
- b. Sanshamana
- c. Ahara and
- d. Vihara.

At the same time, exhaustive list of ayurvedic medications have been taken from the classical texts for the sanshamana phase. This wide list of medications was further presented in front of the clinicians. And depending upon their clinical experience and availability of drugs in the market, they were asked to give their inputs. This resulted in getting the list of the most effective ayurveda medicines from the exhaustive list.

The ahara and vihara based on dinacharya was chosen. The special attention on ahara & vihara during the sanshodhana karma was taken care. As nidana parivarjana is said to be the prime line of treatment, all do's & don'ts have been included in the protocol. The concept of complete health and arriving at total swasthya according to Ayurveda.²¹ includes 'prasanna atmendriya manah' for which regular yoga practice is a necessary component. Now there are several references on the beneficial effects of yoga^{22,23,24,25} in the management of madhumeha. Hence, simple restful practices of integrated approach of yoga therapy for diabetes developed and used in all studies of diabetes at SVYASA has been added as a part under vihara and manah santulana.

3.3.2 Step-2: The compiled literature has been put together in a tabular form to get the common and unique features described in each text. Then, the studies done on different phases of treatment of madhumeha in ayurvedic research institutes were compared with the compiled matter. Starting from shodhana procedure (Table no. 6 & 7) described in classical texts right up to the present day drug trials (Table no. 8) are included. In the same way the do's and don'ts mentioned in ahara has been developed into palatable recipes (Table no. 3) the details mentioned under vihara has been modified for present day life style while tabulating the recommended daily physical activities (Table no. 4).

3.3.3 Step-3: A day wise treatment protocol is developed in the form of flow chart which is supported by classical texts and research evidence. The flow chart shows the criteria for recruitment of patients under two channels i.e. Sthula madhumehi & Krisha madhumehi. The chart further defines various assessments needed for the proceeding towards treatment. Six assessment tools have been developed to define the eligibility at each of the four phases of treatment. This starts from the day of arrival and continues for 30 days.

3.3.4 Step-4: This full module was presented for validation in front of ayurveda experts specialized in Kayachikitsa, Panchakarma, Swastha vritta etc with clinical experience (>5years). There were 11 experts who were requested to participate in the test of content validity for the proposed instrument. The check-list was divided into ten domains (categories of questions): They are- Classical Reference, Classification, Ahara (Diet), Vihara (Daily Routine), Principle of treatment, Deepana & Paachana, Sneha aushadha, Virechana aushadha, Sansarjana Krama and Sanshamana aushadha.

Each expert was asked to rate each the content validity of each domain on a three point scale: "Essential", "Useful but not essential", "Not necessary". The content validity was then calculated using the method of Lawshe (1975).²⁶ If E denotes the number of experts marking a domain as essential and N the total number of experts, then Lawshe's CVR is defined as the ratio of $(E - N/2)$ and $N/2$. The critical values for this CVR statistic are given in Lawshe (1975)²⁶.

3.4 Data analysis

A matrix of the validated results by 11 experts was prepared. Data was analyzed using software 'R' and the statistical test Lawshe's Content Validity Ratio (CVR) was used to check the content validity.

4.0 Results

4.1 Step 1 and 2

References of Prameha are found in "Kaushika sutra" of "Atharva veda" (5000 B.C to 1500 B.C), Agni purana, Garuda purana, Kautilya artha shashtra and the epic Ramayana (4000 B.C to 1000 B.C) providing evidence for description and existence of diabetes (Madhumeha) which has been recognized and documented by man in that era.

Information available in laghutrayis, bhruhatrayis, commentaries like- Dalhana etc, post graduate dissertations from medical colleges were used for this compilation. Table 1 shows the literature from different texts.

