Journal of Ayurveda

A Peer Reviewed Journal

Vol.XI No 3 Jul-Sep 2017

Contents

Editorial

Editorial- Pain Management through *Ayurveda* – Need of Consolidation 03

Prof. Sanjeev Sharma

Clinical Studies

Clinical Evaluation of *Gomutra Bhavita Methika Beej Choorna* and *Sukshma Vyayama* in cardinal symptoms of Non Insulin Dependent Diabetes Mellitus 04

Dr. Durgawati Devi, Prof. Kamalesh Kumar Sharma, Dr. Rekha Jain

Clinical Evaluation of *Bilvadi Leha* in The Management of *Grahani Dosha* with special reference Irritable Bowel Syndrome (IBS) 11

Dr. Gurpreet Kaur, Dr. Naresh K. Kumawat, Dr. Munesh Kumar, Dr. Daya Shankar Mishra

A Comparative Study on *Katak Khadiradi Kashyayam* and *Niruryadi Gulika* in the Management of *Madhumeha* w.s.r. to Hyperglycemia 17

Dr. Shagufta Malhotra. Dr. N. S. Kolhe. Prof. Ram Kishor Joshi

Clinical Study to Evaluate The Effect of *Brahmi Ghrita Uttara Basti* in *Vandhyatva* W.S.R. to Female Infertility 26

Dr Suresh Kumar Solanki, Dr B. Pushpalatha, Dr Khushbu Jain

Study to Evaluate the Preventive Effect of *Pratimarsha Nasya* and *Dhumapana* in *Tamaka Shwasa* w.s.r. to Seasonal Bronchial Asthma 34

Dr. Ravina Mehra, Dr. Kashinath Samagandi

Study on the Immunomodulator effect of *Madhuyashti* Syrup in Children 46

Dr. Krishan Kumar Kaswan, Dr. Rakesh Kumar Nagar, Prof. Ajay Kumar Sharma

Study on The Management of Spasticity In Children Suffering From Cerebral Palsy With An *Ayurvedic* Compound And *Yogic* Postures (*Asanas*) 56

Dr. Sandeep Kumar, Dr. Nisha Ojha

A Clinical Study To Evaluate The Efficacy Of *Vamana* And *Nasya Karma* In The Management of *Peenasa* W.S.R. To Sinusitis 66

Dr. Sarmah Jayanta, Dr. Mangal Gopesh

Acute toxicity Study of *Sanjeevani Vati* according to OECD Guideline 420 73
Dr. Arun Kumar Dutta, Dr. Richa Sharma, Dr. R. K. Sharma (Chulet)

Role of *Agnikarma* in the Management of Plantar Fasciitis 78
Dr.Pooja Arya, Dr.Rahul Sharma, Prof. Sanjeev Sharma, Prof. Hemant K. Kushwah

Pharmaceutical Studies

Pharmaceutical and Analytical Study of *Mehakulanthaka Rasa* 85
Dr. Sakhitha K.S., Prof. P.Suresh, Prof. K. Shankar Rao

Pharmaceutical Standardization Of *Manjishthadi Tailam* 93
Dr. Dattatray Dighe, Dr. Sanjay Kumar

Conceptual Studies

Adiponectin: A potential biomarker in *Madhumeha* (Type 2 Diabetes Mellitus) 99
Dr. Amita, Prof. Pawankumar Godatwar, Dr. Bal Krishan Sevatkar

***Ayurvedic* Management In Diabetic Retinopathy (*Prameha Janya Netra Rogas*)** 104
Singh Karan, Mishra Pramod Kumar, Soni Anamika, Sharma Brahmanand

Literary Reviews

Concept of *Viruddha Ahara*: A Review 108
Dr. Talekar Manisha, Dr. Mandal Sisir Kumar, Dr. Sharma Reetu

The Utility of *Dugdha Chikitsa* (Milk Therapy) in *Udara* (Ascites) - *Dr. Londhe P. D.* 115

Instructions for Authors 119

Short Communication

Ayurveda News & Views - *Dr. Rizwana Parveen* 133

Contributions are invited in the form of :

Research Papers–*Randomized trials, intervention studies, studies of screening and diagnostic tests, cohort studies, cost-effectiveness analyses, and case control studies.*

Short Communications– *Brief accounts of descriptive studies, initial/partial results of a larger trial, and a series of cases;*

Correspondence– *Letters commenting upon recent articles in Journal of Ayurveda, other topics of interest or useful clinical observations. Debate on important issues such as those raised in the editorial forum are most welcome.*

Images in practice– *Interesting and original images which are worth a thousand words and help understand a particular concept. Images should accompany a certificate of ownership.*

A major criteria for acceptance of an article will be addition to existing knowledge and as such manuscripts are required to include 'what this study adds'.

2 copies of Books may be sent for book review section.

EDITORIAL

Pain Management through *Ayurveda* – Need of Consolidation

Pain is one of the primary reason for which a patient visits a physician or hospital. It is thus obviously incumbent upon the physician to relieve the patient by managing the pain. Since pain is a self perceivable factor, the relief achieved by the management can be clearly assessed by the patient. It is commonly assumed that the conventional system of medicine is more successful in managing both acute and chronic pain. Public belief tends heavily towards the opinion that *Ayurveda* can not manage the acute pain effectively and even in the case of chronic pain the patient has to learn to live with the pain till the underlying cause if managed to the non-pain threshold level. Unfortunately, this is far from truth. *Ayurveda*, like any other health care system aims to relieve the patients of the pain both on immediate and sustainable basis. The definition of *Roga* itself states that it is state wherein the person in some sort of pain and *Arogya* means to relieve the person of this pain. Therefore, the approach of *Ayurveda* can never ignore pain management.

Being a holistic system of medicine and pain being the symptom of some underlying cause, the focus in *Ayurveda* management becomes the underlying pathology rather than pain. Ironically, the patient can feel the pain but mostly can not see the underlying pathology however severe that might be. Therefore, if we do not provide relief in pain, then the patient can not appreciate the efforts we are putting in and the possible results thereof. Conventional medicine with their target oriented molecules have been largely able to suppress acute pain but these molecules are also not that effective in managing chronic pain or the risks of their long term use significantly outweighs the benefits. But owing to the results perceived in the acute pain management, conventional medicine is the preferred choice for pain relief.

Ayurvedic management does offer both acute and chronic pain relief. In the ancient times, *Ayurveda* was the only available system of medicine wherein epic and manual battles were fought involving huge armies. The wounded were managed by the *Vaidyas* to enable most of them to commence fighting next day morning. But with time, both the practice and continuous process of contemporary innovation was intermittently halted due to various reasons. This has resulted in a perception that *Ayruveda* is not good in acute pain management. A lot of patients do visit *Ayurveda* for chronic pain and not that few even visit for acute pain. What *Ayurveda* lacks is a systematic target oriented approach, observation based thereon and collection of data accordingly. There are many herbs like leaves of Datura metel, Ricinus communis, Vitex negundo, Adhatoida vasica which offer good pain relief when applied locally. The systemic pain killers were originally developed from plant. The procedures of *Panchakarma* offer significant acute pain relief. Thus, we in *Ayurveda* do not necessarily require to do anything totally new to remove the perception gap that we can not manage acute pain. Only we need to be focussed, target oriented and smart research followed by effective communication of the benefits to the public. Such consolidation of facts will enable *Ayurveda* to meander its way towards effective pain management through *Ayurveda*.

Prof. Sanjeev Sharma
Director

Clinical Study

Clinical Evaluation of *Gomutra Bhavita Methika Beej Choorna* and *Sukshma Vyayama* in cardinal symptoms of Non Insulin Dependent Diabetes Mellitus

*Dr. Durgawati Devi, **Prof. Kamalesh Kumar Sharma, ***Dr. Rekha Jain

Abstract:

The rising burden of Diabetes mellitus and other non-communicable diseases which has occurred with modernization can be understood in the context of 'epidemiological transition. WHO has declared that India will become the "Diabetes Capital of the World" by the year 2025.During year 2014, the number of cases of diabetes worldwide is estimated to be around 422 million; of these more than 90 percent are type 2 diabetes. The International Diabetes Federation predicts that the number of people living with diabetes will to rise from 415 million to 642million by 2040.

Ayurveda is an ancient most science and related with all the aspects of life; basically it deals with two type of principles i.e. first one is preventive and promotive, and second one is curative and rehabilitative. To fulfill the later aim, various types of diseases, their pathogenesis and treatment modalities are discussed in detail. Actually diseases are described in various groups e.g. *prameha, mutraghat, rajyakshama* etc. Approach of *Ayurveda* towards treatment of disease is quite different; it believes in ideal treatment, which should not produce any type of side effect and complication during and after treatment. Therefore, various types of drugs and their combinations are described in detail.

The syndrome of diabetes mellitus is largely covered under the broad heading of *prameha*. Here we have focused on the management of Type 2 DM and for this; we have planned a randomized single blind control clinical trial in this disease. 49 patients of Type 2 DM were selected from the OPD and IPD of the Arogyashala, NIA, Jaipur. These patients were divided into two groups. Plain *methika beej churna* was given in a control group and *gomutra bhavita methika beej churna* and *sukshma vyayama* was given in study group. Observations were recorded very crucially and result was statistically analyzed. The result was very much encouraging and showed the efficacy of therapy.

Key words: *Methika beej churna*, NIDDM, *prameha, sukshmavyayama.*

सारांश–

मधुमेह एवं दूसरे असंचारी रोगों का बढ़ता हुआ भार पाश्चात्य जीवन शैली के कारण है तथा इसको इपिडेमियोलोजिकल ट्रान्जिशन के सन्दर्भ में समझा जा सकता है। विश्व स्वास्थ्य संगठन ने यह घोषित किया है कि भारत 2025 तक विश्व की मधुमेह राजधानी हो जायेगा। वर्ष 2014 तक विश्वभर में मधुमेह से ग्रस्त रोगियों की संख्या 42.2 करोड़ थी, जिसमें से 90 प्रतिशत रोगी टाइप 2 डायबटीज के थे। अन्तर्राष्ट्रीय मधुमेह महासंघ ने अनुमान किया है कि डायबटीज से ग्रस्त रोगियों की संख्या 41.5 करोड़ से बढ़ कर 2040 तक 64.2 करोड़ हो जायेगी।

आयुर्वेद एक प्राचीनतम विज्ञान है तथा जीवन के सभी पहलुओं से सम्बन्धित है। मुख्यतः इसके सिद्धान्त दो प्रकार के है पहला प्रतिषेधात्मक एवं संवर्धनात्मक तथा दूसरा चिकित्सा एवं पुनर्वास। दूसरे उद्देश्य की पूर्ति के लिए विभिन्न प्रकार के रोग, रोगजनक क्रियाविधि तथा चिकित्सा सिद्धान्त को विस्तारपूर्वक वर्णित किया गया है। रोगों को विभिन्न समूहों में वर्णित किया गया है जैसे प्रमेह, मूत्राघात, राजयक्ष्मा, इत्यादि। रोगों की चिकित्सा में आयुर्वेद का दृष्टिकोण पूर्णतः भिन्न है।

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यह आदर्श चिकित्सा में विश्वास करता है, जिसमें चिकित्सा के दौरान तथा बाद में किसी भी प्रकार के दुष्प्रभाव एवं उपद्रव उत्पन्न नही होने चाहिए। इसलिए विभिन्न प्रकार की औषधि एवं उनके योग विस्तारपूर्वक बताये गये है। डायबटीज मलाइटस सिंड्रोम को प्रमेह के अन्तर्गत बताया गया है। यहां पर टाइप 2 डायबटीज मलाइटस की चिकित्सा व्यवस्था पर फोकस किया गया है। टाइप 2 डायबटीज मलाइटस के 49 रोगी आरोग्यशाला, राष्ट्रीय आयुर्वेद संस्थान, जयपुर के बहिरङ्ग एवं अंतरङ्ग विभाग से लिए गये है। इन रोगियों को दो समूहों में विभाजित किया गया है। सादा मेथी का बीज चूर्ण नियन्त्रण समूह को तथा गोमूत्र भावित मेथिका बीज चूर्ण एवं सूक्ष्म व्यायाम अध्ययन समूह को दिया गया। अवलोकित आंकड़ों को बहुत सावधानी के साथ अभिलिखित किया गया एवं परिणामों का सांख्यिकीय विश्लेषण किया गया। परिणाम अत्यधिक उत्साहवर्धक रहे तथा चिकित्सा की प्रभावोत्पादकता को दर्शाया।

Clinical Study

Clinical Evaluation of *Gomutra Bhavita Methika Beej Choorna* and *Sukshma Vyayama* in cardinal symptoms of Non Insulin Dependent Diabetes Mellitus

Dr. Durgawati Devi, Prof. Kamalesh Kumar Sharma, Dr. Rekha Jain

Introduction:

The population in India has an increase susceptibility to diabetes mellitus .The results of prevalence studies of diabetes in India were systematically reviewed with emphasis on those utilizing the standard WHO criteria for diabetes diagnosis. The prevalence of disease in adults was found to be 2.4 percent in rural and 4.0-11.6 percent in urban dwellers. High frequencies of impaired glucose tolerance, shown by those studies, ranging from 3.6-9.1 percent, indicate the potential for further rise in prevalence of diabetes mellitus in the coming decades.[1]

The etiology of Type 2 diabetes mellitus appears to involve complex interactions between environmental and genetic factors. Presumably, the disease develops when a diabetogenic lifestyle (i.e. excessive caloric intake, inadequate caloric expenditure, obesity) is superimposed on a susceptible genotype. The syndrome of diabetes mellitus is largely covered under the broad heading of *Prameha* in context of *Ayurveda*. However, *apathyanimittaja Prameha*(Sushruta), *Sthula Pramehi* (Charaka) and *avaranjanya madhumeha* described in *Ayurvedic* literature have similarity with Non-Insulin Dependent Diabetes Mellitus (NIDDM). The patient of *prameha* is two types by treatment point of view. One is *sthool* and another is *krisha*. Type 2 diabetes is frequently found in obese person.Here the study is focused on Type-2 DM patients only to understand its etiopathogenesis, *Samprapti vighatana* of disease and actual line of treatment from *Ayurveda* view point. In this study the effect of *methika beej choorna* for the lowering of blood sugar level in these patients has been evaluated. *Sukshama-vyayama* has been incorporated in this study for the improvement of results as the disease is critically influenced by haphazard life-style as lack of exercise is considered as one of etiological factor. The study was designed for the improvement of life-style of the diabetic patients as well as prevention of complications by lowering their blood sugar at physiological level. The results were encouraging and very much useful for improving the quality of life of the patients.

Material and Method-

The study has been conducted with following Aims and Objectives-

- To correlate the etiopathogenesis and signs and symptoms of patients of Type-2 DM with *Sthool Pramehi*.
- To evaluate the effect of *methika beej churna* in patients of Type-2 DM.
- To evaulate the effect of *gomutra bhavita methika beej churna* with *sukshmavyayama* in patients of Type-2 DM.
- To compare the effect of *methika beej churna* and *gomutra bhavita methika beej churna* with *sukshmavyayama* in the management of Type-2 DM.

Following material and methods were adopted for this study-

1 **Literary**- Available descriptions of *Prameha* and other relevant topic have been studied from various literary sources of *Ayurveda* and *Yoga* texts and modern medical Science.

2. **Clinical**– It includes the selection of patients, investigations and recording observations and results in this trial.

Study Type: It was a randomized, single blind standard control clinical trial on human subjects.

Study Population: The study population is patients of type 2 DM and selected from OPD and IPD

of *Aarogyashala*, National Institute of *Ayurveda*, Jaipur.

Sample size : The sample size is 60 and randomly divided into two groups of 30 each.

Selection criteria : Based on following points-

(a) Inclusion criteria

1) Patients of both sex and middle aged between 30 to70 years.

2) Known/unknown case of diabetes, who must fulfill the criteria of the diagnosis for Type-2 DM (any 5 characteristic must be present in the patients.):-

- BMI > 30 kg/m^2
- Central obesity
- Hypertension
- With a long history (typically many month) of fatigue, with or without osmotic symptoms (excessive thirst/frequent urination/ increased appetite).
- Weight loss/Gain
- Tingling Sensation-UL/LL
- Burning Sensation - UL/LL
- Delayed wound healing
- Genital Pruritus
- Family History
- Recurrent Infections

3) Patient of Type 2 DM with blood sugar level, FBS- >126 to <220 mg/dl and PPBS- >200 to <300 mg/dl.

(b) Exclusion criteria

- Patients of insulin dependent diabetes mellitus (Type 1 DM)
- Diabetes in pregnancy
- Allergy –asthma,respiratory infection
- Drug induced diabetes mellitus
- Pancreatic disease- pancreatectomy,
- Malignancy
- With Complications of Type-2DM (Retinopathy, Nephropathy, Neuropathy)

Study drug description: *Methika beej churna* has been selected as a trial drug in diabetes considering its properties. It is *katu* in rasa and *vipak, ushnaveerya*, *agnideepan* and *sleshma prasamana*. *Gomutra* were selected as the *bhavanadravya*, which can increase the potency and bioavailability of *methhika beej churn* and physical exercise in form of *sukshma-vyayama*.

Assessment criteria-During the trial and follow up study the registered patient's assessment was conducted at the day baseline 15th, 30th, 45th and 60th day for efficacy and safety measurement.

Efficacy measurement-Specific clinical symptoms were assessed separately at the day of baseline according to grading of symptoms.

Subjective parameters-All the patients registered for the clinical trial were assessed for changes of well being if any, produced after the therapy.

Laboratory Investigation-Investigations were performed in all patients before and after the treatment.

- Fasting blood sugar and Post prandial blood sugar.
- Special investigation HbA1c done

Plan of study:

The patients were subjected to various investigations (as described above) before starting trial. A detailed pro-forma is prepared especially for this purpose consisting of the chief and associated complaints, detailed history of patients. In accordance with this pro-forma a complete general and physical examination was carried out of the patients by means of *Ayurveda* as well as modern medical science. Patients under trial were subdivided randomly into group A *(methika beej churna-* is case control group*)* and group 'B' (*gomutra-bhavita methika beej churna* and *sukshmavyayama* is study group) to compare the efficacy of both therapies. The procedures like were followed exactly as has been discussed in conceptual part.

Management plan-

Group	Drug	Dose	Duration
A	*Methika beej churna*	5 gm BD before meal with luke warm water.	2 month
B	*Gomutra Bhavita methika beej churna* and *Sukshmavyayama*	5 gm BD before meal with luke warm water and *sukshmavyayama* for 45 minutes.	2 month

Assessment of therapy

The assessment was done in the following manner.

The clinical features and blood sugar (FBS, PPBS and glycosylated Hb) levels were assessed before starting treatment, and on 15th day, 30th day, 45th day and 60th day of treatment. Following score pattern was adopted for sign and symptoms (i.e. Chief and associated complaints).