Table 1: Literature from different texts

Vedas/ puranas / Samhitas/ Studies	Introductio n	Etiology	Classificati on	Clinical features	Complicatio n	Management (Shodhana)	Managemen t (Shamana)	Ahara / Vihar a
Atharva veda	√	-	-	-	-	-	√	-
Agni purana	√	-	-	√	-	-	-	-
Ramayana	-	-	-	√	-	-	-	-
Kautilya Artha- Shastra	√	-	-	-	-	-	-	-
Charaka Samhita	√	√	√	√	√	√	√	√
Sushruta Samhita	√	√	√	√	√	√	√	√
Astanga Hrudaya	√	√	√	√	√	√	√	√
Astanga Samgraha	√	√	√	√	√	√	√	√
Parashara Samhita	√	-	-	√	-	□	√	√
Bhela Samhita	√	-	√	-	-	√	√	√
Harita Samhita	√	-	√	√	√	-	√	√
Kasyap Samhita	-	-	-	√	-	-	-	-
Sharangadhar Samhita	-	-	√	-	-	-	√	√
Rasendra sara samgraha	-	-	-	-	-	-	√	-
Bhaisajya Ratnavali	-	-	-	-	-	-	√	√
Sahastra Yoga Samgraha	-	-	-	-	-	-	√	-
Yogratnakar	-	-	-	-	-	-	√	-
Madhavakara	-	√	√	-	-	-	-	-
Gayadasa	-	√	-	√	-	-	-	-
Chakrapanidatta	√	√	√	√	√	√	√	√
Dalhana	√	√	√	√	√	√	√	√
Bhavamishra	-	√	-	-	-	-	√	√

The introduction, etiology and clinical features responsible to correlate the disease with modern perspectives were found in most the samhitas. When referring to the treatment or management of diabetes we found that very few classical texts (Charaka Samhita, Sushruta Samhita, Bhel Samhita, Astanga Samgraha & Hrudyam) provide detailed descriptions of the principles of management. Some texts (Rasendra sara samgraha, Sahastra Yogam, yoga Ratnakar etc) recommend only Shamana with Ahara & Vihara or nidana parivarjana. Thus, this compilation of the treatment protocol evolved after an exhaustive literature search from all available samhitas, vedas & puranas.

Figure 1 shows the day wise flow chart of the treatment protocol.

As the patient arrives to the campus, he will be subjected to various assessments. An ayurveda physician will document his case history and assess the subject's eligibility for sthaulya and karshya channel on the basis of physical examination, BMI and shodhana yogya-ayogya criteria.

If the patient falls under karshya category, then he will be taken up for samshamana chikitsa.²⁷ If the patient fits into the criteria of sthula, then agni, ama & kostha will be assessed. This helps in fixing the duration & dosage of deepana, pachana . The deepana & pachana will be completed within **3 to 7 days**. In the same way by assessing agni, ama & kostha, dosage of snehapana will also be calculated.^{28,29} As sneha siddha lakshanas are seen, abhyanga will be started for three consecutive days followed by atapa swedana. The snehapana completes in **3 to 7 days (Approx. 10-12 days after admission)** and abhyanga in **3 days (Approx. 15-17 days after admission)**. For the assessment of sneha sidha lakshanas, a separate column of sneha jeernamana assessment has been prepared (Table-2).

Just after the third day of abhyanga, the subject is taken up for virechana by administering virechanopaga drugs. This will be done for **one day** and the assessment of shuddhi will be done by shuddhi assessment chart provided in the case sheet (Table-2). Depending upon the result of shuddhi assessment, the number of days necessary for sansarjana krama will be finalized. Sansarjana krama completes in **3 to 7 days (Approx. 22-25 days after admission)**. And this will be followed by samshamana chikitsa.²⁷

4.2 Step 3

As the patient arrives to the campus, he will be subjected to various assessments. An ayurveda physician will document his case history and assess the subject's eligibility for sthaulya and karshya channel on the basis of physical examination, BMI and shodhana yogya-ayogya criteria. Figure 1 shows the day wise flow chart of the treatment protocol.

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Figure 1: Stepwise Treatment/Management protocol for Madhumeha

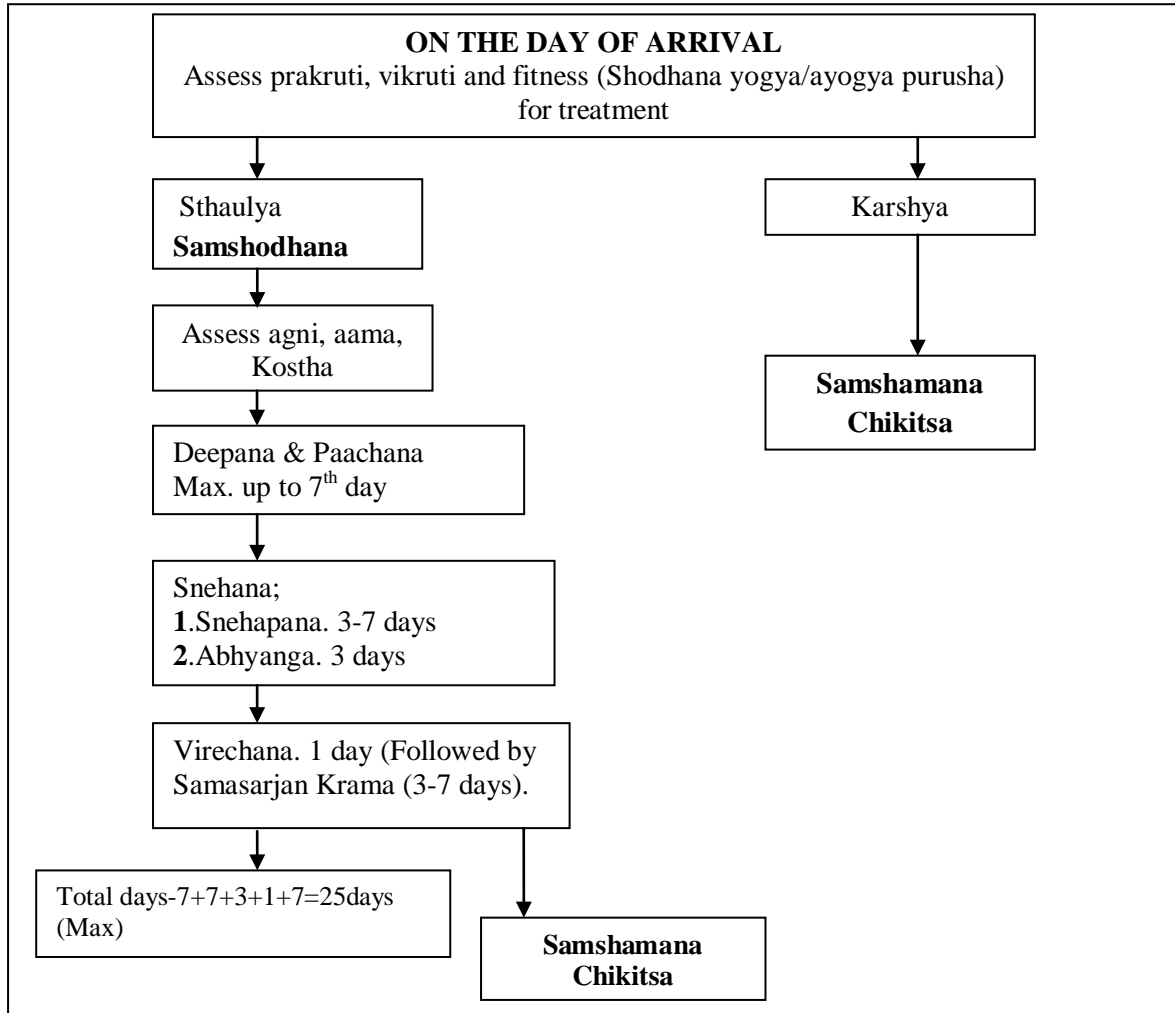


Table 2: list of assessments to be satisfied before the patient moves on to the next step

I	Assessment of agni for Deepana drug dosage	Agni assessment Column in case sheet
II	Assessment of ama for Pachana drug dosage	Ama assessment Column in case sheet
III	Assesment of Kostha	Kostha assessment Column in case sheet
IV	Assessment of Sneha & Sneha lakshanas	Sneha Jeeranaman assessment column in case sheet.
V	Assessment of vegiki, Lingiki & manaki Shuddhi	Vega assessment column in case sheet.