Grading of symptoms:

0- No symptoms

1- Presence of mild symptoms

2- Presence of moderate symptoms

3- Presence of severe symptoms

4- Presence of very severe symptoms

Following symptoms of Type-2 DM patients were assessed before and after the therapy:

- *Prabhootmutrata* (Polyuria),
- *Hastapada* and *Sandhi Shula* (Pain in hands, feet and joints)
- *Pipasaadhikya,* (Polydipsia)
- *Karpada-daha* (Burning sensation in hands and feet)
- *Kshudhadhikya* (Polyphagia)
- *Madhurasyata* (Sweetness in mouth)
- *Swedo-anga-gandhata* (Bad body odour)
- *Karapadasupti* (Numbness in hands and feet)
- *Klama* (Early fatigue)
- Bhara-kshaya (weight loss)/ Bhara-vriddhi (Weight gain)
- *Aalasya* (Lassitude)
- Recurrent infections
- *Mukha Shosha* (Dryness in mouth)
- Delayed wound healing
- *Vibandh* (Constipation)
- *Daurbalya* (Weakness)
- *Atinidra* (Excessive sleep)

Preparation of drug: *Methika beej* is soaked in *gomutra* in whole day and night, after that dried in shadow. The procedure is repeated three times. After that *methika beej* has powdered.

Observations and Results-Total 68 patients were registered for the study in which 49 were completed and 19 patients left treatment against medical advice. Out of these 24 patients in-group A, and 25 in group B, were completed treatment.

Observations:

- It has been observed that maximum number of patients belongs to 51-70 years (65.3%) of age group as this disease is predominant in older age.
- Majority of patients (79.59%) belongs to sedentary type of nature of job as sedentary life-style plays a major role in causation of the disease.
- Life-style wise observation shows that all of the patients follow irregular dietary pattern as *adhyashan, vishmasana*, etc. 61.22% patients had taken *madhura* predominant diet regularly. 91.33% patients had history of *diwaswapna* regularly. All these malpractices of life-style are risk factors of the disease.
- 84-100% patients showed the cardinal features

of the disease. But polyuria has been found in 100% of the patients. It shows that pathogenesis of urine formation and act of urination is the cardinal symptom of the disease. It clearly indicated why Ayurveda scholars considered *madhumeha*/ diabetes mellitus under the heading of *prameha*.

- Most of the patients 91-96% had presented with classical symptoms of *madhumeha* like *daurbalya, klama, vibandha, hasta-pada-sandhishula*, etc. These symptoms show the involvement of *vatadosha* in *madhumeha*/ diabetes mellitus.

Results:

Table I: Effect of therapy on subjective symptoms-

Symptoms	*Grp.*	Mean		Mean Diff	% Relief	SD (±)	SE (±)	`t`	*p*
		BT	AT						
Prabhuta Mutrata	A-24	1.75	0.91	0.833	47.6	0.48	0.098	<0.0001	HS
(polyuria)	B-25	2.08	1.08	1.00	50.00	0.40	0.08	<0.0001	HS
Kshudhadhikya	A-24	1.25	0.79	0.45	36.00	0.50	0.10	<0.001	HS
(polyphagia)	B-25	1.36	0.80	0.56	43.07	0.50	0.10	<0.0001	HS
Trishnadhikya	A-24	0.91	0.54	0.37	40.65	0.49	0.10	<0.0039	HS
(polydypsia)	B-25	1.84	0.80	1.040	57.77	0.53	0.10	<0.0001	HS

Table II: Effect of therapy on objective symptoms-

Symptoms	*Grp.*	Mean Score	SD (±)	SE (±)	`t`	*Diff*	*P*	*S*
FBS	A-24	63.29	20.52	4.19	1.08	47	0.14	NS
	B-25	71.08	28.62	5.73				
PPBS	A-24	74.29	27.05	5.52	3.08	47	0.0017	HS
	B-25	101	34.32	6.86				
Glycosylated Hb	A-24	0.53	0.72	0.14	1.93	47	0.029	S
	B-25	1.08	1.18	0.23				

Table III: Overall effect of therapy in group A (*n*=24)

Group A	Clinical symptoms	%	FBS	%	PPBS	%	GHB	%
Controlled	0	0	0	0	0	0	0	0
Marked Relief	1	4.16	0	0	0	0	0	0
Moderate Relief	4	16.66	2	8.33	1	4.16	5	20.83
Mild Relief	13	54.16	22	91.66	22	91.66	17	70.83
No Relief	6	25.00	0	0	1	4.16	2	8.33

Table IV: Overall effect of therapy in group B (*n*=25)

Group B	Clinical symptoms	%	FBS	%	PPBS	%	GHB	%
Controlled	1	4.00	0	0	0	0	0	0.00
Marked Relief	1	4.00	1	4.00	2	8.00	0	0.00
Moderate Relief	12	48.00	21	84.00	5	20.00	4	16.00
Mild Relief	10	40.00	2	8.00	18	72.0	15	60.00
No Relief	1	4.00	0	0	0	0	6	24.00

Discussion-

***Prabhootmutrata* (polyuria)**

It is evident that statistically highly significant (P<0.0001) result was obtained in both groups but percentage of relief were more in B group(50%) than A group (47%). Polyuria is due to osmotic diuresis,relief in this symptom indicates that blood Sugar level is controlled. It is due to hypoglycemic effect of *methika beej* and percentage of relief is more in B group is due to increased potency of *methika beej* by *bhavana* of *gomutra* and additional effect of *sukshmavyayama*.

***Kshudhadhikya* (polyphagia)-**

Results in both group were highly significant (<0.001), but percentage of relief was more (43.07%) in B group. Besides that we consider group 'B' the symptom was well under control than group'A'. First reason for polyphagia is the intracellular starvation. As in diabetes either there is absence or the resistance to insulin action so glucose cannot move into the cells and thus cells are starved of glucose. Improvement in symptom indicates gel forming dietary fiber reduces the release and gastric inhibitory polypeptides. Thus high fibers containing fenugreek seeds (*methika*) reduces blood sugar levels. Fenugreek seeds increases peripheral insulin activity. The hypoglycemic action produces by fenugreek seeds is due to the effect on insulin receptors and as well as at the gastro intestinal level. The soluble dietary fibers (SDF) is said to be responsible for this effects.

***Trishnadhikya* (polydypsia)-**

Result in both group A and B are highly significant at p <0.0039, and P<0.0001. But % of relief was more (57.77%) in group B due to combine effect of therapy. This is usually a result of osmotic diuresis, relief in symptoms indicates that blood sugar level is controlled and hypoglycemic effect of *methika beej* is well proved.

FBS, PPBS and Glycosylated Hb-

Both therapies are equally significant on FBS, PPBS and glycemic hemoglobin control. Mean score of FBS in group A is 63.29 and group B 71.08. Mean score of PPBS level in group A is 74.29 and group B is 101.00.Mean score of GHB in group A is 0.53 and in group B is 1.08.

Conclusion-

Methika beej and *gomutra*, both are rich in *tikta rasa* so, it seems that tikta, *kashaya* and *katu rasa* play *kledopshoshana, meda lekhana* and *kapha-pitta* defending role. They especially do *kledashoshana* which is one of the prime *dushya* in pathogenesis of *Prameha*. Whereas by *Sheetaruksha,* property they prevents liquefaction of the already *dravashleshma, abaddhameda* and other *apya-pradhanadushyas* involved in the pathogenesis hence also participating indefending phenomenon.

Action of fenugreek seeds are hypoglycemic, hypolipidaemic, galactagogue, demulcent, anti-inflammatory and carminative.[2] Proposed mechanisms of the hypoglycemic include insulinotropic activity of 4-hydroxyisoleucine, observed in vitro and in animal studies confirming a hypoglycemic effect through the inhibition of carbohydrate digestion and absorption.

Results of this trial are very satisfactory on clinical symptoms of *prameha* as *prabhootmutrta,*

kshudadhikya, trishnadhikya and also significant on controlling blood sugar level. Main aim of our study has been completed which is to enhance hypoglycemic effect of *methika beej* by adding *gomutra*in drug and exercise in life-style. It has proved by the real fact that percentage of relief is greater in "B" group than "A" group.

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Clinical Study

Clinical Evaluation of *Bilvadi Leha* in The Management of *Grahani Dosha* with special reference Irritable Bowel Syndrome (IBS)

*Dr. Gurpreet Kaur, **Dr. Naresh K. Kumawat, ***Dr. Munesh Kumar, ****Dr. Daya Shankar Mishra

Abstract:

IBS is chronic relapsing disorder of gastrointestinal function, the main features are abdominal pain associated with an altered bowel habit (may present with diarrhea or constipation or intermittently both) in the absence of any structural pathology. A careful review of the clinical picture of various GIT diseases, described in *Ayurveda* reveals that some of the disorders definitely have some clinical symptoms which observed in patients of IBS. So according to pathogenesis and sign & symptom, IBS can be a stage of *Grahani Dosha*. The present study was interventional, open label, prospective with time and single group. There was fifty two patients which clinically diagnosed case of IBS as per Rome III criteria were administered trial drugs *Bilvadi Leha* 10 gm twice daily orally after taking meal with lukewarm water as a *Anupana* within duration of 12 weeks. For assessment of results, IBS severity score, WHO QOL score, *Ayurvedic* parameters, hematology and microscopic stool examination were used. The study was showed significant results in fifty one (one patient dropped) patients in management of IBS (*Grahani Dosha*) with safety profile as an important therapeutic agent.

Key Word: IBS (Irritable bowel syndrome), *Grahani Dosha*, *Bilvadi Leha*

सारांश–

इरीटेबल बोवल सिन्डरोम अन्नवह स्त्रोतस् का जीर्ण रोग है, जिसका मुख्य लक्षण उदरशूल व असम्यक मल प्रवृत्ति है (अतिसार और विबन्ध मे से कोई एक या दोनों) जिसमें कोई भी रचनात्मक विकृति नहीं होती है। लक्षणों का अस्थिर स्वभाव, शारीरिक क्षीणता और मानसिक अवसाद के साथ सम्बन्धित निदान में सहायता करता है। आयुर्वेद शास्त्र के अनुसार अन्नवह स्त्रोतस के अनेक रोगों के लक्षण इरीटेबलबोवल सिन्ड्रोम के लक्षणों से मिलते हैं। इन रोगों की सम्प्राप्ति के अनुसार इरीटेबल बोवल सिन्ड्रोम ग्रहणी दोष की प्रारम्भिक अवस्था मात्र है। प्रस्तुत शोध कार्य में 52 रोगियों पर (एक रोगी निष्कासित) बिल्वादिलेह का चिकित्सकीय उपयोगिता का अध्ययन एक ही समूह में 12 सप्ताह तक किया गया। चिकित्सकीय शोधकार्य के अंत में आधुनिक व आयुर्वेद मानकों में सिग्नीफिकेंनेट परिणाम प्राप्त हुए एवं बिल्वादिलेह का चिकित्सकीय प्रयोग सुरक्षित एवं प्रभावकारी सिद्ध हुआ है।

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Clinical Study

Clinical Evaluation of *Bilvadi Leha* in The Management of *Grahani Dosha* with special reference Irritable Bowel Syndrome (IBS)

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Introduction:

Today, man is subjected to a major event of stress in modern fast way of life and the balance is frequently disturbed. The system is constantly kept under sympathetic stimulations without enough time for the parasympathetic system to do its job. This repeated sympathetic stimulation in the body lead to intermittent upsurges of heart rate, poor digestion, elevated blood glucose etc. due to secretion of neurotransmitters i.e. serotonin etc.[1] The large bowel is very sensitive to nervous excitations. Diarrhea during examination is a common experience. In a person who is highly sensitive and tensed with much emotional suppressions, the colon cries by purging. IBS is a functional bowel disorder characterized by abdominal pain or discomfort and altered bowel habits in the absence of detectable structural abnormalities. Throughout the world, about 10-20 % of adults and adolescents have symptoms consistent with IBS, and most studies show a female predominance.[2]

Grahani Roga as described in *Ayurveda* is a chronic bowel disease affecting the *Maha Srotasa*, means the GIT (Gastro intestinal tract). The cardinal symptom of *Grahani Roga* is alternate constipation and diarrhoea with blood or mucous along with abdominal pain and progressive emaciation. *Grahani Roga* is caused by *Mandagni.* Due to *Mandagni* all the *Dosha's* will vitiate, consequently it causes structural impairment of the *Grahani*, which in turn leads to malfunctioning of *Grahani*, resulting into infrequent evacuation of the bowel, which are hard or in liquid form.[3] The parameters of assessment were made more relevant to the purpose of study with emphasis on the improvement in the pattern of absorption from the gut, improvement of general health and relief from symptoms of *Grahani Roga*. In presented study, *Bilvadi Leha* was used in patients of *Grahani Roga* for clinical evaluation of trial drug.

Aim and Objectives: The study was undertaken with the following specific objectives which divided into-

- **Primary Objectives:** To assess the effect of *Bilvadi Leha* on IBS Severity Score.
- **Secondary Objectives:**

- To study the conceptual basis of IBS in comparison with various similar Ayurvedic conditions described in literature.
- To assess the effect of *Bilvadi Leha* on WHO-QOL BREF score.
- To assess the safety of *Bilvadi Leha* in patients of IBS.

Materials and Methods:

The study was an interventional, open label, not controlled, prospective, single group, clinical trial using pretest-posttest design and the study population was collected from the OPD and IPD of P.G. Department of Kayachikitsa at Arogyashala, National Institute of Ayurveda and SSBH, Jaipur (Raj.) and Department of Gastroenterology, SMS Medical College and Hospital, Jaipur (Raj.). Sample size was fifty two number of patients (1 patients dropped out and 51 completed) and who was diagnosed according to as per Rome III criteria.

The trial drug *Bilvadi Leha* (API- Part II: Vol-1: Page no.7-9)[4] was given 10 mg per orally twice a day after food with lukewarm water for 12 consecutive weeks. Patients were guided regarding *Pathya/Apathya* regimen. Patients were followed after every 14^{th} days during treatment and after every 28^{th} days after completed trial. The *bilvadi Leha* was provided by CCRAS and was prepared By ***Arya Vaidya Sala Kottakkal, Kerala.***

Bilvadi Leha having following contents: *Bilva* in 128 Parts (*Aeglemarmelos*, *Root*),[5] *Musta* (*Cyperu srotundus, Root tuber*) *Dhanyaka* (*Coriandrum sativum, Fruit),*[6] *Jiraka* (*Cuminum cyminum, Fruit*), *Ella (Elettariacardamomum, Seed), Twaka (Cinnamomum zeylanicum, Stem bark), Nagkesera (Mesua ferrea, Stamens), Sunthi (Zingiberofficinale, Rhizome), Maricha (Piper nigrum, Fruits), Pippali (piper longum, Fruit),* in 12 part of each and *Jirnaguda (Old Jaggery)* in 64 Parts.

Method of Preparation of Trial Drug: Firstly make *Bilva Kwath*, added Jaggery and also added *Prakshepa Dravya's* (*Musta* to *Pippali,* 9 drugs) continue heating till the preparation attains the consistency of *Leha* confirmed.[7]

Inclusion Criteria: The following inclusion criteria was followed for selecting the patients-

- Patients of either sex with age between 18 and 65 years.
- Known case of IBS as per Rome III criteria.

Symptoms of recurrent abdominal pain or discomfort and a marked change in bowel habit for at least six months, with symptoms experienced on at least 3 days/month in the last months associated with two or more of the following:-

- Pain is relieved by defecation.
- Onset associated with change of frequency of stools.
- Onset associated with a change in form (appearance) of stools.
- Willing and able to participate in the study.

Exclusion Criteria: The following was followed as exclusion criteria for selecting the patients-

- Patients with bleeding per rectum.
- Patients with evidence of malignancy.
- Alcoholic and/or drug abusers.
- Pregnant and lactating woman.
- Patients with Diabetes Mellitus, Hypertension, Mixed infection with intestinal parasites.
- Patients with prolonged (>6 weeks) medication such as corticosteroids, antidepressants etc.
- Patients suffering from major systemic illness necessitating long term drug treatment such as Rheumatoid arthritis, tuberculosis etc.
- Patients who have a past history of Atrial fibrillation, MI, Stroke, severe arrhythmia in the last 6 months and with clinical evidence of Heart failure.
- Patients with concurrent serious hepatic disorders, renal disorders, severe pulmonary dysfunctions.
- Patients who have completed participation in any other clinical trial during the past six months and have a P/H/O hypersenstivity.

Methods of Assessment:

- **Prior to selection (Screening):** Informed consent, Eligibility evaluation, and Physical examination and Laboratory investigation.
- **During selection (baseline):** General information, physical and systemic examination, Assessment of Ayurvedic parameters, IBS Severity Score, WHO QOL BREF Score.
- **During treatment i.e.14th, 28th days etc.:** Assessing drug compliance, physical and systemic examination, Assessment of Ayurvedic parameters, IBS Severity Score.
- **At the end of the treatment i.e. 84th days (at the end of 12 weeks):** Assessing drug compliance, physical and clinical examination, Assessment of Ayurvedic parameters, IBS Severity Score and laboratory investigations.
- **Assessment at the end of 16 weeks:** clinical assessments, Assessment of Ayurvedic parameters, IBS Severity Score and WHO QOL BREF Score.

Laboratory Parameters:

- Hemoglobin, Total Leucocyte Count (TLC), differential leucocyte count, Erythrocyte Sedimentation Rate (ESR), CBC.
- Biochemical investigations: FBS, PPBS, Liver function test (LFT), Renal function test(RFT).

- Stool for routine and microscopic examination.

Statistical Analysis:

The quantitative data was assessed by using paired student t test when compared before and after study in a single group (intragroup) and one- way analysis of variance (ANOVA) was applied to IBS Score and WHO QOL BREF Score.

- In IBS Score the comparison between BT and all follow ups was done with the help of ANOVA.
- In WHO QOL BREF Score the comparison between BT, AT and 4th weeks follow up after treatment was done with the help of ANOVA.

The P< 0.05 was considered as statistically significant, P>0.05 was considered as statistically not significant.

Results and Observations:

The observation made on 52 patients of IBS showed that maximum number of patients belonged to 18-30 years age group (53.84%), Male(84.61%), Married (65.38%), Literate(84.61%), above poverty line(75%), Urban habitat(67.3%), Hindu religion (88.46%), Vegetarian (67%), non- addicted (75%). 53.84% patients were having disturbed sleep pattern. A maximum patient belongs to *Vata-Pittaja Prakriti*(60%), *Madhyama Samhanana* (67.3%), *Avara Aahara Shakti* (77%) and *Madhyama Vyayama Shakti* (75%).

In this study, recurrent abdominal discomfort or pain was presented in all patients and abdominal bloating was present in 46.15% patients, 23% of constipation and 78.84 % of having diarrhea. There was 46.15% of patients having urgency of bowel movements, 92.43% of patients were having feeling of incomplete evacuation and 15.38% patients were having mucous with stool.

There were significant improvements in chief complaints and *Ayurvedic* parameters. In IBS score % of improvement of symptoms was continuously increasing from 0 to 84th days. Percentage change in the improvement of symptoms from 0 to 16th weeks was reduced as comparative to 84th days depends on successive follow-ups there was variation of results. [Table no. 1]. In WHO score, Domain 1 (Physical health) and 2 (Psychological health) were showed significant results from 0 to 84th days and 0 to 16 weeks where as insignificant results were showed from 84th days to 16th weeks. There was insignificant results in laboratory parameters after completion of trial also which showed that the safety profile of trial drugs.

Table no. 1: ANOVA for IBS Score (Kruskal Wallis Test{non parametric test}.

S. no.	Comparison	Mean Diff.	% Change	S.D. ±	S.E. ±	p- value	Remarks
1	0 & 14th day	67.33	27.06	75.038	10.507	<0.05	S.
2	0 & 28th day	102.33	41.14	78.797	11.034	<0.001	H.S.
3	0 & 42th day	120.8	48.64	83.505	11.693	<0.001	H.S.
4	0 & 56th day	142.76	57.39	76.2	10.67	<0.001	H.S.
5	0 & 70th day	151.0	60.70	73.083	10.234	<0.001	H.S.
6	0 & 84th day	150.61	60.54	73.224	10.253	<0.001	H.S.
7	0th D & 16th week	78.64	31.617	77.489	10.851	<0.001	H.S.
8	14th& 28th day	35.0	19.293	46.087	6.4535	<0.05	N.S.

9	14th& 42th day	53.47	29.47	63.722	8.9229	<0.05	N.S.
10	14th& 56th day	75.43	41.58	59.767	8.3404	<0.001	H.S.
11	14th& 70th day	83.66	46.12	68.803	8.6263	<0.001	H.S.
12	14th& 84th day	83.27	45.904	53.707	8.369	<0.001	H.S.
13	14th D& 16th week	11.31	6.236	51.271	9.6343	<0.05	N.S.
14	28th& 42th day	18.47	12.616	54.37	7.5206	<0.05	N.S.
15	28th& 56th day	40.43	27.615	51.271	7.1793	<0.05	N.S.
16	28th& 70th day	48.66	33.24	54.37	7.6133	<0.05	N.S.
17	28th& 84th day	48.27	32.97	51.866	7.2626	<0.05	N.S.
18	28th D& 16th week	-23.68	-16.18	73.742	10.326	<0.05	N.S.
19	42th& 56th day	21.96	17.165	38.106	5.3359	<0.05	N.S.
20	42th& 70th day	30.19	23.602	41.94	5.8728	<0.05	N.S.
21	42th& 84th day	29.80	23.295	41.352	5.7904	<0.05	N.S.
22	42th D& 16th week	-42.17	-32.95	68.966	9.6571	<0.05	N.S.
23	56th& 70th day	8.235	7.77	24.755	3.4664	<0.05	N.S.
24	56th& 84th day	7.843	7.400	23.071	3.2305	<0.05	N.S.
25	56thD & 16th week	-64.11	-60.5	59.705	8.3604	<0.05	S.
26	70th& 84th day	-0.392	-0.401	16.699	2.3383	<0.05	N.S.
27	70thD & 16th week	-72.35	-74.02	55.384	7.7553	<0.001	H.S.
28	84thD & 16th week	-71.96	-73.33	55.804	7.8141	<0.001	H.S.

Discussion:

In *Ayurveda,* the action of drugs is determined on Pharmacodynamics factors as *Rasa, Guna, Veerya* and *Vipaka* along with certain specific properties called *Prabhava (Karma)*, which cannot be explained on these principles inherited by the drugs. ***Grahani Dosha***(IBS) is the disease of *Agnivikriti* and *Manshika Dosha Vikriti*. Formation of *Ama Dosha* at different levels is the main *Samprapti*responsible for the disease. So for the *Samprapti Vighatana* of the disease, the drug should remove *Ama Dosha* at various levels, correct the *Agni* and cleanses the *Srotasa* as well as equilibrium of *Manshika* and *Sharirika Dosha's*. The main ingredient of *Bilvadi Leha* is *Bilva* which acts as *Agnideepana*, *Amapachana* and having *Grahi* properties. The ingredients of *Bilvadi Leha* were having maximum of *Katu Rasa* followed by *Tikta Rasa* and *Katu Vipaka* and *Ushana Veerya* which act as *Deepana, Pachana, Ruchikara, Shodhana, Krimihara* and *Kaphaghna* properties. *Ushana Veerya* helps in cleanses the *Srotasa* (*Srotoshodhaka*) and *Kaphaghna* properties. *Sunthi,*

Pippali, Musta etc. are maintaining the equilibrium of *Manshika* and *Sharirika Dosha's* on the basis of previous researches.

Conclusion:

The Observations and Results obtained in a series of patients of IBS treated with *Bilvadi Leha* had showed good recovery in clinical manifestation of the diseases and well tolerated by all patients and no unwanted effects was seen. There was significant results showed in IBS score and WHO QOL BREF score (Physical and psychological as well as Physical and mental health). Thus it can be concluded that *Bilvadi Leha* can be used as a safe and "important Therapeutic agent" in the management of Irritable Bowel Syndrome (IBS).

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Clinical Study

A Comparative Study on *Katak Khadiradi Kashyayam* and *Niruryadi Gulika* in the Management of *Madhumeha* w.s.r. to Hyperglycemia

*Dr. Shagufta Malhotra. **Dr. N. S. Kolhe. ***Prof. Ram Kishor Joshi

Abstract

In Ayurveda, a condition in which a person passes honey like urine is called *Madhumeha* (Hyperglycemia). It is one among 20 types of *prameha*. Similarly, Diabetes, "*diabainein"*, is excessive urination associated with the disease; the Greek word *mellitus*, means "like honey". As of 2016, 422 million people have diabetes worldwide. It is a growing health hazard in developing countries. So the study was conducted with objective of clinical evaluation and comparison of the efficacy of *Katak Khadiradi Kashyayam* and *Niruryadi Gulika* in the management of *Madhumeha* (Hyperglycemia). The study was conducted on 30 clinically diagnosed patients of hyperglycemia randomly divided into three groups of 10 patients each. GROUP- I was given *Katak Khadiradi Kashyayam* in a dose of 20 ml twice daily for a period of 30 days before meal; GROUP- II was given *Niruryadi Gulika* in a dose of 2 tablet (each of 500 mg) with lukewarm water twice daily for a period of 30 days before meal; and GROUP- III was given both the drugs. The study confirms that *Katak Khadiradi Kashyayam* and *Niruryadi Gulika* were effective in management of *Madhumeha* and reduce the symptoms of illness. The chosen drug was effective in reducing Post Prandial Blood Sugar and Post Prandial Urine Sugar (highly significant in group 3 and significant in group 2), only PPBS in Group 1 (significant result). No adverse effects were noted in any of the patients during the trial period.

Keywords: Hyperglycemia, *Madhumeha*, *Prameha.*

सारांश–

आयुर्वेद मे, वह स्थिति जिसमे व्यक्ति मधु के समान मूत्र त्याग करते है वह मधुमेह रोग कहा जाता है। यह 20 प्रकार के प्रमेह मे से एक है। इसी प्रकार डायबिटीज का अर्थ बहुमूत्रता एवं मेलाइटस का अर्थ मधु के समान होता है। सन् 2016 तक विश्व मे 422 मिलियन लोग डायबिटीज से ग्रसित है। डायबिटीज मेलाइटस विकासशील देशों में बढ़ता हुआ स्वास्थ्य सम्बन्धित खतरा है। इसलिए मधुमेह रोग मे कतक खदिरादि कषाय एवं निरुर्यादि गुलिका की तुलनात्मक प्रभावोत्पादकता और नैदानिक मूल्यांकन के लिये यह अध्ययन किया गया इस अध्ययन के लिए 30 मधुमेह के रोगियो को यादृच्छित रुप से चुनकर तीन वर्गो मे बांट दिया गया, हर एक वर्ग मे 10 रोगियों को रखा गया। वर्ग 1 रोगियों को कतक खदिरादि कषाय 20 मिलि मात्रा मे दिन मे दो बार भोजन पूर्व 30 दिन तक दिया गया । वर्ग 2 रोगियों को निरुर्यादि गुलिका 2 वटी (500 मि.ग्रा.) कोष्ण जल से भोजन पूर्व 30 दिन तक दिया गया। वर्ग 3 मे दोनो औषधियाँ दी गयी। इस अध्ययन से पता चलता है कि ये औषधियाँ मधुमेह मे प्रभावी है और पी.पी.बी.एस एवं पी.पी.यु.एस.को भी कम करती है प्रयोग के दौरान किसी भी प्रकार का विपरीत प्रभाव नही पाया गया ।

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Clinical Study

A Comparative Study on *Katak Khadiradi Kashyayam* and *Niruryadi Gulika* in the Management of *Madhumeha* w.s.r. to Hyperglycemia

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Introduction

All those patients who pass urine which is sweet and honey like is said to be suffering from *Madhumeha* (Hyperglycemia). It is one among 20 types of *prameha* described in various *Ayurvedic* classics. In *brihatrayi* detailed description of aetiological factors of *madhumeha*[1] are available and etiology described there is very near to current aetiological factors for DM (Diabetes mellitus). Diabetes, "*diabainein"*, referring to the excessive urination associated with the disease; the Greek word *mellitus*, meaning "like honey".

Diabetes Mellitus, the most common endocrine disorder and a clinical syndrome, is characterized by hyperglycemia due to relative or absolute deficiency of insulin resulting in long standing metabolic derangements associated with pathophysiological changes in multiple organ system of eyes, kidneys, nerves and vascular system being characteristically susceptible.[2]

As of 2016, 422 million people have diabetes worldwide. Diabetes mellitus is a growing health hazard in developing countries; calling India the diabetes capital of the world. It is projected to increase to 69.9 million by 2025. Currently, up to 11% of India's urban population and 3% of rural population above the age of 15 has diabetes.

Aims And Objectives

1. To evaluate Antihyperglycemic effects of the *Katak Khadiradi Kashyayam* (Sahasra Yogam, CCRAS publication, *pratham prakaran – kashyaya yog* 71, page no.16) and *Niruryadi Gulika* (Sahasra Yogam, CCRAS publication, dwitiya prakaran – gutika yoga 69, page no.142)[3] in a series of patients suffering from *Madhumeha* on various scientific parameters.
2. To compare the efficacy of Antihyperglycemic effects of the *Katak Khadiradi Kashyayam* and *Niruryadi Gulika.*

Materials And Methods

1. Selection of cases - 30 clinically diagnosed patients of *Madhumeha* (hyperglycemic) selected from O.P.D. / I.P.D. unit of P.G. Department of Kayachikitsa, National Institute of Ayurveda, Jaipur.

(a) Inclusion criteria

- Patient with clinical history of DM.
- Patient having hyperglycaemia confirmed by laboratory investigation.
- Presence of cardinal symptoms of *madhumeha* as described in *Ayurveda* texts.

(b) Exclusion criteria

- Patient having Type 1 DM.
- Age below 20 and above 70 years.
- Patient of Type II DM who were on insulin therapy.
- Complication with DM.
- Patient having any serious illness.
- Patient having a FBS >250 and PPBS >300.

2. Selection of drugs

Taking the symptoms and the *samprapti* of *madhumeha* into consideration, *"katak khadiradi kashyayam* and *niruryadi gulika"* were selected. These drugs were having *tikta, katu, kashaya rasa, katu vipaka, laghu, ruksha & tikshna guna* and *mutrasagrahaniya, jatharagni vardhak, vayasthapana, chakshushya, rasayan, vrishya, grahi, lekhana, deepana, oja vardhana* and *pachana* properties.

Table 1: Showing the Contents of *Katak Khadiradi Kashyayam*

S. No.	Drug	Botanical name	Part used	Qty. (gm)
1	*Katak*	*Strychnous potatorum*	Seed	1.852
2	*Khadir*	*Acacia catechu*	Heart wood	1.852
3	*Amalaki*	*Emblica officinalis*	Fruit rind	1.852
4	*Saptachakra*	*Salacia chinensis*	Root	1.852
5	*Daruharidra*	*Berberis aristata*	Bark	1.852
6	*Samanga (Lajjalu)*	*Mimosa pudica*	Whole plant	1.852
7	*Vidula (Chotapashanbheda)*	*Homonoia riparia*	Root	1.852
8	*Haridra*	*Curcuma longa*	Rhizome	1.852
9	*Patha*	*Cissampalos pareira*	Rhizome	1.852
10	*Amra*	*Mangifera indica*	Seed	1.852
11	*Haritaki*	*Terminalia chebula*	Fruit rind	1.852
12	*Abda (Nagarmotha)*	*Cyperus rotundus*	Rhizome	1.852

Method of preparation of *Kashyayam:* The drugs were taken in equal quantity. After that, two teaspoon (10 gm) of their *yavakuta churna* (coarse powder) was taken in the 80 ml of water, heated and reduced up to 20 ml; filtered through the muslin cloth. The medicine *yavakuta churna* (coarse powder) was prepared in the pharmacy of N.I.A., Jaipur.

Method of administration: Orally 20 ml twice a day before meal.

Duration of the trial: The clinical trial was continued for 30 days with each patient with a 15 days review.

Table 2: Showing the contents of *Niruryadi Gulika*

S. No.	Drug	Botanical name	Part used	Qty. (gm)
1	*Niruri*	*Phylanthus reticulate*	Root	0.03
2	*Saptachakra*	*Salacia chinensis*	Root	0.03
3	*Nirmali*	*Strychnous potatoum*	Fruit	0.03
4	*Samudraphen*	-	Cuttle fish bone	0.03
5	*Emali*	*Tamarandus indica*	Bark of Seed	0.03
6	*Haritaki*	*Terminalia chebula*	Fruit rind	0.03
7	*Vibhitak*	*Terminalia belerica*	Fruit rind	0.03
8	*Amalaki*	*Emblica officinallis*	Fruit rind	0.03
9	*Kapittha*	*Limonia accedecima*	Niryasa(Resin)	0.03
10	*Kumud*	*Nymphea alba*	Seed	0.03
11	*Ayaskant*	*Magnetic iron*	*Bhasma*	0.03

12	*Gairika*	*Ochre*	*Bhasma*	0.03
13	*Haridra*	*Curcuma longa*	Rhizome	0.03
14	*Daruharidra*	*Berberis aristata*	Root	0.03
15	*Chandana*	*Santalum album*	Heart wood	0.03
16	*Sarkara*	-	-	0.03
17	*Udumbar*	*Ficus Glomerata*	Bark	0.03

Niruryadi gulika was purchased from pharmacy of Arya vaidya sala, Kotakkal.

Dose and *Anupana*: 2 tablets (each of 500 mg) twice a day before meals with Luke warm water for 30 days.

3. Pre Treatment Observations

After preliminary registration, patients were subjected to detailed case history taking, physical, general and systemic examinations.

4. Administration of Drug & Treatment Schedule

30 registered, clinically diagnosed and confirmed patients of *Madhumeha* (Hyperglycemic) were selected for the present clinical trial and randomly divided into following three groups.

GROUP- I: 10 patients of *Madhumeha* (Hyperglycemic) were administered *Katak Khadiradi Kashyayam* in a dose of 20 ml twice daily for a period of 30 days before meal.

GROUP- II: 10 patients of *Madhumeha* (Hyperglycemic) were administered *Niruryadi Gulika* in a dose of 2 tablet (each of 500 mg) with lukewarm water twice daily for a period of 30 days before meal.

GROUP- III: 10 patients of *Madhumeha* (Hyperglycemic) were administered *Katak Khadiradi Kashyayam* in a dose of 20 ml twice daily for a period of 30 days before meal and *Niruryadi Gulika* in a dose of 2 tablet (each of 500 mg) with lukewarm water twice daily for a period of 30 days before meal.

All the patients were advised to undergo following laboratory investigations before starting the trial to rule out hyperglycemia and other illness; if present then exclude them from the trial.

a) Blood Examinations-

i. F.B.S. (Fasting Blood Sugar)

ii. P.P.B.S. (Post Prandial Blood Sugar)

iii. C.B.C. and E.S.R.

b) Urine Examination-

i. Routine Examination

ii. Microscopic examination.

iii. F.U.S. (Fasting Urine Sugar)

iv. P.P.U.S. (Post Prandial Urine Sugar).

Patients were followed up after 15 days and changes, improvements, deterioration and any other effects produced after the therapy were noted down.

5. Criteria for Assessment

After the completion of the treatment, the results were assessed by adopting the following criteria.

- Improvement in signs and symptoms of disease on the basis of symptoms score.
- Improvement in laboratory investigation (i.e. reduce levels) on the basis of lab reports.
- Reduction in objective assessment parameters.

1. Subjective assessment

All symptoms taken for the assessment of clinical improvements were thoroughly examined and the severity of each symptom was rated before and after the trial for clinical assessment. For this purpose the following “Symptom Rating Scale” was used.

A. *Prabhoot Mootrata* (Polyuria)

o	Frequency of Urine 3-6 times/day, rarely at night	-	0
o	7-9 times /day, 0-2 times/night	-	1
o	10-12 times /day, 2-4 times/night	-	2
o	13 times /day, >4 times/night	–	3

B. *Swedadhikya* (Excessive Sweating)

o	Normal Perspiration	–	0
o	Mild after doing exertion	–	1
o	Moderate after exertion	–	2
o	Severe after exertion	-	3
o	Perspiration without exertion	–	4

C. *Klama* (Early fatigue)

o	No fatigue	-	0
o	Mild after doing work	-	1
o	Moderate after doing work	-	2
o	Severe after doing work	–	3
o	Feeling fatigue without doing work	–	4

D. *Aalasya* (Lassitude)

o	Normally active	–	0
o	Hesitate to start work but once started completed	-	1
o	Starts but does not complete	-	2
o	Start work under compulsion	-	3

E. *Mukha Shosha* (Dryness in mouth)

o	Absent	–	0
o	Mild	–	1
o	Moderate	–	2
o	Severe	-	3

F. *Vibandha* (Constipation)

o	Pass stool as per normal schedule	-	0
o	Passes stool with strain, sometimes takes purgative	–	1
o	Pass stool usually after 24 hrs, frequently takes purgative	-	2
o	Pass stool/ per 2day	-	3
o	Purgative doesn't work	-	4

2. Objective assessment

Assessment of Body Mass Index (B.M.I). (Weight in kg/height in meter²)

0	18.5-24.9	-	0
0	25 – 29.9	-	1
0	30 -34.9	-	2
0	35 -39.9	-	3
0	>40	–	4

Observations And Results

Relative Incidence Of Various Symptoms (*Lakshanas*)

Sr. No.	Symptoms	Group A (n =10)	Group B (n =10)	Group C (n =10)	Total	%
1.	*Prabhootamutrata* (Polyuria)	8	5	7	20	66.66
2.	*Avilmutrata* (Turbidity in urine)	10	7	6	23	76.66
3.	*Pipasadhikya* (Polydipsia)	8	7	8	23	76.66
4.	*Kshudhaadhikya* (Polyphagia)	9	8	8	25	83.33
5.	*Atisweda* (Excess Sweating)	9	6	7	22	73.33
6.	*Hasta Pada & Sandhi shoola* (Pains in hands, feet and joints)	7	9	9	27	90
7.	*Klama* (Early fatigue)	8	7	9	24	80
8.	*Mukha Shosha* (Dryness of mouth)	9	5	8	22	73.33
9.	*Aalasya* (Lassitude)	9	7	10	26	86.66
10.	*Vibandha* (Constipation)	7	6	5	18	60
11.	*Karpadatala daha* (Burning sensation in hands & feet)	5	4	5	14	46.66
12.	*Aasya madhuryam* (Sweetness in mouth)	5	2	5	12	40
13.	*Karapada supti* (Numbness in hands & feet)	4	5	3	12	40
14.	*Jannang Kandu* (Genital pruritus)	1	0	1	2	6.66

Subjective improvement -

There was marked improvement in the *prabhuta mutrata* (polyuria), *klama* (early fatigue), *alasya* (lassitude), *vibandh* (constipation) (in Group 3) including *ati sweda* (sweating), m*ukha shosha* (dryness of mouth) (in Group 1).