VI	Assessment of Sthula/Karshya category	1. Physical Examination. 2. BMI. 3. Shodhana Yogya/Ayogya column in case sheet
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Table 3: Ahara table with palatable recepies by following Nidan Parivarjana

Ahara ^{30,31, 32}							
	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Break fast	Broken Wheat (Dalia) roasted.	Vegetable of - Spinach, Bottle guard etc.	Barley saktu mixed with cows Milk & honey	Barley grain dipped in triphala decoction soaked overnight & taken with honey.	Broken Wheat (Dalia) roasted.	Vegetable of - Spinach, Bottle guard etc.	Barley saktu mixed with cows Milk & honey
	Diluted milk with water (1:2)	Malt (Barleychurned drink)	Triphala Juice, Turmeric with Honey	Diluted milk with water (1:2)	Malt (Barley churned drink)	Diluted milk with water (1:2)	Triphala rasa, Turmeric with Honey
Lunch	soup of Lentils (Moong)	Soup of half cooked rice	Boiled Barley Soup	Lentils Soup	Soup of half cooked rice	soup of Lentils (Moong)	Boiled Barley Soup
	Bitter gourd vegetable cooked in Taila of Mustard	Patola vegetable cooked in Taila of Mustard	Bottle gourd vegetable cooked in Taila of Mustard	Jack fruit vegetable cooked in Taila of Mustard	Bitter gourd vegetable cooked in Taila of Mustard	Patola vegetable cooked in Taila of Mustard	Bottle gourd vegetable cooked in Taila of Mustard
	Red rice (Rata shali)	Broken wheat	Red rice (Rata shali)	Broken wheat	Red rice (Rata shali)	Broken wheat	Red rice (Rata shali)
	Chapati of Wheat	Chapati of Barley	Chapati of Wheat	Chapati of Barley	Chapati of Wheat	Chapati of Barley	Chapati of Wheat
	Floor of Barley-mixed with water and cooked.	Floor of Barley- mixed with water and cooked.	Floor of Barley-mixed with water and cooked.	Floor of Barley-mixed with water and cooked.	Floor of Barley-mixed with water and cooked.	Floor of Barley- mixed with water and cooked.	Floor of Barley-mixed with water and cooked.
Dinner	Lentils Soup	Boiled Barley Soup	Soup of half cooked rice	Lentils soup	Maize Soup	Boiled Barley Soup	Soup of half cooked rice
	Jackfruit/ashgourd vegetable cooked in Taila of Mustard	Kasheru/ Lauki vegetable cooked in Taila of Mustard	Patola vegetable cooked in Taila of Mustard	Karela vegetable cooked in Taila of Mustard	Jackfruit/ashgourd vegetable cooked in Taila of Mustard	Bottle gourd vegetable cooked in Taila of Mustard	Patola vegetable cooked in Taila of Mustard
	Broken wheat	Red rice (Rata shali)	Broken wheat	Red rice (Rata shali)	Broken wheat	Red rice (Rata shali)	Broken wheat
	Chapati of Barley	Chapati of Wheat	Chapati of Barley	Chapati of Wheat	Chapati of Barley	Chapati of Wheat	Chapati of Barley

Floor of Barley-mixed with water and cooked.	Floor of Barley- mixed with water and cooked.	Floor of Barley-mixed with water and cooked.	Floor of Barley-mixed with water and cooked.	Floor of Barley-mixed with water and cooked.	Floor of Barley-mixed with water and cooked.	Floor of Barley- mixed with water and cooked.	Floor of Barley-mixed with water and cooked.
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Table 4: Vihara table with accepted daily routine following Nidan Parivarjana

Vihara ³³	
Time	What to do
5.30am- 6.00am	Wake up and fresh
6.00am-7.15am	Purva karma/ morning walk /Special techniques of DM.
7.15am-8.00am	Maitri Milan
8.00am-8.30am	Breakfast (except during snehapana/ pradhana karma)
8.30am-9.30am	Bath & Wash
9.30am-11.30am	Library Reading/karma Yoga
11.30am-1.00pm	Pranayama & Special technique of DM (Not at Snehapana and pradhana karma period- So MSRT at that time)
1.00pm-2.00pm	Lunch
2.00pm-2.30pm	Normal walking/DRT
2.30pm-4.30pm	TV Shows Like- Mahabharat/Ramayan/Vishnupuran etc.
4.30pm-6.00pm	Evening Walk/ Exercise after shodhana/ Tuning to the nature
6.00pm-7.00pm	Wash & Fresh
7.00pm-7.30pm	Bhajan
7.30pm-8.30pm	Dinner
8.30pm-9.30pm	Library Reading
9.30pm-10.00pm	Going back to room & lights off.

4.3 Step 4

Validation:

Our calculations show that the various domains have a CVR as shown in table-5. The average CVR was 0.85. For a total of eleven experts, the critical value of the CVR is 0.58. We conclude from table-5, that each domain has satisfactory content validity and that the entire instrument too has satisfactory content validity.

Table 5: Lawshe's Content Validity Ratio (CVR) for domains

Variables	1	2	3	4	5	6	7	8	9	10	11		
	Dr Aja y	Dr Rama krish na	Dr Shara da	Dr Mam ta	Dr Vasud ev	Dr Sang a Mitra	Dr Anita	Dr Sweta	Dr Vasud ha	Dr Sriniv as	Dr Umes h	SUM	CVR
Classical reference	U	E	E	E	E	E	E	E	E	E	E	10	0.8
Classification	E	E	E	E	E	E	E	E	E	E	E	11	1.0
Ahara	E	E	E	E	E	E	E	E	E	E	E	11	1.0
Vihara	E	E	E	U	E	E	E	E	E	E	E	10	0.8
Principle of treatment	E	E	E	E	E	E	E	E	E	E	U	10	0.8
Deepana & Paachana	E	E	E	E	E	E	E	E	E	E	U	10	0.8
Snehaushadha	E	E	E	E	E	E	U	E	E	E	U	9	0.6
Virechanaushadha	E	E	E	E	E	E	E	E	E	E	U	10	0.8
Samsarjanakrama	E	E	E	E	E	E	E	E	E	E	E	11	1.0
Shamanaushadha	E	E	E	E	E	E	E	E	E	E	U	10	0.8
												Average	0.85

5.0 Discussion

This study provides a validated ayurveda treatment protocol for treatment of adult DM2 patients without major complications (heart, kidney or the eyes). The detailed principle and protocol of treatment which are scattered in different sections of Brhatrayis, Laghutrayis and others (18 texts) have been compiled. Not all texts provide a comprehensive protocol for management of madhumeha.^{27, 34, 35}

5.1 Madhumeha vs Prameha

Table-6: Treatment/management of Prameha

Prameha Chi.	Sa. Yog	Cha. Sa.	Su. Sa	Astan. Sa	Ast. Hru	Bhel. Sa	Ha. Sa	Bh. Pr.	Sha.Sa	Yog. Ra
Vamana	-	Chi.6/1 5,16	Chi. 11/5	Chi.14/2 ,3,4	12/1,2, 3	-	-	38/44	-	-
Virechana	-	Chi.6/1 5,16	Chi. 11/5	Chi.14/2 ,3,4	12/1,2, 3	-	-	38/44	-	-
Basti	-	-	Chi. 11/5	Chi.14/2 ,3,4	12/1,2, 3	-	-	38/44	-	-
Only shansamana	Ka.pr	-	-	-	-	7/1,2 (Teekshna Dravyas)	28/6- 25	-	-	Utt.Pra m.Chi
Others	-	-	-	-	-	-	-	-	7/59-62 Ganana	-

Most of the texts (Table-6) describe the treatment protocol under the heading of prameha and not madhumeha.³⁵ But it is known that madhumeha is very different from prameha. Madhumeha is considered as one of vataja pramehas and when the prameha is not treated properly and becomes chronic then it takes the form of madhumeha. Further this madhumeha condition leads to various complications such as- excess medas, Pidikas etc. So the treatment of madhumeha is different from prameha.