Table 3: Showing the overall comparative improvement in clinical feature of *madhumeha* in three treated groups

S. No.	Symptoms	Group I			Group II			Group III		
		%	P	Result	%	P	Result	%	P	Result
1.	*Prabhotamutrata*	33.33	< 0.05	S.	50	> 0.05	N.S.	33.3	<0.05	S.
2.	*Avilmutrata*	21.1	> 0.05	N.S.	21.1	> 0.05	N.S.	44.4	> 0.05	N.S
3.	*Pipasadhikya*	22.2	> 0.05	N.S.	22.2	> 0.05	N.S.	41.7	> 0.05	N.S.
4.	*Kshudhadhikya*	27.3	> 0.05	N.S.	0	> 0.05	N.S.	16.7	> 0.05	N.S.
5.	*Ati sweda*	42.9	< 0.01	S.	33.3	> 0.05	N.S.	20	> 0.05	N.S.
6.	*Hastapada & Sandhi shoola*	37.5	> 0.05	N.S.	30	>0.05	N.S.	23.1	> 0.05	N.S.
7.	*Klama*	25	> 0.05	N.S.	46.2	> 0.05	N.S.	38.9	<0.05	S.
8.	*Mukha shosha*	38.5	< 0.01	S.	44.4	> 0.05	N.S.	0	> 0.05	N.S.
9.	*Alasya*	40	<0.05	S.	44.4	> 0.05	N.S.	53.3	<0.05	S.
10.	*Vibandh*	50	<0.05	S.	28.6	> 0.05	N.S.	87.5	<0.05	S.
11.	*Karapada tala daha*	11.1	> 0.05	N.S.	16.7	> 0.05	N.S.	28.6	> 0.05	N.S.
12.	*Mukhamadhurya*	40	> 0.05	N.S.	50	> 0.05	N.S.	40	> 0.05	N.S.
13.	*Jananang Kandu*	-	-	-	0	> 0.05	N.S.	100	> 0.05	N.S.
14.	*Kara pada tala supti*	-	-	-	42.9	> 0.05	N.S.	0	> 0.05	N.S.

Objective improvement-

Study on changes in blood sugar have revealed that there was significant reduction (Group I and II) and highly significant (in Group III) in the level of post Prandial blood sugar in the all the patients of three groups but the percentage of reduction was maximum in patients of Group-III, where *Katak Khadiradi Kashyayam* was administered with *Niruryadi Gulika*, also significant reduction in fasting blood sugar in patient of Group-III. (Table No. IV)

Significant reduction in the level of post prandial urine sugar in Group-II and highly significant reduction was observed in patients of Group-III. (Table No. IV)

Table 4: Showing the overall comparative improvement in lab parameters of *Madhumeha* in three treated groups

S. No.	Lab Investigation	Group I			Group II			Group III		
		%	P	Result	%	P	Result	%	P	Result
1.	**Fasting Blood Sugar**	6.85	> 0.05	N.S.	13.72	> 0.05	N.S.	18.51	<0.05	S.
2.	**Post Prandial Blood Sugar**	16.97	<0.05	S.	13.86	<0.05	S.	18.65	<0.001	H.S.

3.	**Fasting Urine Sugar**	20	> 0.05	N.S.	12.5	> 0.05	N.S.	66.7	> 0.05	N.S.
4.	**Post Prandial Urine Sugar**	17.9	> 0.05	N.S.	42.1	<0.05	S.	88.9	<0.001	H.S.
5.	**HB gm%**	3.27	> 0.05	N.S.	1.5	> 0.05	N.S.	0.23	> 0.05	N.S.
6.	**ESR**	20.4	> 0.05	N.S.	40	> 0.05	N.S.	10.5	> 0.05	N.S.
7.	**TLC**	7.29	> 0.05	N.S.	6	> 0.05	N.S.	9.06	> 0.05	N.S.

Discussion-

Katak khadiradi kashyayam has *katu, tikta rasa* and *jatharagni mandya* is present in *madhumeha*; it may act in *agnivardhana*. *Kashaya rasa* is present up to 83.33%, which may produce *mutrasamgrahniya prabhava*. *Tikta, kashaya rasa* present in this formulation produces *shoshana* effect. Hence the *Prabhoota mutrata* in p*rameha* tend to regress. Most of the drugs possess *laghu, ruksha guna* (i.e. 100% and 75%). *Ruksha guna* helps in alleviation of *bahudrava shleshma* and *abaddha meda*, the annexation of two being initial triggering event in *samprapti* of disease.[4] Obstruction of *vata* by *kapha* and *medas* as *kapha* here *aarambhak dosha* and *vata* is *preraka dosha*. *Laghu* and *ruksha guna* by virtue of their *kaphaghana* and *medoghana prabhava* help in reducing tissue weight.[5] Now it can be suspected that *kashaya rasa, laghu, ruksha guna* like properties can further aggravate vitiated *vata dosha* in *madhumeha*. In this context it is proposed that here it is obstructed v*ata* (primarily by *kapha & medas*) which is causing trouble; v*ata* here may not be increased quantity wise in body, only obstruction is there in its natural passages which can be alleviated by *kaphahara, medohara* drugs. In the compound majority of drugs are found to have *ushna virya* and helps in alleviation of *kapha* and *vata*. As far as v*ipaka* is concerned *katu vipaka* enhances *jatharagni, dhatvagni* and normalize metabolic process. *Sheeta virya* and *madhura vipaka* helps in replenishment of o*jus* which become depleted with disease progression owing to continued exposure of body to vitiated v*ata*. It has been clear from above account that *katak khadiradi kashyayam* can well disintegrate *samprapti* of *madhumeha* by acting at various levels i.e. alleviating *dhatvagnimandya* owing to presence of certain *deepana pachana* drugs in it like *brihati, mustak* and *haridra* also *rukshata* and *laghuta* present in drug will combat increased *kapha* and *meda* which similitude in their properties. *Aamalki* and *haritaki* are two drugs, which are known to exert *rasayan prabhava* too thereby causing *oja vardhana*, which is being depleted in body of *madhumehi* owing to chronic exposure to *vata* in body.

In *Niruryadi Gulika*, maximum drugs were having k*ashaya, tikta* and m*adhur ras; laghu*, *rukshya* and *guru guna*; *sheeta virya; madhur* and *katu vipaka*. *Kashaya rasa* (64.70%) possess properties like *sangrahi, sthambhan, sharir-kledasyopayokta*. *Tikta rasa* (58.82%) having a properties like *srotomukhavishodhan, ama pachaka, murcha, daha, kandu, kushatha, trushna prashamana, dipan, pachana, lekhana, sharira kleda soshana, meda soshana, lasika soshana, swada soshana, mutra soshana*.[6] From these properties it is very clear that in the complication of *madhumeha* like *murcha, daha, kandu* and *kushtha* it plays a role. The above described *kleda, meda*, etc. *shoshana* properties of this *rasa* helps in breakdown of *dosha –dushaya samurchana*. *Madhura rasa* have properties like *bala-varnakar, marutagna, trushana, daha prashaman, prinan, jivan, santarpana, brumhana, sthryakara, murcha prashamana*. So, provides strength to the *madhumehi* patients because all *dhatu kshaya* are found in *madhumeha*[7] (*ojomeha*) and also helps to nourish all dhatu (*saptadhatu poshak*). *Laghu guna* (70.58%) is *lekhana* therefore, it works on *avabadhya meda, kleda,* and *mamsa; rukshya* (52.94%) is *shoshana* and *stambhana* properties. *Katu vipaka* also do the same.

Conclusion

Madhumeha has been discussed in *prameha roga* as one of the *vataj prameha*. Literary evidence

proves its modern correlate as diabetes mellitus. In this study it is found that *madhumeha* mostly affects individuals in 5^{th}, 6^{th} and 7^{th} decade of life with slight male preponderance. Prevalence is seen more in married. The study confirms that *katak khadiradi kashyayam* and *niruryadi gulika* is effective in management of *madhumeha* and definitely reduces the symptoms of illness that includes *prabhuta mutrata* (polyuria), *klama* (early fatigue), *alasya* (lassitude), *vibandh* (constipation) (in Group 3), including *ati sweda* (sweating), *mukha shosha* (dryness of mouth) (in Group 1). The chosen drug was effective in reducing Post Prandial Blood Sugar and Post Prandial Urine Sugar (In group 2 and 3) (highly significant in group 3 and significant in group 2) and also shows a significant result in Group 1 P.P.B.S. All the patients tolerated medicines very well and no side effects were reported by any of the patients, suggesting that the drugs selected for current clinical trial are absolutely safe for internal use. After overall scrutiny, it can be concluded that the proposed *Katak Khadiradi Kashyayam* and *Niruryadi Gulika* in current research exhibits significant hypoglycaemic activity and can be given safely in patients of *madhumeha.*

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Clinical Study

Clinical Study to Evaluate The Effect of *Brahmi Ghrita Uttara Basti* in *Vandhyatva* W.S.R. to Female Infertility

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Abstract :

In today's fast world due to lack of time, mode of life and increasing mental stress, infertility is emerging as a major disorder affecting the social and psychological aspect of the life of the masses. Infertility is defined as inability of couple to achieve conception after one year of unprotected coitus. *Acharya Sushruta* has mentioned four factors for the proper conception i.e *Ritu*, *Kshetra*, *Ambu* and *Beeja*. Absence or abnormality in any of the above factors may cause *Vandhyatva*.

In *Vandhyatva*, main vitiated *Dosa* is *Vata*. *Sneha* and *Basti* is the best *Chikitsa* for *Vata Dosa*. In gynaecological disorders *Uttara Basti* is the best treatment. Hence *Uttara Basti* was selected as a procedure. Due to "*Samskaranuvarti Guna*" *Ghrita* is the best *Sneha* among *Mahasneha*s.

Considering all these points, *Brahmi Ghrita* have been selected from *Ashtang Hridaya Uttara Sthanam Adhyaay* 6 /23-25 for the present clinical study.

A clinical study was completed on 30 clinically diagnosed patients of female infertility in P.G. department of *Prasuti* and *Striroga*, National Institute of *Ayurveda* at Jaipur (Raj.). Patients were randomly divided into three groups of 10 patients each with the aim to see the effect of *Brahmi Ghrita Uttara Basti* and orally alone or in combination and to compare the effect of therapy in different groups in the management of female infertility.

Significant result observed in Oral Group and Oral along with *Uttara Basti* Group in follicular study, endometrial thickness, fern pattern, cervical mucus length and conception.

Keywords – *Vandhyatva, Brahmi Ghrita, Uttara Basti*

सारांश–

आज तेजी से भागती दुनिया में समय की कमी के कारण, रहन सहन के कारण और बढते मानसिक तनाव के कारण बन्ध्यत्व लोगों के जीवन के सामाजिक और मनोवैज्ञानिक पहलू को प्रभावित करने वाले एक प्रमुख विकार के रूप में उभर रहा है। बन्धयत्व में मुख्य दोष वात है। स्नेह और बस्ति वात की प्रमुख चिकित्सा है। संस्कारानुवर्तन होने के कारण घृत स्नेह में प्रमुख है, तथा उत्तरबस्ति बस्ति में प्रमुख है। अत: वर्तमान अध्ययन में कटु उष्ण वीर्य औषधियों युक्त ब्राह्मी घृत का चयन किया गया। इस चिकित्सकीय अध्ययन में कुल 30 रूग्णाओं को तीन वर्गों में विभक्त कर ब्राह्मी घृत को मुख से तथा उसी की उतरबस्ति दी गई। इस अध्ययन में उपरोक्त चिकित्सा का प्रभाव उल्लेखनीय रहा।

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Clinical Study

Clinical Study to Evaluate The Effect of *Brahmi Ghrita Uttara Basti* in *Vandhyatva* W.S.R. to Female Infertility

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Introduction

In today's fast world due to lack of time, mode of life and increasing mental stress, infertility is emerging as a major disorder affecting the social and psychological aspect of the life of the masses. Ten to fifteen percent of marriages prove to be childless.[1]

Reproductive endocrinologists consider a couple to be infertile if:

- The couple has not conceived after 12 months of unprotected intercourse if the female is under the age of 35.
- The couple has not conceived after 6 months of unprotected intercourse if the female is over the age of 35.
- The female is incapable of carrying a pregnancy to term.

Types Of Infertility

1. **Primary infertility:** It denotes those patients who have never conceived.
2. **Secondary infertility:** It indicates previous pregnancy but failure to conceive subsequently.

Conception depends on the fertility potential of both the male and female partner. The contribution of both of them is as follows:

Male	30-40%
Female	40-55%
Both	10%
Unexplained	10%[2]

In *Ayurveda* Infertility is termed as "*Vandhyatva*".

ध्रुवं चतुर्णां सान्निध्यात् गर्भः स्यात् विधिपूर्वकः।
ऋतुक्षेत्राम्बुबीजानां सामग्र्यादंकुरो यथा॥ (सु.शा.2/34)

According to this the four main factors required for the proper conception are *Ritu*, *Kshetra*, *Ambu* and *Beeja*[3]. Absence or abnormality in any of the above factors may cause *Vandhyatva*.

Drug and Procedure Selection:

न हि वातादृते योनिर्नारीणां संप्रदुष्यति। (च.चि.३०/११५)

In *Ayurveda* the word "*Yoni*" refers to reproductive organs collectively. Without *Vata, Yoni* never gets spoilt[4]. *Vata Dosha* is the governing factor of the whole reproductive physiology; therefore any vitiation in *Vata* will certainly affect the normal phenomenon of fertility. Female infertility is a *Yoni Gata Vikara* and pacification of vitiated *Vata* is the best cure for *Yoni Gata Vikaras* and *Sneha* and *Basti* are the best treatment for *Vata*. *Uttara Basti* is a specialized form of *Basti* treatment, which imparts excellent qualities to the reproductive system. Therefore *Uttara Basti* with *Sneha* will definitely act on *Yonigata Vikara* and hence on female Infertility. Thus "***Brahmi Ghrita***" indicated in *Vandhya*[5] described in *Ashtang Hridaya Uttara Sthanam Adhyaay* 6 /23-25 has been selected for the present study.

Keeping all these views in mind a clinical study was planned to evaluate the efficacy of *Brahmi Ghrita Uttara Basti* and Orally. So to find a sure shot treatment of *Vandhyatva*, without any side effect, *Uttara Basti* as well as oral treatment was selected.

Aims and Objectives:

1. To provide safe, cheapest, non surgical treatment.
2. To avoid the undue social and psychological stress due to infertility.
3. To evaluate the effect of *Brahmi Ghrita* in female infertility.
4. To evaluate the efficacy of *Uttara Basti* and Oral therapy.

Material and Methods

Selection of Patients

The study was completed on 30 clinically diagnosed and confirmed patients of infertility at P.G. Department of *Prasuti* and *Striroga* of N.I.A. Jaipur (Raj.). Patients were selected with written informed consent, from O.P.D. / I.P.D. of NIA, Jaipur and were examined thoroughly as per the case sheet specially prepared for this clinical study.

Inclusion criteria

1. All primary and secondary cases of infertility
2. Age group between 20 to 35 years
3. Male counterpart should be normal in all aspects
4. Duration of infertility less than 10 years

Exclusion criteria

1. Infertility more than 10 years
2. Female less than 20 yrs and more than 35 years of age
3. Congenital anatomical defect
4. Surgical cases of Infertility
5. Infertility due to abnormality in male partner
6. Infertility due to chronic systemic diseases
7. Tubal blockage

Criteria for Diagnosis

Investigations (Before Treatment)

1. Blood test - Hb%, TLC, DLC, ESR, VDRL, Montoux test, RBS/FBS (if needed)

2. Urine test - Routine and Microscopic

3. Routine tests – X-ray chest PA view, TSH, FSH, LH, Pap smear (if needed)

4. Special tests for infertility

i. Semen Analysis

ii. Cervical mucus
(a) Spinnbarkeit test (b) Fern Test

iii. Post coital test

iv. USG- uterus and Adnexa, Follicular study (if needed)

v. HSG or SSG

vi. Antisperm Antibody Test (if needed)

vii. Endometrial Biopsy (if needed).

viii. Laparoscopy (If required)

Investigation (After Treatment)

1. Cervical Mucus Study for Spinnbarkeit, Ferning and PCT.
2. Hormonal Study (if needed)
3. Transvaginal Sonography – Follicular study (D 10-D18)
4. Urine Pregnancy Test (Gravindex Test) - After 7^{th} day of missed period.

Treatment protocol

30 patients were randomly categorized in three groups. Each group consists of 10 patients.

Group A - Intrauterine *Uttara Basti* with *Brahmi Ghrita*

Kala - Ritukala

Dose - 5ml

Duration - 3 days alternatively in a month for consecutive three cycles (After 24 hours of cessation of menses)

Uttarabasti was started after one *Niruha (Dashmoola Kwatha)* and one *Anuvasana Basti* (*Dashmoola* oil).

Group B - Oral administration of *Brahmi Ghrita*

Dose - 5 ml BD orally with milk (200 ml) for 3 months.

Group C - *Uttara Basti* with Oral administration of *Brahmi Ghrita*

Criteria for Assessment - To facilitate the statistical analysis of the efficacy of therapy, scoring system was adopted.

Scoring Pattern –

1. Fern test on 22nd day –

o	No crystallization	-	0
o	Atypical Fern formation	-	1
o	Formation of 1-2 Stem	-	2
o	Formation of 3-4 Stem	-	3

2. Post coital test on 14th day -

o	Motile sperm and Adequate Quantity	-	0
o	Motile sperm and Inadequate Quantity	-	1
o	Dead sperm and Adequate Quantity	-	2
o	Dead sperm and Inadequate Quantity	-	3

3. Amount of blood loss during menses -

o	Normal bleeding (2-3 Pads/ day)	-	0
o	Scanty (1-2 Pads / day)	-	1
o	Moderately high (3-5 Pads / day)	-	2
o	Excessive (More than 5 Pads / day)	-	3

4. Spinnbarkeit Test

o	> 8 cm	-	0
o	5-8 cm	-	1
o	1-4 cm	-	2
o	< 1 cm	-	3

5. Assessment of Follicular Study (By USG)

o	Follicle size normal and ruptured	-	0
o	Follicle size normal and un-ruptured	-	1
o	Small follicle(s) and un-ruptured	-	2
o	No follicle in both sides	-	3

6. Assessment of Size of Endometrium (By USG)

o	≥ 11 mm	-	0
o	8- 10.9 mm	-	1
o	5- 7.9 mm	-	2
o	≤ 4.9 mm	-	3

7. Pain during menses -

o	No Pain	-	0
o	Mild (Local tolerable pain often)	-	1
o	Moderate (Severe pain radiating to adjacent area)	-	2
o	Excessive (Pain at rest with disturbance of sleep)	-	3

8. Leucorrhea –

o	Absence of discharge	-	0
o	Mild (Persistent vulval moistness)	-	1
o	Moderate (Staining of undergarments)	-	2
o	Excessive (Need to wear a vulval pad)	-	3

9. Conception -

o	conception	-	0
o	No Conception	-	1

Follow Up Study -

After completion of trial follow up was done monthly upto two months.

Presentation of Data -

The data collected from the trial was subjected to statistical analysis.

All values of qualitative variables were expressed as percentage and all values of quantitative variables were calculated as mean ± S.D., S.E. t and P values were calculated by using paired 't' test. Inter-group comparison was done by Anova Test.

Observation And Result

Registered Patients -

Total 39 patients were registered for the present study. Out of them 09 patients were dropped out.

Maximum number of patients i.e. 63.33% had secondary infertility followed by primary infertility patients i.e 36.66 %.

Table 1: Effect of therapy on subjective parameters in Group A

S. No.	Parameters	*n*	Mean		Mean Diff	% Relief	SD (±)	SE (±)	`t`	*p*	Result
			BT	AT							
1.	Amount of menses	10	0.2	0.0	0.2	100	0.63	0.2	1.000	>0.1	NS
2.	Pain during menses	10	0.9	0.1	0.8	88.88	0.63	0.20	4.00	<0.01	HS
3.	Leucorrhoea	10	0.7	0.1	0.6	85.71	0.69	0.22	2.714	<0.05	S

In Group A, highly significant result was observed in pain during menses and significant result was observed in leucorrhoea.

Table 2: Effect of therapy on subjective parameters in Group B

S. No.	Parameters	*n*	Mean		Mean Diff	% Relief	SD (±)	SE (±)	`*t*`	*p*	Result
			BT	AT							
1.	Amount of menses	10	0.7	0.2	0.5	71.42	0.84	0.26	1.861	>0.05	NQS
2.	Pain during menses	10	1.0	0.2	0.8	80.00	0.63	0.20	4.00	<0.01	HS
3.	Leucorrhoea	10	0.8	0.3	0.5	62.50	0.70	0.22	2.236	>0.05	NQS

In Group B, highly significant result was observed in pain during menses.

Table 3: Effect of therapy on subjective parameters in Group C

S. No.	Parameters	*n*	Mean		Mean Diff	% Relief	SD (±)	SE (±)	`*t*`	*p*	Result
			BT	AT							
1.	Amount of menses	10	0.3	0.1	0.2	66.66	0.63	0.20	1.000	>0.1	NS
2.	Pain during menses	10	0.9	0.2	0.7	77.77	0.67	0.21	3.280	<0.01	HS
3.	Leucorrhoea	10	0.5	0.0	0.5	100.0	0.52	0.16	3.000	<0.05	**S**

In Group C, highly significant result was observed in pain during menses and significant result was observed in leucorrhoea.

Table 4: Effect of therapy on objective parameters in Group A

S. No.	Parameters	*n*	Mean		Mean Diff	% Relief	SD (±)	SE (±)	`*t*`	*p*	Result
			BT	AT							
1.	Follicular study	10	1.1	1.9	-0.8	-72.00	0.63	0.20	-4.00	<0.01	HS
2.	Endometrial thickness	10	1.8	2.5	-0.7	-38.88	0.67	0.21	-3.28	<0.01	HS
3.	Fern test	10	0.7	0.6	0.1	14.28	0.56	0.17	0.55	>0.1	NS
4.	Spinnbarkeit test	10	0.8	1.5	-0.7	-87.5	0.67	0.21	-3.28	<0.01	HS
5.	Post coital test	10	0.0	0.0	0.0	00.00	0.00	0.00	0.00	-	No Change

In Group A, highly significant result were observed in follicular study, endometrial thickness and spinnbarkeit test.

Table 5: Effect of therapy on objective parameters in Group B

S. No.	Parameters	*n*	Mean		Mean Diff	% Relief	SD (±)	SE (±)	`*t*`	*p*	Result
			BT	AT							
1.	Follicular study	10	1.8	2.6	-0.8	-44.44	0.63	0.20	-4.00	<0.01	HS
2.	Endometrial thickness	10	2.1	2.7	-0.6	-28.33	0.51	0.16	-3.67	<0.01	HS
3.	Fern test	10	0.7	0.5	0.2	28.75	0.63	0.2000	1.000	>0.1	NS
4.	Spinnbarkeit test	10	1.0	1.2	-0.2	-20.0	0.63	0.2000	-1.00	>0.1	NS
5.	Post coital test	10	0.2	0.1	0.1	50.00	0.31	0.1000	1.00	>0.1	NS

In Group B, highly significant result were observed in follicular study and endometrial thickness.

Table 6: Effect of therapy on objective parameters in Group C

S. No.	Parameters	*n*	Mean		Mean Diff	% Relief	SD (±)	SE (±)	`*t*`	*p*	Result
			BT	AT							
1.	Follicular study	10	1.3	2.4	-1.1	-84.61	1.10	0.3480	-3.16	<0.05	S
2.	Endometrial thickness	10	1.8	2.9	-1.1	-61.11	0.73	0.2333	-4.714	<0.01	HS
3.	Fern test	10	0.6	0.5	0.1	16.66.	0.73	0.2333	0.4286	>0.1	NS
4.	Spinnbarkeit test	10	1.2	1.8	-0.6	-50.0	0.51	0.1633	-3.67	<0.01	HS
5.	Post coital test	10	0.2	0.1	0.1	50.00	0.31	0.1000	1.00	>0.1	NS

In Group C, highly significant result were observed in endometrial thickness and spinnbarkeit test and significant result was observed in follicular study.

Effect of therapy based on conception -

S. No.	Group	Total no. of pts.	Effect based on conception		
			conception	No conception	% relief
1.	Group A	10	02	08	20.00
2.	Group B	10	05	05	50.00
3.	Group C	10	01	09	10.00

Discussion

- ✓ Majority of drugs in *Brahmi Ghrita* have *Vatapittashamaka*, *Vrishya, Rasayana*, *Balya* and *Garbhasthapaka* properties.
- ✓ Bacopa monniera Linn.(*Brahmi*) have anxiolytic, anti-depressant properties. The *brahmi* extract augmented both the cognitive function and mental retention capacity[6]. It is recommended for the treatment of amenorrhea, diseases of the female genitourinary tract[7]. Saponin acts like natural steroids, thus it can regulate the hypothalamo-pituitary–ovarian axis and helps in ovulation. This drug is also recognized for its efficacy in relieving acute pain and inflammation, through selective inhibition of cyclo-oxygenase-2 (COX-2) enzyme and consequent reduction in COX-2-mediated prostanoid mediators[8]. Since *Brahmi* is good nervine tonic, in cases of infertility also it might regulate the vitiated *Apanavayu* i.e. autonomic system governing the functions of reproductive organs and maintain normal follicular phase, ovulation and secretory phase.
- ✓ *Shankhpushpi* is *Vrishya, Tridoshahara* specially *Vattapittahara*. Nitrogen containing active

principle of drug produced marked reduction in I-131 uptake, acetylcholine, suggesting its effect on various glands through neurohumors particularly acetylcholine[9]. These actions shows that *Shankhpushpi* acts on hypothalamus and regulate various functions, so it might acts on HPO axis and helps in ovulation.

- ✓ *Pippali* has *Vrishya*, *Agnideepana*, *Vatanulomaka* properties. As the data shows that *Agnideepana* and *Vatanulomana* properties might support the proper function of receptor in the endometrium specially in ferning pattern.
- ✓ *Saptala, Danti, Trivrita, Argvadha* have the *Virechak Guna*, hence they regulate *Doshas* by *Samshodhana Karma*. The vitiation of *Vata* may be due to *Margavrodha* (*Avrita Apana Vayu)* with *Kapha Dosha,* treatment should be *Agnideepaka, Vatanulomaka, Srotoshodhana* and *Pakvashaya Shuddikara*. Thus *Samshodhana karma* clear the GIT and regulates function of *Tridosha* specially *Avrita Apana Vayu*.
- ✓ *Goghrita* has *Rochana, Deepana, Rasayana, Vrishya* properties so it regulate *Tridoshas* and help to destruct the *Samprapti* of *Vandhyatva* .

Probable Mode of Action of *Uttara Basti*

The *Vatanulomaka* and *Srotoshodhana* effect of *Basti* is well known. *Uttarabasti* which is given in *Garbhashaya* i.e. *Artavavaha Strotas* stimulates the *Strotas* as well as the *Beejagranthi*. By the stimulation of ovary, the *Sanga* in the *Beejagranthi* is removed and *Vata* performs its proper function i.e. *Vibhajana*.

Due to *Sukshma guna* of *Ghrita*, it enters the *Artavavaha Strotas* and due to its *Snigdha guna* it causes the *Vatashamana*. *Uttarabasti* regulates the ANS controlling the pelvic organs there by gives proper feedback to the Hypothalamus. By governing the H-P-O axis, it helps in the maintenance of Follicular growth, Ovulation and Corpus luteum.

Conclusion

The overall effect of therapies in female infertility shows that the administration of *Brahmi Ghrita* orally (Group B) and orally with *Brahmi Ghrita Uttara Basti* (Group C) was more effective to increase the factors towards fertility in comparison to *Uttara Basti Brahmi Ghrita* alone(Group A).

In conception Group B is good than Group A and better than Group C.

No side effects were observed during treatment in all 3 groups. Thus we can recommend the *Brahmi Ghrita* administered as orally or with *Uttara Basti* in the management of *Vandhyatva*.

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Clinical Study

Study to Evaluate the Preventive Effect of *Pratimarsha Nasya* and *Dhumapana* in *Tamaka Shwasa* w.s.r. to Seasonal Bronchial Asthma

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Abstract

Asthma is one of the most prevalent chronic health conditions among children and adults. Due to increasing incidence and prevalence of *Tamaka Shwasa* (bronchial asthma) there is a need of prevention. In modern medical science various medicines are available for management but results are unsatisfactory and they have many adverse effect. So the prevention is the only alternative. In *Ayurveda* for management of *Tamaka Shwasa* medicines are available which have minimum or no side effect and for prevention some methods are available like *Dhumapana*, *Vaman*, *Swedan*, *Virechan*, *Nasya* (*Pratimarshya Nasya) Karma*. It may helps to releive the complaints, and prevents further attack. So there is a need to find a suitable measure for this purpose. So effect of *Pratimarsha Nasya* and *Dhumapana* in prevention of *Tamaka Shwasa* (Seasonal Bronchial Asthma) was assessed in this study. **Materials & Methods:** A open Randomised clinical trial was carried out on 30 patients which were equally divided into two groups ,between the age of 18-60 years at P.G. department of *Swasthavritta & Yoga,* National Institute of Ayurveda.. The duration of treatment was 2 months. Clinical evaluation done by assessment criteria, subjective and objective parameter. **Results**: *Pratimarsha Nasya and Dhumapana* is effective in decreased AEC and increased FVC, FEV1 of studied cases. AEC was decreased by 6.73 % in Group A and 5.24% in Group B, which was statistically significant ($p<0.01$) in both groups. FVC was increased by 3.57% in Group A and 2% in Group B, which was statistically significant ($p<0.01$) in both groups. FEV1 was increased by 3% in Group A and 2.30% in Group B, which was statistically significant ($p<0.01$) in both groups and Result showed significant results ($P <0.01$,) regarding subjective parameters – *Shwsakrichatta, Kasa, Ghurghurrak, peenas, Parsva avgrihyate*, and *lalaten svidyata* with % relief of 52.28%, 64.60%, 46% 66.66%, 46%, 56.60% in group A and 36.30%, 53.75% , 37.73% , 75%, 54.79% and 49.46% in group B. **Discussion & Conclusion:** It can be concluded that *Pratimarsha nasya and Dhumapana* can be used as effective and safe therapeutic procedure in the prevention of *Tamaka Shwasa* (Seasonal Bronchial Asthma). Drugs are quite safe and acts as a bronchodilator, antihistaminic, anti-inflammatory, expectorant and anti-allergic.

Key words: *Dhumapana, Pratimarsha Nasya*, *Tamaka Shwasa*.

सारांश–

पृष्ठभूमि–आज के समय में श्वास रोग (अस्थमा) युवा वर्ग एवं बच्चों में बहुत आमतौर पर पायी जाने वाली व्याधि है। विश्व स्वास्थ्य संगठन के अनुमानानुसार दुनिया भर में 300 मिलियन व्यक्तियों को श्वास रोग (अस्थमा) है। यदि यह प्रवृत्ति जारी रही तो यह आंकड़ा 2025 तक 400 मिलियन तक बढ़ सकता है। तमक श्वास के व्यापकता और प्रसार को देखते हुए, इसके प्रबन्धन के लिए प्रभावी और सुरक्षित औषधि की जरूरत है। विभिन्न आयुर्वेद ग्रन्थों में श्वास रोग के प्रबन्धन के लिए अनेक औषध चिकित्सा बताई गयी है जिनका श्वास रोग पर बहुत अच्छा परिणाम मिलता है। साथ ही इसके रोकथाम के भी उपाय बताए है। श्वास रोग के नियन्त्रण के दो उपाय बताए गये है, पहला–जिस समय अस्थमा के दौरे आते है उसी समय औषध व्यवस्था करके, और दूसरा–भावी आने वाले श्वास रोग आक्रमण (अस्थमेटिक अटैक) को रोककर, श्वास रोग कारकों हेतु (अस्थमा के ट्रिगर फैक्टर) को नियन्त्रित करके आयुर्वेद में श्वास रोग के रोकथाम के लिए वमन, विरेचन,

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धूम्रपान, नस्य आदि बताए गये है। अतः उक्त चिकित्सीय परीक्षण तमक श्वास के रोकथाम में प्रतिमर्श नस्य एवं धूमपान की नैदानिक प्रभावकारिता निर्धारित करने के लिए किया गया था।

विधि–राष्ट्रीय आयुर्वेद संस्थान के स्वस्थवृत्त एवं योग विभाग में यह चिकित्सकीय परीक्षण 18–60 साल की आयु के बीच 30 रोगियों पर किया गया, जो कि दो ग्रुप में बराबर–बराबर विभाजित किये गये थे। इलाज की अवधि 2 महीनें थी। चिकित्सकीय मूल्यांकन विभिन्न मानदंडों के आधार पर किया गया।

परिणाम–प्रतिमर्श नस्य एवं धूमपान, AEC की कमी एवं FVC, FEV_1 की वृद्धि में प्रभावी है। सांख्यिकी आधार पर वर्ग ए एवं वर्ग बी में क्महत्वपूर्ण नतीजे से (पी) महत्वपूर्ण परिणाम प्राप्त हुए है। व्यक्तिपरक मापदण्डों के संदर्भ में– श्वासकृच्छता, कास, घुर्घुरक, पीनस, पार्श्वशूल, ललाटेन स्विद्यता, विशुष्कास्यम् में क्रमशः वर्ग ए में एवं वर्ग बी में का सुधार पाया गया ।

विचार विमर्श एवं निष्कर्ष – उपरोक्त अध्ययन के आधार पर निष्कर्ष निकाला जा सकता है कि प्रतिमर्श नस्य एवं धूमपान अस्थमा के रोकथाम में प्रभावी है। यह चिकित्सा सुरक्षित है। और ब्रोंकोडाइलेटर, हिस्टामीन के प्रभाव को निष्फल करने वाला, शोथहर एवं एंटी एलर्जी के रूप में कार्य करता है।

Clinical Study

Study to Evaluate the Preventive Effect of *Pratimarsha Nasya* and *Dhumapana* in *Tamaka Shwasa* w.s.r. to Seasonal Bronchial Asthma

Dr. Ravina Mehra, Dr. Kashinath Samagandi

Introduction

"*Asthma* as a chronic inflammatory disorder of the airways associated with increased airway hyper-responsiveness, recurrent episodes of wheezing, breathlessness, chest tightness and coughing, particularly at night/early morning. Airway inflammation produces airflow limitation through acute broncho constriction, chronic mucus plug formation and airway wall swelling or remodelling. These episodes are usually associated with wide spread but variable airflow obstruction that is often reversible either spontaneously or with treatment."[1]

Prevalence Of Asthma

An estimated 300 million people worldwide suffer from asthma.It is estimated that the number of people with asthma will increase by more than 100 million by year 2025.[1] World Health Organization. Global surveillance, prevention and control of chronic respiratory diseases: a comprehensive approach, 2007. The annual death rate due to asthma is estimated to be 250,000 and the majority of deaths occur in low and middle income countries.[2]

According to the **National Family Health Survey-2 (NFHS-2)** report the estimated prevalence of asthma in India is 2468 per 100,000 persons. The prevalence was higher in rural than in urban areas (2649v. 1966). The prevalence among males was slightly higher (2561) than among females (2369). Among those below 15 years of age, asthma was seen in 950 per 100,000 persons. The prevalence rate was 2309 persons among the subjects of the age group 15-59 years and 10,375 in age group above 60 years.[3]

The disease causes, limitations in daily activities, and sleep disturbances. Lung function impairment also occurs, resulting in decreased quality of life and a high annual financial burden. Achievement and maintenance of control through assessment of clinical manifestations and future risk has become the aim of treatment over the years.[4]

Patients from low and middle income countries have more severe symptoms than those in high income countries, possibly due to incorrect diagnoses, poor access to health care, unaffordability of therapy, exposure to environmental irritants, and genetic susceptibility to more severe disease.[5] *Tamaka Shwasa* is analogous to bronchial asthma due to similarity in symptoms, onset, causes, precipitating factors and pathogenesis.

Vata and *Kapha* are the two key pathological factors involved in the *Samprapti* of *Tamaka Shwasa*. Due to the predominant morbidity of *Vata* and *Kapha Dosha* which stems out from the *Pitta sthana*, afflicting the *Rasa Dhatu*, disturbing the function of *Pranavaha Srotas* leading to the manifestation of *Tamaka Shwasa*. This unique pathology determines episodic nature of the illness that runs a chronic course.

Where in, the balanced rational treatment aimed at rectification of morbidity of *Vata dosha* by *Snigdha Chikitsa* and *Kapha dosha* by *Ruksha Chikitsa* is essential but difficult. Affliction of the *Hridaya* and depletion of *Rasa Dhatu* during the chronic course of the illness adds to the difficulty in planning the treatment. Hence in such a complex circumstance where the disease is life threatening by involving the vital organs it is found to be challenging one to the physicians. So *Tamaka Shwasa* demands distinct remedy.

The currently used drugs for the treatment of this disease in modern medicine are far from satisfactory as they provide only symptomatic relief, produce several adverse effects and may lose effectiveness on continued use. Asthmatic patient

has to take medicine for long duration and intake of bio- incompatible drugs for long duration further deranged body immunity and worsen the pathology. In such circumstances bio-compatible herbs provide better solution. Herbs with cost effectiveness, high efficacy, easy availability and least side effects give an opportunity for research and hope for complete cure of disease.