Shusruta has said that patients suffering from madhumeha should be always treated by teevra virechana. Mridu virechana cannot help them because of their body being pervaded by excessive meda.³⁷ In the same manner Harita samhita says that madhumeha is vataja prameha and this is very difficult to cure or sometimes incurable. Hence the treatment should be done after giving a small virechana.³⁸ Harita samhita also describes the shaman aushadhis for chronic prameha which are- Haritaki, Jayapalaa churna as well as making the lehya of triphala.³⁸ All these three are vatanulomaka and can lead to virechana. Astanga Samgraha says similar to shusruta for the treatment of chronic pramehi. It says that chronic pramehis should be treated by giving teevra virechana because they have excess of medas.³⁹ Therefore it was concluded that the treatment of madhumeha will be done by teevra virechana followed by shamana aushadis and Nidana parivarjana (strict adherence to prescribed ahara and vihara).

Table 7 shows the treatment principle of madhumeha in classical texts

Table-7 Treatment/Management of Madhumeha

Madhumeha Chikitsa	Bhe.Sa	Ha.Sa	Su.Sa	Astan.Sa
Vamana	-	-	-	-
Virechana	Chi.7/29	Pram.28/16,17	Chi.12/6	Chi.14/21
Basti	-	-	-	-
Only shansamana	-	-	-	-
others	-	-	-	-

The shamana chikitsa described in all the classical texts are similar. There are some preparations which are different but most of the herbs used in different preparations are the same. Those preparations which are common in most of the classical texts, and are used by the clinicians frequently were given the top priority in our protocol. Modern research studies carried out using some of these formulations have been referred and thus a list of shamana drugs has been finalized.

Table-8 Sanshamana formulations in classical texts with research studies

Name of the Herbs/ Preparation	Research contribution	Classical reference
Phalatrikadi ghan vati	Mani Raj singh et al, 1972 ⁴⁰	Bh.Pra. 38/59
Nisha Kathakadi Kasaya	Shardamani, K.R. et al – 1988 ⁴¹	S.Y.Kasaya yo. pra.
Kathaka Khadiradi Kasaya	Mohammad. N. P., et al-1999 ⁴²	S.Y.Kasaya yo. pra.
Nishamlaki	Yadav, R. K., et al-2001 ⁴³	Ast.Hru. 12
Shilajitwadi lauha	Mane Vijaya 1999 ⁴⁴	Bh.Ra. Pra.Pa.3
Shilajitwadi Vati	Shweta, M. K., 2008 ⁴⁵	Bh.Ra. Pra.Pa.3
Amrutadi churna	Rajalaxmii, K. et al – 2010 ⁴⁶	S.Y.Churna yo.pra.
ChandraPrabha vati	Jamwal, V. D., 1978 ⁴⁷	R.S.S. 3/21-25
Vidangadi ghan vati	Patel Asha, J. – 2004 ⁴⁸	S.Yo. Vati Yog. Pra.

Most of the ahara & vihara mentioned in classical texts are same. Therefore the ahara and vihara to be avoided were listed and those which are permitted are used in the protocol considering the palatability and acceptability.

6.0 Limitations of the study

The validation was done by experts from one medical college in Bangalore.

7.0 Strength of the study

First of this type of study using modern scientific methods for validating a protocol. This makes the module acceptable and generalizable.

8.0 Suggestions for future work

This may be refined by taking the opinion of different experts from different schools of ayurveda to make it more acceptable as a protocol to be used in all ayurveda centers in the country and abroad. This validated protocol has to be tested through randomized control studies to prove its efficacy.

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