In *Ayurvedic* literature, a number of herbal preparations are described for the management of *Tamaka Shwasa*. Various *Acharya* have given guiding principles for management of *Tamaka Shwasa* The drug which having *Vata Kaphahaghna, Ushna* and *Vatanuloman* properties are prescribed. *Ayurveda* contributes several modalities of treatment for this disease. For prevention of further attacks, some methods are available like *virechan, dhumapana, Nasya,* etc.[6] *Pratimarsha Nasya* and *Dhumapana* one of such Procedure is very much valued for its beneficial effects in prevention of *Tamaka shwasa* (bronchial asthma). *Pratimarsha Nasya* is given by *anu tail,* Main constituents of *anu tail is Jeevanti, Devdaru, Bala, Shataari, Brihti, Kantakari, Rasna, Daruharidra, Tejpatra, Ela, Twak, Vidanga, shalparni, Prishnaparni* etc.[7] and *Dhumavarti* contains *devdaru, bala, jatamansi*.[8] Most of the individual ingredients of *Anu Tail* and *dhumapana* are well reported in modern scientific research papers, having anti-inflammatory, anti-asthmatic, anti allergic, antihistaminic, anti-oxidant, immunomodulatory activity. In the light of above background the present study aimed to evaluate the Preventive effect of *Pratimarsha Nasya* and *Dhumapana* in *Tamaka Shwasa* (Seasonal bronchial Asthma).

Material & Methods

Aims and Objectives

1. To evaluate the effect of *Pratimarsha Nasya* in prevention of *Tamaka Shwasa*.
2. To evaluate the effect of *Dhumapana* in prevention of *Tamaka Shwasa*.
3. To evaluate the comparative effect of *Pratimarsha nasya* and *Dhumapana* in prevention of *Tamaka Shwasa*.

Study design and duration

The study design was open clinical trial of over 30 cases of *Tamaka Shwasa* (Seasonal bronchial asthma). The patients were selected by random sampling method. The duration of treatment was 2 months. Patients were equally divided into two groups,each group contains 15 patients. *Pratimarsha Nasya* is given in group A and *Dhumapana* is given in group B.

Selection of cases-

Patient suffering from *Tamaka Shwasa* (Seasonal Bronchial Asthma) fulfilling the inclusion and diagnostic criteria were selected from O.P.D. & I.P.D of Swasthavritta & Yoga and Kaya Chikitisa department, National institute of Ayurveda (NIA) Hospital, Jaipur, Rajasthan. 30 cases were selected for the present study.

Inclusion criteria

1. Age between 18 to 60 years
2. Irrespective of gender, religion and occupation.
3. Samples showing the classical sign and symptoms of *Tamaka Shwasa* (Seasonal Bronchial Asthma

Exclusion criteria

1. Other complicated respiratory disease.
2. Cardiac Complaints.
3. *Tamaka Shwasa* with other Systemic disorders.
4. Endocrine disorders like diabetes, Thyroid dysfunction etc

Assessment criteria:

Assessment of severity & improvement of subjective parameters (breathlessness, cough, coryza,wheezing,chest tightness, dryness of mouth, sweating on forehead) & objective parameters (ESR, AEC, FVC, FEV1, FEV1/FVC, PEFR,) were assessed by Assessment criteria.

Subjective Criteria

1. *Shwasakrichatta* (Dyspnoea)

	B.T.	A.T.
Absence of Dyspnea	0	0
Occasionally < 2 Times /week	1	1
Very often > 2 Times/week	2	2
Always throughout a week	3	3

***2. Kasa* (Cough)**

	B.T.	A.T.
No Cough	0	0
Cough with no expectoration	1	1
Cough with easy expectoration	2	2
Cough with difficult expectoration	3	3

***3. Ghurghurrak* (Wheezing)**

	B.T.	A.T.
No wheeze	0	0
Unilateral wheeze audible on auscultation	1	1
Bilateral wheeze audible on auscultation	2	2
Unilateral or bilateral wheeze audible without auscultation	3	3

4. *Peenas* (Coryza)

	B.T.	A.T.
No Coryza	0	0
Occasionally	1	1
Very often	2	2
Always (Daily)	3	3

5. *Parsva avgrihyate* (Chest tightness).

	B.T.	A.T.
No	0	0
Occasionally	1	1
Very often	2	2
Always	3	3

6. *Lalaten Svidyata* (Profuse sweating on fore head).

	B.T.	A.T.
No	0	0
Occasionally	1	1
Very Often	2	2
Always	3	3

7. *Vishuskaasyam*.(Dryness of mouth)

	B.T.	A.T.
No	0	0
Occasionally	1	1
Very Often	2	2
Always	3	3

Objective Criteria :

These are based on Laboratory investigations.

A) Blood Examination - Before & after clinical trial.

1. ESR (Erythrocyte Sedimentation Rate)
2. AEC (Absolute Eosinophil Count)

B) Spirometry - Before & After clinical trial.

1. FVC % (Forced vital capacity)
2. FEV 1% (Forced expiratory volume)
3. FEV1/FVC ratio
4. PEFR % (Peak expiratory flow rate).

Trial drug:

Group A. *Pratimarsha Nasya* - By *Anu Taila*

Anu Taila was prepared in the Pharmacy of National Institute of Ayurveda Jaipur. *Taila* was prepared according to method mentioned in *Ashtanga Hridya* by *Acharya Vagbhatta.*

- **Dose** : Two drops in each nostril, twice a day (morning and evening)
- **Duration** : Two months
- **Route of Administration**: Nasal route.

Procedure :

Patients were examined and explained about the *Nasya* briefly and the time chosen was morning and in the evening.[9]

Nasya Karma :

Pradhana Karma :

- Patient made to lie down in supine position.
- The head of the patient is lowered (*Pravilambita)* up to an extent.
- Eyes of the patient were closed.
- The tip of patients nose was drawn upward by the left thumb.
- At the same time with the right hand instilled 2 drop of *Anu Tail* in both nostril, alternately and asked the patient to inhale deeply.

Paschatkarma :

- Patient in lying position is asked to count up to 100 *matra* i.e. approximately 2 minutes.
- The patient was asked to expel out the drug which comes in oropharynx.

Group B. *Dhumapana* - By *Devdarvadi Dhumavarti*

Preparation of Dhumavarti :

Dhumavarti was prepared in the pharmacy

of National Institute of Ayurveda, Jaipur. *Dhumavarti* was prepaired according to method mentioned in *Shwasa chikitisa* in *Bhavaprakash Samhita* by *Acharya Bhavaprakash.*

Dose : Three puffs each in each nostril, three times continuously, twice a day (morning and evening after meal).[10]

Duration : Two months

Route and form of Administration: Nasal. Inhalation of the medicated smoke through nose and exhalation through mouth.[10]

Method of *dhumapana:*

- To begin with the patient was thoroughly examined to confirm the indications as well as to rule out any of the contra indications.
- Then the patient was made to sit in a knee high chair with his body erect and looking forwards.
- He should have full concentration on the therapy and should not have any reason for distraction of mind like *Kama, Krodha, Bhaya* etc.
- Both the eyes should be closed during the procedure.
- For *dhumpana* I have used chillum or pipe, it is straight conical pipe with end to end channel, made of clay.When smoking place chillum on left hand, hold chillum in finger, Adjust either hand as needed until you find a comfortable position with your hands. Traditionally wrap a piece of cloth or mouthpiece of the chillum to act as a filter.
- The *Dhumavarti* is soaked in ghee for a day or night.
- Then it should be inserted into the chillum (pipe)
- Lit with the fire and smoke is inhaled
- The right side of the nostril was closed by pressing with the right index finger
- Then the patient was asked to inhale the *Dhuma* through the left nose.
- And then the patient was allowed to exhale the *Dhuma* only through the mouth.
- This was repeated for three times in one nostril.
- The same procedure was applied to the opposite nostril by closing the left nostril with the left index finger, the smoke inhaled and expelled through the mouth.
- The procedure is repeated for three times.
- During the procedure if the sputum comes out the patient is asked to spit it out.
- Following *Dhumapana* the patient was advised to take rest for several minutes and then allowed to do his routines.
- *Pathya apathya* was advised to the patient.

Follow up study

Patients were asked to attend the O.P.D in every 15 days for the follow up study.

Statistical analysis

- The information gathered on the basis of observation made about various parameters was subjected to statistical analysis in terms of Mean, Standard Deviation and Standard error (SE). All the results calculated by using software: Graph Pad In Stat 3.
- For nonparametric data **Wilcoxon matched-pairs signed ranks test** was used, while for parametric data **Paired 't' Test** was used and results calculated in each group.

Observation and Results

Table No.1 : Demographic profile

S. No.	Findings	Predominance	Percent
1.	Age	16-30 (young adults)	43.33% (13)
2.	Sex	Male	63.33% (19)
3.	Religion	Hindu	93.33% (28)
4.	Habitat	Urban	76.66% (23)
5.	Socio-economic status	Upper middle class	56.66% (17)
6.	Occupation	Service	40% (12)
7.	Family History	Absent	83.33% (25)
8.	Addiction	Tea/coffee	46.66% (14)
9.	Chronicity of disease	1-3 Year	56.66% (17)
10.	*Aharaja Nidana*	*Vishmashana*	73.33% (22)
11.	*Viharaja Nidana*	*Dhuma*	76.66% (23)

Table No. 2: Showing effect of therapy in all subjective parameters in group A. (Wilcoxon matched paired single ranked test)

Variable	Mean		Mean Diff.	% Relief	SD (±)	SE± (±)	P	S
	BT	AT						
***Shwasakrichatta* (Dyspnoea)**	1.53	0.73	0.80	52.28%	0.676	0.174	P<0.001	H.S.
***Kasa* (Cough)**	1.13	0.40	0.73	64.60%	0.593	0.153	P<0.001	H.S.
***Ghurghurrak* (Wheezing)**	1.00	0.53	0.46	46%	0.516	0.133	P<0.01	S.
***Peenas* (Coryza)**	0.60	0.20	0.40	66.66%	0.507	0.130	P<0.01	S.
***Parsva avgrihyate* (Chest tightness)**	1.00	0.53	0.46	46	0.516	0.133	P <0.01	S.
***Lalaten svidyata* (Sweating on forehead)**	1.06	0.46	0.60	56.60%	0.828	0.213	P <0.01	S.
***Vishuskaasyam* (Dryness of mouth)**	1.33	0.86	0.46	34.58	0.743	0.191	P< 0.1	N.S.

Table No. 3: Showing effect of therapy in all subjective parameters in group B. (Wilcoxon matched paired single ranked test)

Variable	Mean		Mean Diff.	% Relief	SD (±)	SE± (±)	P	S
	BT	AT						
Shwasakrichatta **(Dyspnoea)**	1.46	0.93	0.53	36.30	0.639	0.165	P <0.01	S.
Kasa **(Cough)**	1.60	0.73	0.86	53.75	0.743	0.191	P <0.001	H.S.
Ghurghurrak **(Wheezing)**	1.06	0.66	0.40	37.73	0.507	0.130	P < 0.01	S.
Peenas **(Coryza)**	0.80	0.20	0.60	75	0.828	0.213	P <0.01	S.
Parsva avgrihyate **(Chest tightness)**	0.73	0.33	0.40	54.79	0.507	0.130	P <0.01	S.
Lalaten svidyata **(Sweating on forehead)**	0.93	0.46	0.46	49.46%	0.639	0.165	P<0.01	S.
Vishuskaasyam **(Dryness of mouth)**	0.93	0.66	0.26	27.95	0.457	0.118	P< 0.1	N.S.

Table No.4 Showing effect of therapy on Objective Parameters in Group A (Paired't' Test)

Parameters	Mean		Diff	% Relief	SD ±	SE ±	T	P	S
	BT	AT							
ESR	19.46	18.93	0.53	2.73%	1.457	0.376	1.41	P> 0.01	N.S.
AEC	264.47	246.67	17.8	6.73%	29.20	7.541	2.36	P <0.01	S.
FVC	65.20	67.53	-2.33	3.57%	3.132	0.808	2.88	P<0.01	S.
FEV1	57.86	59.60	-1.74	3.00%	2.520	0.650	2.66	P< 0.01	S.
FEV1/FVC	93.60	95.93	-2.33	2.48%	5.627	1.453	1.60	P< 0.1	N.S.
PEFR	51.66	52.86	-1.2	2.32%	3.668	0.947	1.26	P<0.1	N.S.

Table No.5 Showing effect of therapy on Objective Parameters in Group B. (Paired't' Test)

Parameters	Mean		Diff	% Relief	SD ±	SE ±	T	P	S
	BT	AT							
ESR	16.66	16.26	0.40	2.40	1.298	0.335	1.19	P> 0.01	N.S.
AEC	255.40	242.00	13.4	5.24	19.99	5.162	2.59	P <0.01	S.
FVC	60.00	61.20	-1.20	2	1.897	0.489	2.44	P< 0.01	S.
FEV1	63.40	64.86	-1.46	2.30	2.475	0.638	2.29	P< 0.01	S.
FEV1/FVC	98.93	100.80	- 1.87	1.89	4.086	1.055	1.76	<0.1	N.S.
PEFR	57.33	58.46	-1.13	1.97	2.850	0.735	1.54	<0.1	N.S.

Discussion On Results

Group–A (*Pratimarsha Nasya*)- The effect of *Pratimarshya Nasya* Group on symptomatology provided highly significant (p<0.001) with Moderate Relief with 52.28% in *Shwasakrichatta* and with 64.60% in *Kasa*, Statistically significant(P<0.01) with Moderate relief with 66.66% in *Peenas* and with 56.60% in *Lalaten svidyata* Mild Relief with 46% in *Ghurghurrak* and with 46% in *Parsva avgrihyate*.

Statistically non-significant (p<0.1) with mild relief in 34.58% in *Vishuskaasyam*.

Group – B *(Dhumapana)* -The effect of *Dhumapana* Group on symptomatology provided highly significant (p<0.001) with Moderate Relief with 53.75% in *Kasa*.

Statistically significant (P<0.01)with Moderate relief 75% in *peenas,* 54.79% in *Parsva avgrihyate* and mild relief with 36.30% in *Shwasakrichatta,* 37.73% in *Ghurghurrak,*and *with* 49.46% in *Lalaten svidyata*.

Statistically non-significant (p<0.1) with Mild Relief with 27.95% in *Vishuskaasyam*.

Thus we may conclude that *Pratimarsha Nasya of Anu tail* is more effective on *Vata* and *Kapha Dosha* which provide better result in all signs and symptoms as compare to *Dhumapana,* whereas it was observed that *Dhumapana* is more effective in *Peenas* and *Parsva avgrihyate* as compared to *Pratimarsha Nasya*.

Effect of Trial on Objective Parameter

On the basis of both groups

Effect on ESR - ESR was decreased by 2.73% in Group A and 2.40% in Group B, which was Non significant (p<0.1) in both groups.

Effect on AEC – AEC was decreased by 6.73% in Group A and 5.24% in Group B, which was statistically significant (p<0.01) in both groups.

Effect on Spirometry

FVC% - FVC was increased by 3.57% in Group A and 2% in Group B, which was statistically significant (p<0.01) in both groups.

FEV1% - FEV1 was increased by 3% in Group A and 2.30% in Group B, which was statistically significant (p<0.01) in both groups.

FEV1/FVC Ratio – FEV1/FVC Ratio was increased by 2.48% in Group A and 1.89% in Group B, which was statistically Non significant(P<0.1) in both groups.

PEFR% - PEFR was increased by 2.32% in Group A and 1.97% in Group B, which was statistically Non significant(P<0.1) in both groups.

Discussion On Subjective Parameters

Effect on *Shwasakrichatta* – The result was found statistically highly significant in group A, and Significant in group B. When the *pranavahasrotas* is obstructed by the *kapha* it causes dysfunction of *prana vayu* leading to discomfort in breathing, *kapha-vattaghana* property of *Nasya (Anu taila*) reduces the elevated *kapha* and its *lekhana* property cleans the *srotas* allowing the path for the movement of *vayu*. Same as *Dhumapana* (*devdaru, bala, jatamansi*) has *kapha-vataghna* property and with its *katu vipaka ushna veerya & tikshna guna,* it reduces the symptom by doing *srotoshodhana*.[11]

Effect on *Kasa* - The result was found statistically highly significant in the both group, Cough is a defense mechanism of *praavahasrotas*, the presence of which is indicative of irritating *sleshma* in the *srotas*. The reduction in the cough implies its tenacious sputum is liquefied by the medicine (*nasya and dhumapana*) and its expectoration is easy. The medication is also effective when it reduces production of sputum in the *srotas*.

Effect on *ghurghurrak* sound- The result was found statistically significant in both group. Increased *Kapha* situated in *Srotas (Kantha)* obstructs the airway causes wheezing sound. Most of the ingredients of both group possesses *Kapha Shamaka* and *Shothahara* properties with *Lekhana Guna*. Hence they are helpful in this symptom and When *Dhumapana* was taken stimulating expectoration, so it clears the airways and decrease wheezing.[11]

Effect on *Peenas* -*Peenas* is a *kapha vata*

predominance disease and most of the ingredients of *nasya* having *kaphavataghna* property as its local effect of elimination of vitiated *doshas* from *nasa marga* and gives relief from *peenas*. Majority of ingredients of *Anutaila* show *Tikta Rasa* and *Laghu guna* properties. These properties are very much in favour of clearing the *Srotas*.It dries up *Kelda* and purulent discharge. *Katu vipaka*, *Ushna Virya* and *Tikshna* properties of drugs of *dhumapana* exert *srotoshodhan* effect and produce *Draveekarana (Vilayana)* and *Chedana* of vitiated *Kapha*.[11]

Effect on *parsva avgrihyate* -The result was found statistically significant the both the groups. Pain in the chest and flank is due to vitiated *kapha*.Due to obstruction of air by mucous congestion in alveoli, if it is not expelled in time it obstruct the path of air in alveoli which is responsible for the phenomena of chest tightness. Drugs of both groups has *vataanuloman* and *kaphanisarak* property, so above result is derived.[11]

Effect on *Lalaten svidyata* -The result was found statistically significant in both groups with mild relief. This might be due to the reason that asthmatic attack causes rapid respiration and hence exertion which in turn is the reason for sweating, and when difficulty in breathing subsides this symptom of sweating gets subsided automatically.

Effect on *Vishuskaasyam* -The result was found statistically insignificant in both groups. This might be due to the reason that property of the trial drug may be unable to pacify the symptom *vishuskaasyam*.

Discussion Of Objective Parameter

Effect On ESR

There was no significant difference noticed in ESR during the course of whole treatment.

Effect On AEC

There was significant result found on AEC in both group. High eosinophil value suggests allergic condition and extrinsic type of asthma,Due to antihistaminic properties of drug and improvement in the immune system with the both drug reduction in AEC value was observed.

Effect On Spirometry

Spirometry measures the amount (volume) and speed or flow of air that can be inhaled and exhaled. It helps in detecting the narrowing or obstruction of airways. The most common measurements used are FVC, FEV1,FEV1/FVC ratio and PEFR. Improvement in the value suggest improvement in airway obstruction in alveoli and inflamed airway and broncho constriction in asthma improved. Due to expectorant, antispasmodic, and anti-inflammatory property of drug this significant result was observed.

Probable Action Of Drug

Pratimarsha Nasya of *anu tail* and *dhumapana* including the drugs having Antinflammatory, Antihistaminic, Antiallergic, bronchodilator and expectorant properties.[12,13,14,15,16,17] which are effective and safe therapeutic procedure in the prevention of *Tamaka Shwasa* (Seasonal Bronchial Asthma).

Conclusion

The prevalence of *Tamaka Shwasa* (Bronchial Asthma) is increasing due to excessive pollution, overcrowding and industrialization as well as urbanization.It is found that *Tamaka Shwasa* is most common in 3rd decade of life in this study.Significant results was found in subjective parameter as well as objective parameter in both groups. Statistically significant improvement in FVC (%) and FEV1% was observed in patients of both groups, significant reduction in AEC was observed in patients of both groups**..** Overall comparison of all the parameter showed that effect of *Pratimarsha nasya* was better than *Dhumapana*. It can be said that *Pratimarsha nasya* is more effective to control all parameters due to its highly *Vata-kaphahara and Vataanuloman* properties compared to *Dhumapana*. Thus it can be concluded that *Pratimarsha nasya* and *Dhumapana* effective in reducing the severity of attack and can be used as effective and safe therapeutic procedure in the prevention of *Tamaka Shwasa* (Seasonal Bronchial Asthma). This Clinical study proves that most of the *Ayurvedic* drugs used in this research project possess anti-inflammatory, antiallergic, antihistaminic, Bronchodilator and expectorant properties.

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Clinical Study

Study on the Immunomodulator effect of *Madhuyashti* Syrup in Children

*Dr. Krishan Kumar Kaswan, **Dr.Rakesh Kumar Nagar, ***Prof.Ajay Kumar Sharma

Abstract:

A double blind placebo control study was carried out to evaluate the Immunomodulatory efficacy of "*Madhuyashti syrup*" a classical *Rasayana* drug mentioned in *Charak Samhita*. The clinical study was done in 60 patients randomly selected from OPD & IPD of Balroga department, N.I.A. Jaipur. The drug was administered in the form of syrup at a dose of 1ml/kg/day in 2 divided doses. The placebo was also administered in same dose for 3 months. After 3 months of treatment drug group showed highly significant improvement in all morbidity features like running nose, Cough etc. except dyspnoea & sore throat. Placebo group showed insignificant improvement after 3 months of treatment in above mentioned criteria. Thus *Madhuyashti syrup* is a very good alternative for the immunomodulatory effect.

Key words - *Madhuyashti* syrup, morbidity features, Running nose, Cough, Immunomodulator effect.

सारांशः-

प्रस्तुत अध्ययन में बालकों के व्याधिक्षमत्व को सही करने के लिये आयुर्वेद शास्त्र मे वर्णित रसायन औषधि मधुयष्टी शार्कर का प्रयोग करके देखा गया है। पहले समूह (ए) मे 30 बच्चों को औषधि (मधुयष्टी) को शार्कर के रुप मे मात्रा 1 मि.लि/कि.ग्रा. प्रतिदिन दो बार मे विभाजित करके दिया गया। तथा बाकी 30 बच्चों को (समूह बी) प्लेसिबो को शार्कर के रुप मे दिया गया। प्लेसिबो की मात्रा व समय मधुयष्टी शार्कर के समान रखा गया। तीन महीने की चिकित्सा के बाद समूह ए में कास, नासा स्राव, गले में खराश, अतिसार, ज्वर आदि लक्षणों में सार्थक सुधार देखा गया। जबकि तीन महीने के प्रयोग के बाद समूह बी में उपरोक्त लक्षणों में कोई सुधार प्राप्त नही हुआ। इस प्रकार से बालको की व्याधिक्षमत्व को सही करने के लिये मधुयष्टी शार्कर एक बहुत अच्छा विकल्प है।

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Clinical Study

Study on the Immunomodulator effect of *Madhuyashti* Syrup in Children

Dr. Krishan Kumar Kaswan, Dr. Rakesh Kumar Nagar, Prof. Ajay Kumar Sharma

Introduction:

Now a day's most of the diseases in children are preventable through rational use of antibiotics and immunization schedule. But antibiotics have their own side effects and at the present time immunization is far from its satisfactory level. The reappearance of diseases like tuberculosis, polio and also the resistant strain in various earlier believed controllable or curable diseases has led to a serious question of the affectivity of the immunization procedure in total. Despite of high advance in immunization to boost up the defence mechanism, the medical science is yet to reach a full proof mechanism against the virulent organism and some time we lose out in battle of survival.

By all means we can say that the children should be supported externally in order to prevent the infection and at the same time measures should be taken for the proper development of immune system. The defence mechanism of child has to be developed to be free from disease.

Ayurveda fits, in such a concept having various immunomodulator drug described under the categories of *Rasayana, balya, ojovardhak,* some regimens and diet which are capable to improve non-specific immunity of the body without any untoward effect.

Aim And Objectives:.

- To observe the immunomodulatory effect of *Madhuyashti* syrup
- Evaluation of the side effects of the study drug.

Materials And Method:

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

Clinical study - Subjects

- **Source:** Patients were randomly selected from O.P.D/I.P.D. National Institute of *Ayurveda*, Jaipur, (Rajasthan).
- **Age Group:** Children between 1 to 8 years were selected for the study.
- **Number of cases:** Overall 67 patients were registered out of which 60 patients completed the study and 7 cases discontinued.

Grouping of patients:

This study was conducted in form of double blind randomized controlled group study. Total 67 patients were registered and randomly divided into 2 groups and treated according to following schedules. Out of 67 patients, 7 patients were dropped out. Rest 60 patients (Group A – 30, Group B - 30) were continued the clinical trial.

1) Group A - Receiving *Madhuyashti* Syrup in children.
2) Group B - Receiving Placebo Syrup in children.

The coded medicine (Study drug / Placebo) was given as per instructions. The coding of study drug and placebo was done by another person not related with study. Coded document was sealed and kept under safe custody. The envelope was opened after completing the study to decode it for interpretation. Observations documented during study were analyzed and findings were evaluated by using statistical analysis to establish the efficacy.

Study drug

Madhuyashti

Glycyrriza Glabra have been reported to have immunomodulatory properties and its ingredients) has been reported to have immunopotentiating and immunoprophylactic activity[2].

The drugs were prepared in the syrup form in order to enhance its palatability for easy administration in children. They were prepared in the pharmacy of N.I.A., Jaipur.

Dose and Duration -1ml/kg/ day in two divided doses for 3 months.

Placebo: The placebo for the study was also in the form of Syrup prepared from sugar, flavouring and colouring agents.

Diagnostic Criteria

A. Inclusion criteria

1. Children aged between 01 to 08 years of either sex.
2. Children with recurrent respiratory infections.
3. Children with recurrent G.I.T. diseases.
4. Children with other recurrent disease.

B. Exclusion criteria

1. Children below 01 and above 08 years of age.
2. Children with severe diseases.
3. Children with chronic diseases.
4. Children with any genetic disorder.
5. Children having congenital anomalies.

C. Discontinuation criteria

1. Any acute or severe illness.
2. Parents not willing to continue the treatment.

D. Side effect and Adverse effect assessment criteria

To rule out the possible adverse effects of studied drug, clinical criteria were adopted. It incorporated the records of information from the patient on each and every follow up, related to the features as nausea, vomiting, pain abdomen, loose stool, constipation and other non specific symptoms.

E. Assessment criteria

The result of the clinical study was assessed based on the observations of clinical features and laboratory findings. Following parameters shall be adopted for assessing the patients before, during and after treatment.

I. Clinical assessment:

- Running nose frequency and consistency
- Nasal obstruction
- Cough frequency and character
- Sore throat
- Enlarge tonsils
- Dyspnoea
- Diarrhoea frequency and consistency
- Fever frequency and character

Above mentioned morbidity features were used to evaluate the morbidity pattern of the child and drug effect also.

II. Laboratory parameters

IgG, Hb gm%, TLC, Neutrophil count, Lymphocyte count, Eosinophil count, ESR. These tests were done in both Group A (*Madhuyashti* treated group) and Group B (Placebo group). 20 patients of each group were randomly selected by Chitt method.

Above investigations have been carried out to rule out the underlying illness and also for establishing the efficacy of trial therapy.

Method

Calculation of final score = Frequency × Severity

Follow-up and monitoring

All patients were followed on an interval of 15 days i.e. on day 15, day 30, day 45, day 60, day 75, day 90 after recruitment. A window period of +3 days was given to allow for holidays and weekends.

Assessment of Results

The clinical study was analyzed after the treatment for the effect on clinical features, and laboratorial parameters.

Observations And Results:

- In the study it was found that out of 60 majority of patients i.e 68% were in 1-6 years age group, 60% of them Hindu by religion, with male dominency (58%), 65% patients enrolled in the study were belonging to Nuclear families. It was observed that Maximum (40%) patients were found in lower class, followed by 32% in lower

middle, 24% in middle class and 5% in upper middle class . No single patient was found in upper class.

- It was observed that majority of patients were delivered as full-term gestation 52(87%). Maximum patients 47(78%) had given history of Breast feeding initiation Immediate after birth. Majority of patients (66%) were given complementary food during 06-12 months of age. However 12% of patients were observed that weaning was done even before 06 months of age and in 22% of patients, weaning was done after completion of 01 year of age.
- It was observed that majority of patients i.e. 77% were partially immunized as per national immunisation schedule and complete immunization found in 23% patients.
- It was observed that, majority of patients 55% were vegetarian. Only 45% patients were found to have mixed pattern of diet.
- Majority of patients enrolled in the study were having Vata-Kapha Prakriti 49% followed by Vata-Pitta Prakriti in 29% and Kapha-Pitta Prakriti in 22% of patients.
- Out of total 60 patients maximum 31(52%) were found with *Manda Agni*, followed by 39% *Vishma Agni* and 05% with *Tikshna Agni,* only one patient found with *Sama Agni*.
- It was observed that maximum 49 (82%) patients were suffered from recurrent episodes of cough, followed by 43(72%) with recurrent running nose, 41(69%) with Nasal obstruction , 62% with recurrent fever and 58% with Sore throat.

Statistical Analysis of Before Treatment and After Treatment

Table No:-01 Showing Statistical Analysis of Group A

S. N.	Disease	BT Mean ±Sd	AT Mean ±Sd	Mean Diff.	N	t Value	P Value	Remark
1	Run. Nose Freq	12.47±3.14	9.90±2.06	-2.57	21	8.423	<0.001	HS
2	Run. Nose Consist.	11.61±3.42	9.38±3.10	-2.23	21	6.930	<0.001	HS
3	Nasal Obstr.	9.39± 2.54	6.944±1.765	-2.23	18	6.896	<0.001	HS
4	Cough Freq.	12.25±3.72	8.95±3.05	-3.30	24	13.89	<0.001	HS
5	Cough Character	11.5±3.09	8.60±2.51	-2.90	24	11.47	<0.001	HS
6	Sore Throat	8.89± 2.30	7.48± 1.41	-1.41	19	4.571	<0.01	S
7	Enlarge Tonsils	8.58± 1.90	6.52± 0.94	-3.06	17	5.182	<0.001	HS
8	Dyspnoea	8.33± 2.09	6.46± 0.91	-1.86	15	4.961	<0.01	S
9	Diarrhoea Freq.	10.66±2.84	7.91±2.15	-2.75	12	7.838	<0.001	HS
10	Diarrhoea Consist.	10.75±3.36	8.16±2.33	-2.59	12	6.490	<0.001	HS
11	Fever Character	11.22±3.02	8.08± 2.23	-3.06	18	9.935	<0.001	HS
12	Fever Freq.	10.83±3.09	8.11± 2.35	-2.72	18	9.410	<0.001	HS
	Total Morbidity	**10.54±3.08**	**7.99±2.16**	**-2.55**	**219**	**6.278**	**<0.001**	**HS**

In Group A where drug (*Madhuyashti* Syrup) was given, significant results were observed All scores were found Highly significant except Dyspnoea and Sore throat. At the level of change in mass morbidity rate it was observed Highly significant (BT-,10.54±3.08 AT- 7.99±2.16 t value-6.278, p value-<0.001)

Table No:-02 Showing Statistical Analysis of Group B

S. N.	Disease	BT Mean ±Sd	AT Mean ±Sd	Mean Diff.	N	t Value	P Value	Remark
1	Run. Nose Freq.	11.71±3.45	11.66±3.41	0.05	20	0.3262	>0.1	IS
2	Run. Nose Consist.	11.25±3.52	11.15±3.66	-0.10	21	0.3697	>0.1	IS
3	Nasal Obstruction	9.54±2.54	9.63±2.73	-0.09	17	0.8101	>0.1	IS
4	Cough Frequency	11.87±3.64	11.69±3.54	0.18	25	1.164	>0.1	IS
5	Cough Character	12.09±3.13	11.78±3.16	0.31	25	1.576	>0.1	IS
6	Sore Throat	8.95± 2.72	8.66±2.45	0.29	16	1.826	>0.1	IS
7	Enlarge Tonsils	9.82± 2.70	10.04±2.72	-0.22	12	1.096	>0.1	IS
8	Dyspnoea	8.66 ±2.17	9.09±2.14	0.43	14	1.868	>0.1	IS
9	Diarrhoea Frequency	11.22±2.96	10.89±3.09	-0.33	09	1.239	>0.1	IS
10	Diarrhoea Consistency	9.75±2.93	9.66±2.88	-0.09	09	0.4839	>0.1	IS
11	Fever Character	11.94±2.47	12.23±2.61	0.29	19	0.8435	>0.1	IS
12	Fever Frequency	9.79± 2.09	10.05±2.41	0.26	19	0.8875	>0.1	IS
	Total Morbidity	10.61±3.06	10.46±2.93	-0.15	206	0.3378	>0.1	IS

- In Group B where Placebo was given, insignificant result was observed, all scores were found insignificant. At the level of change in mass morbidity rate it was observed insignificant (BT-10.61±3.06, AT-, 10.46±2.93 n-206, t value-0.3378, p value->0.1).
- It shows that in Group A there was highly significant change, Group B had shown insignificant change in almost all morbidity features.
- Group A where *Madhuyashti* Syrup was given shown decreased morbidity rate, on other hand Group B (Placebo group) shown minimal changes in morbidity. This results show that *Madhuyashti* Syrup modulates the immunity of child by which he/she can fight with diseases.
- At the level of change in mass morbidity rate it was observed Highly significant (BT- 10.54 ± 3.08, AT- 7.99 ± 2.55, n=219, t value- 6.278, p value- <0.001) but AT morbidity rate was higher than the BT (mean difference= -2.55).
- It shows that there was Highly significant change in morbidity rate of *Madhuyashti* Syrup treated (group A) children.
- In group B where placebo (*Madhuyashti* Syrup B) was given, all scores were found insignificant. At the level of change in mass morbidity rate it was observed insignificant (BT-10.61±3.06, AT-,10.46±2.93 n-206, t value-0.3378, p value->0.1) but BT morbidity rate was higher than the AT (mean difference= -0.15).
- It reveals that Group B (Placebo treated) had shown insignificant changes in Morbidity features or increase morbidity rate was found. It may be due to no effect of simple sugar syrup (Placebo) on immunity of child.

Table No. 03:- Statistical analysis of investigation in group A

S. N.	Investigation	BT Mean ±Sd	AT Mean ±Sd	Mean Diff.	t	P Value	Remark Value
1	IgG g/l	10.83± 3.6	12.92 ± 4.1	-2.09	2.187	<0.01	S
2	Hb gm%	11.64 ±0.89	11.93 ± 0.43	-0.29	0.892	>0. 1	IS
3	TLC	8275± 1090.0	6895± 765.0	1380 ±325	4.071	<0.01	S
4	Neutrophil	49.5± 10.43	49.24± 10.89	0.26	0.2982	>0. 1	IS
5	Lymphocyte	42.44 ± 10.20	42.59 ± 9.90	-0.15	0.1826	>0. 1	IS
6	Eosinophil	1.65± 0.66	1.30± 0.81	0.35	1.9350	<0.01	S
7	ESR	11.15 ± 7.83	10.30 ± 6.87	0.85	1.226	<0.01	S

Table No.04:- Statistical analysis of investigation in group B

S. N.	Investigation	BT Mean ±Sd	AT Mean ±Sd	Mean Diff.	t	P Value	Remark Value
1	IgG g/l	7.88 ± 2.99	8.45 ± 3.34	-0.57	0.6975	>0.1	IS
2	Hb gm%	11.39 ± 1.53	11.43 ± 1.01	-0.04	0.8655	>0.1	IS
3	TLC	9945 ±967.55	9880± 933.46	65	0.2675	>0.1	IS
4	Neutrophil	52.15 ± 9.31	51.34± 9.84	0.81	0.9225	>0.1	IS
5	Lymphocyte	39.40 ±10.90	39.60± 10.45	-0.20	0.1730	>0.1	IS
6	Eosinophil	1.880± 0.96	2.22 ±0.87	-0.34	1.662	<0.01	S
7	ESR	10.45 ±8.65	10.36± 8.28	0.09	0.2268	>0.1	IS

Discussion

- Out of 60 patients 35(58%) patients were male child and 25 (42%) patients were female child. There is no specific relation between sex and immunological status of the children, as it was observed in the present study.
- Most of the patients (65%) enrolled in the study were belonging to Nuclear families and other 35% were from joint families. It may be due to selection of urban area for this study and it is seen that in urban area maximum people lives in nuclear families in spite of joint families.[3]
- It was evident that, majority of patients i.e. 36 (60%) were Hindu by religion. Only 24(40%) patient was found to be Muslim by religion. It was due to Hindu predominance in study area, no study shows that Hindu are more venerable to infectious diseases.
- It was observed that Maximum (40%) patients were from lower class, followed by 32% in lower middle, 24% in middle class and 5% in upper middle class. No single patient was from upper class. The data shows the general trend in the population attending the OPD in Govt. hospitals where the medical services if offered free of cost.
- It was observed that majority of patients were delivered as full-term gestation 52(87%). Only 8% of patients were found to be delivered pre-term and 05% post-term also. It is known that children who had assisted problem in delivery may develop problems in the future life especially that related to growth and development. The uninterrupted growth and

development are essential for healthy including that related with immune system. In the present study any such observation were not found.

- Maximum patients 47(78%) had given history of Breast feeding initiation Immediate after birth and rest 13(22%) after some days of delivery. Data reviels that mothers prefers breast feeding more than other type of feeding. Reasons may be economically cheaper than other milk or may be that maximum birth(87%) were full-term and there is no problem for mother in production and secretion of breast milk for full term baby.
- Majority of patients (66%) were given complementary food during 06-12 months of age. However in 12% of patients it was observed that weaning was done even before 06 months of age and in 22% of patients, weaning was done after completion of 01 year of age. It is shown that early as well as late weaning hampers both child's nutritional and morbidity status.[4] In this study data does not match with this theory.
- It was observed that majority of patients i.e. 77% were partially immunized as per National Immunization Schedule. Complete immunizations were found only in 23% patients. It is seen due to unawareness, less advertising and some myth regarding vaccination. Statistics shows that in lack of immunization or partial immunization morbidity rate increases compare to fully immunization[5].
- It was observed that, majority of patients (55%) were vegetarian. Only 45 % patients were found to have mixed pattern of diet. There is no direct relation of type of diet to recurrent infections or immunity because the quality of diet matters the nutrition of the individual and if the nutrition is proper then immune system will also prompt. [6]
- Majority of patients enrolled in the study were having *Vata-Kapha Prakriti* 29(48%). There is predominance of *Kapha* in *Balyavastha* so chances of *Kapha Sthan (Uraha) Gata Vyadhi* (URTI) is more in children and low immunity may be due to *Srotavarodha, Aparipakva Dhatu, Alpa Ojas*. In other reference *Vata Prakriti* children also have *Alpa Bala*, so may be *Vata-Kapha Prakriti* is more vuinerable for higher morbidity. [7,8,9]
- Majority of patients 31(52%) enrolled in the study were of *Heena Satva*, followed by 27(45%) *Madhyam Satva* and only 03% were found with *Pravara Satva*). This data is in concordance to *Ayurvedic* concept that children are delicate and having *Madhyam Satva* and *alpa-satva*.[10]
- As we considered only major Sara, maximum 42% were found with *Twak Sara*, followed by 22% *Asthi sara, Mamsa & Rakta Sara* each 11% and minimum 00% in *Shukra Sara*. This data does not match with Ayurvedic concept because in Ayurveda Maximum *Vyadhikshamatava* is found in *Asthi, Mamsa* and *Rakata Sara Purush*.
- Out of total 60 patients maximum 31(52%) were found with *Manda Agni*, followed by 39% *Vishma Agni* and 05% with *Tikshna Agni*. *Sama Agni* found in 1 patient. *Agni Dushti (Visham or Manda)* is main cause of *Ama* production, which is responsible for *Vyadhikshamatava Hrasa*.
- It was observed that maximum 49 (82%) patients were suffered from recurrent episodes of cough, followed by 43(72%) with recurrent running nose, 41(69%) with Nasal obstruction, 62% with recurrent fever and 58% with Sore throat. WHO data also reveals that upper respiratory tract infection is a most common cause of morbidity in children. Recurrent cough, running nose, cough and nasal blockage are major features of URTI.[11]
- In the study it was found that out of 60 patients, 21(34%) were same in the age group 1-3 years and 3-6 years, followed by 20(32%) in 6-8 years of age group. it means in age group of 1-6 years there were 42(68%) patients.

Discussion on the effect of therapy

The acceptance of a medicine in the medical field is purely based on the results obtained by Randomized Clinical Trials, which is considered to be the Gold Standard in the world of Evidence Based Medicine. To conduct a model RCT in the field of Ayurveda within the restrictions of academic limitations is not constantly possible. Our medicines act on a multi plane and individual considerations play a key role in therapies.

In present study patients were treated in two individual Groups. In Group A Syrup *Madhuyashti Syrup* and in Group B Syrup Placebo were administered. The results were drawn as under on each individual symptom at the end of entire course.

The clinical efficacy of the drug was analyzed statistically on all parameters mentioned in the Assessment criteria. Scoring of morbidity features were done before, at follow-ups, after treatment and one month after discontinuation of the drug.

Thus, obtained results in each group were statistically analyzed by using "Student's paired' test" for the variation and significance of effect seen in individual groups and "unpaired' test" was used for intergroup differences between all groups.

Results shows that in group A there was highly significant change, group B had shown insignificant change in almost all morbidity features. Group A where *Madhuyashti* Syrup was given shown decreased morbidity rate, on other hand group B (placebo group shown minimal changes in morbidity. This results shows that *Madhuyashti* syrup modulates the immunity of child by which he/she can fight with diseases.

- At the level of change in mass morbidity rate it was observed Highly significant (BT- 10.88 ± 3.39, AT- 10.89 ± 2.28, n=384, t value- 0.1044, p value- >0.1) but AT morbidity rate was higher than the BT (mean difference= -0.013).
- It shows that there was highly significant change in morbidity rate of *Madhuyashti* syrup treated (Group A) children.
- In group B where placebo (*Madhuyashti* Syrup B) was given, all scores were found insignificant. At the level of change in mass morbidity rate it was observed insignificant (BT- 10.56 ± 3.26, AT- 14.75 ± 3.09, n=356, t value- 27.735, p value- <0.001) but AT morbidity rate was higher than the BT (mean difference= -4.194).
- It reveals that Group B (Placebo treated) had shown insignificant changes in morbidity features or increase morbidity rate was found. It may be due to no effect of simple sugar syrup (Placebo) on immunity of child.
- Data shows that in Group A there was significantly increase in IgG level as compare to Group B where insignificant change or decreased IgG level was found. It means *Madhuyashti* increases the IgG level which is main component for immunity boosting.

At the level of Neutrophil and Lymphocyte Insignificant changes were found in both group A and group B. It means that *Madhuyashti* does not show any effect on Neutrophil as well as lymphocyte count.

In case of Eosinophil both groups shown significant results (p value - <0.01) but in Group A there was increase and Group B decrease in the number of Eosinophils. It means *Madhuyashti* is very good effective in allergic conditions where eosinophil counts increases due to hyper responsiveness of immune system.

Observation shown that In Group A there was significant (p value - < 0.01) decrease in ESR as compare to Group B where insignificant change (p value - > 0.1) was found. It reveals that *Madhuyashti* has good anti infective properties.

In Group A (*Madhuyashti* treated) there was significantly increase in IgG level as compare to Group B where insignificant change or decreased IgG level was found. It means *Madhuyashti* increases the IgG level which is main component for immunity boosting.

Mode of Drug Action

Pharmacodynamic properties of herbal drug *Madhuyashti* shows it have Madhur *Rasa*, *Ghuru, Snigdha Gunas, Sheeta Veerya, Madhur Vipaka, Tridoshahara, Karma*.[12]

In upper respiratory tract infection the *Pranavaha Srotas* is basically involved (*Pratishyaya* and *Kasa Roga*). In this disorder the Dosha involved are *Kapha Vatapradhan* and *Alpa Pitta*. *Dushya* involved is *Rasa* and *Rakta Dhatu* and Srotas affected are *Pranavaha, Annavaha* and *Udakavaha Srotas*.

Considering above factors, the drug chosen besides having a *Tridoshahara* activity should have strong affinity to act on *Pranavaha Srotas (Kasa-Swas Hara)*. Drug possesses *Laghu Guna* and also *Kasa-Swas Hara* properties. Its *Sheet Guna* doesn't hamper other *Khaphaghna* properties.

As discussed earlier in the conceptual section that o*jas* is responsible for bala[12] i.e. immunity and it's the essence of all the *dhatus*. The *dhatus* formed by assimilation of dietary items and influence the characteristics and behaviour of the *doshas*. Dhatus are arranged in hierarchical fashion *rasadhatu* being the primordial tissue. The tissue receives nutrients from the *rasadhatu*, picking up the component they need. It is obvious then, that the quality of the *rasadhatu* is important and also follows that it would influence the working of subsequent tissues and their purest form *ojas*.

Specific drug called *Rasayana* in *Ayurveda* acts to prevention of disease and promotion of health by improving immunity or *Kshamatva*.[13] *Ojas* play an important role in maintaining the resistance power of the body and it is extract of all *Dhatus*. So the drug *Rasayana* are responsible to potentiate *Ojas* or intermediate *Dhatus* directly or by enhancing *Dhatwagnies* or by *Srotoshodhanam*. *Madhuyashti* is a drug that play a very good role in immunomodulation

Rassayana drugs improve the quality of *rasadhatu* and thereby the entire status of the body. This is the probable mode of action of the drug. *Madhuyashti* have *Rasayana Prabhava*. The Rasayana drugs are supposed to increase all the *Sharira Dhatu*, both qualitatively and quantitatively. It has immunomodulator effect as per related study; the researcher has concluded that immunomodulatory regimen well play a key role in future therapies for URTI. (Anwei cheng et al..2008.,) These treatment modalities may not only treat URTI, but also be beneficial in reducing the morbidity and mortality for which it is responsible.

The *Madhuyashti* have *Jeevaniya* and *Balya* properties also[14,15]. Thus the effect of drug in enhancing the *Vyadhikshamatva* can be attributed to the multiple mechanism of actions of drug.

Conclusion

Following conclusion can be drawn from the present research work:

- Children with *Vata-Kapha* predominant *Sharirika Prakriti* are more prone to high morbidity rate.
- Present research work shows that morbidity rate is high among 1-6 years of age group, in which recurrent cough and running nose are main component.
- Ayurveda can augment the recovery of children suffering from high morbidity features with its *Rasayana* therapy.
- In the present study, the trial drug *Madhuyashti* Syrup increased haemoglobin concentration, decreased TLC, increased IgG level in Children at a statistical significant level suggesting the effectiveness of the drug.
- *Madhuyashti* works like an immunomodulator to decrease the morbidity rate.
- A simple and cost effective formulation of *Madhuyashti* is capable to bring down the morbidity status of children.
- No adverse effects of the drug therapy were observed during the present study.
- At the level of laboratorial investigation larger sample can be promoted and all immunoglobulin, specifically all IgG can be measured.

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Clinical Study

Study on The Management of Spasticity In Children Suffering From Cerebral Palsy With An *Ayurvedic* Compound And *Yogic* Postures (*Asanas*)

*Dr. Sandeep Kumar, **Dr. Nisha Ojha

Abstract

Cerebral palsy is one amongst common paediatric neurological disorder described by loss or impairment of motor function. It affects body movement, muscle control, muscle coordination, muscle tone, reflex, posture and balance. It can also hamper fine motor skills, gross motor skills and oromotor functioning.

Disability treatment and management in this country and world at large is a big challenge. Cerebral palsy is worst among them with prevalence of 4 per 1000 live birth. Till date, there has been no effective cure for cerebral palsy in modern medicine. Modern science relies on symptomatic and supportive care which is complicated as well as expensive and results are also not satisfactory. People are now looking at alternative systems like Ayurveda in search of new hope.

Various procedures of *Panchakarma* like *Abhyanga* and *Shalishastika pinda sweda* are well known for reducing spasticity of muscles. Apart from the common methods of treatment, *Yoga* Postures help to reduce high muscle tone in children with Cerebral Palsy. When the *yoga* postures are being performed, the muscles and tendons stretch and the overall rigidity of muscles and joints are reduced. Present clinical study with an *Ayurveda* compound and *yoga* postures proved effective in the management of cerebral palsy in children.

Keywords: cerebralpalsy, *panchkarma, abhyanga, Shalishastika pinda sweda, asanas.*

सारांश-

सेरेब्रल पाल्सी सामान्य बाल चिकित्सा तंत्रिका संबंधी विकारो में से एक है जो मोटर फंक्शन के नुकसान या हानि के कारण होता है। यह शारीरिक चेष्टा, मांसपेशियों पर नियंत्रण, मांसपेशियों के समन्वय, मांसपेशी की टोन, रिफ्लेक्शन, स्थिति और संतुलन को प्रभावित करता है। यह फाइन मोटर क्षमता, ग्रोस मोटर क्षमता और ओरो मोटर कामकाज में भी बाधा कर सकते हैं।

इस देश में और दुनियाभर में बड़े पैमाने पर विकलांगता उपचार और चिकित्सा एक बड़ी चुनौती है। सेरेब्रल पाल्सी 4 प्रति 10 जीवित जन्म की व्यापकता के साथ उन के बीच ये व्याधि निकृष्टतम है। आज तक, आधुनिक चिकित्सा पद्धति में सेरेब्रल पाल्सी के लिए कोई प्रभावी इलाज का अनुसन्धान नहीं हासिल हुआ है। आधुनिक चिकित्सा पद्धति रोग सूचक और सहायक देखभाल पर निर्भर करता है जो महंगा और जटिल है और जिसके परिणाम भी संतोषजनक नहीं हैं। लोग अब आशा की नई किरण की रुप में आयुर्वेद जैसे वैकल्पिक चिकित्सा प्रणालियों को देख रहे हैं।

अभ्यंग और शालि षष्टिक पिंड स्वेद जैसे पंचकर्म के विभिन्न प्रक्रियाएं मांसपेशियों के काठिन्य को कम करने के लिए अच्छी तरह से काम करता है। उपचार के सामान्य तरीकों के अलावा, योगासन सेरेब्रल पाल्सी वाले बच्चों में मांसपेशियों की बढ़ी हुई टोन को कम करने में मदद करता है। योगासन करते समय, मांसपेशियाँ और उनकी कन्डराए खिँच जाती है जिस कारण से मांसपेशियाँ और जोड़ों का काठिन्य कम करने मे मदद होती है। बच्चों में सेरेब्रल पाल्सी के चिकित्सा में आयुर्वेदिक योग और योगासन के साथ वर्तमान नैदानिक अध्ययन प्रभावी साबित हुआ।

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Clinical Study

Study on The Management of Spasticity In Children Suffering From Cerebral Palsy With An *Ayurvedic* Compound And *Yogic* Postures (*Asanas*)

Dr. Sandeep Kumar, Dr. Nisha Ojha

Introduction

Cerebral Palsy is the leading cause of disability in children [1], making them physically and mentally handicapped and socially apart. Cerebral Palsy (CP) is not a single disease but it is a symptom complex. It is a broad term encompassing a group of non progressive, non contagious condition that causes motor impairment syndrome characterized by abnormalities in movement, posture and tone [2]. It results as a consequence of damage to the developing brain at anytime during prenatal, natal and postnatal period of life.

Worldwide the incidence of Cerebral Palsy is 2.5/1000 live births [3] and for India it is 3/1000 live births[4].

Children with cerebral palsy exhibit a wide variety of symptoms such as lack of muscle co-ordination while performing voluntary movement (Ataxia), Stiff or tight muscle and exaggerated reflexes (spasticity), Walking with one foot, a crouched gait or scissor gait, Variation of muscle tone, either too stiff or too floppy, Excessive drooling of saliva, Difficulties in swallowing or speaking, Difficulty with precise motion such as writing or buttoning a shirt.[5]

Various other impairments are associated with cerebral palsy like Mental retardation (50-75%), Seizure disorders (25-33%), Delayed growth and developmental problems (15-20%).[6]

In the causation of CP many etiological factors are considered including idiopathic cause (still exactly unknown). Its treatment includes multiple alternatives i.e. Medication, Physiotherapy, Speech therapy, Occupational therapy and Surgery. Multisystem involvement in CP makes its management different than symptomatic treatment. Therefore multidisciplinary approach is desired for the management of CP.[7]

Considering the signs and symptoms of CP, this disease entity seems very closer to the presentation *Vata Vyadhi*. *Vata* is the chief and dominant *Dosha* among *Tridosha* and has larger value for the maintenance of health and production of disease. Therefore *Vata Vyadhi* stands with major contribution to pathophysiology in *Ayurveda* aspects.If *Vata* is considered as major contributing factor for CP, *Vata* pacifying measures becomes essential component in the treatment. Treatment of *Vata Dosha* consists of a variety of treatment modalities including *Snehana, Swedana, Basti* etc. *Snehana* and *Swedana* are said preliminary procedures before administration of main Procedure. In addition to the role of *Snehana* and *Swedana* as primary and preparatory procedures, they are also independent therapies for certain conditions. They are said to be very beneficial for treating *Vata Dosha* and their application is found helpful in improving clinical condition of CP. With this approach, the present study has been undertaken.

Aims & Objectives

1. To improve quality of life of the patients of cerebral palsy.
2. To enhance the functional capacities of the children in order to make him/her self dependent.
3. Early rehabilitation and to prevent further complications.

Materials And Method

Study Design- Interventional

Purpose-Treatment

Masking- Open label

Control- Controlled

Timing- Prospective

End Point- Efficacy & Therapy

Number of Groups- Two

Number of Patients (Sample size)- 40 (20 in each group)

Selection Of Cases

For the study, affected children of the age group of 1 to 12 years were selected after evaluating them clinically, from O.P.D. and I.P.D. of Ayurveda pediatrics Department of National Institute of Ayurveda, Jaipur. Minimum 40 cases were registered for the study and randomly divided in two groups.

Group A-*Ayurveda* compound + *Panchakarma* procedure +Yoga postures

Group B-*Panchakarma* procedure + Yoga postures

Inclusion Criteria

1. Age group of 1 to 12 years of either sex.
2. Diagnosed Case of cerebral palsy without seizures.

Exclusion Criteria

1. Individuals below one year and above 12 year of age.
2. Progressive neurological disorder.

Discontinuation Criteria

1. Parent/Guardian is not willing to continue the treatment.
2. Patient develops life threatening complication during treatment.
3. Any other severe illness.

Patient Information And Consent / Assent Form

A voluntary, signed witnessed Informed Consent / Assent was obtained from the Participant / Parent(s) / Guardian(s) prior to any clinical trial related procedure.

Assessment Criteria

1. Gross motor function Classification Scale (GMFCS)
2. CDC (Centers for Disease Control and Prevention) grading scale for motor milestones
3. Spasticity – Modified Ashworth Scale
4. MRC (Medical Research Council) Power scaling

Study Drug

A hypothetical *Ayurveda* compound "*Badaradiyog*" was prepared for the study. The compound was used in form of syrup to enhance palatability and easy administration in children. It was prepared in the pharmacy of National Institute of Ayurveda, Jaipur.

Table no. 01 ingredients of *Badaradiyog*

S.No.	Name	Botanical Name	Parts Used	Ratio
1.	*Ashwagandha*	*Withania somnifera*	Root	1
2.	*Bala*	*Sida cordifolia*	Root	1
3.	*Vidarikanda*	*Pueraria tuberosa*	Tuber	1
4.	*Badar*	*Zizypus jujuba*	Fruit	1
5.	*Tagar*	*Valeriana wallichii*	Root	1

Drug dose and Duration

Doses were according to the body weight of the child (2 ml/ kg / day) in 2 divided doses for 6 months. Children were called for follow up after end of 1 month. Any discomfort or untoward side effects were also documented.

Duration of trial: - 06 Months

***Panchakarma* Procedures**

The following procedures were carried out during clinical trial

- *Abhyanga*.
- *Shashtika Shali Pinda Sweda*.
- *Shirodhara*

Abhyanga

Abhyanga is procedure of anointing of oil on the body of individuals for the purpose of bringing stability and to normalize the *vata dosha*. *Abhyanga* was done by *Ksheerbala* tail.

Duration: - 15 to 20 minute daily for 1st two weeks of 1st months then again on 4th week of 1st month, after that whole procedure repeated for 2nd and 3rd week of next five months.

Shastika shali pinda sweda

It is a process by which the patients were anointed with oil and were massaged with the help of *pottali* on affected part of the body.

1. Preparation of *Bala mula Kwatha*

Balamula 250gm + 4 litre water ——1/4 reduced to 1 lt. *Kwatha*

2. Preparation of *Krishara*

150 gm of *Shastik Shali* were cooked in ½ litre *Kwatha* and ½ litre milk to prepare *Krishara*.

3. Preparation of Pottally

Four *pottallies* were prepared with cooked *Krishara* and dipped in hot mixture of ½ litre *Balamula Kasaya* and ½ litre milk. *Pinda Sweda* was done with these *pottallies* on affected part of body.

Duration: - 30 to 35 minute daily for 1st two weeks of 1st month then again on 4th week of 1st month, after that whole procedure repeated for 2nd and 3rd week of next five months.

Shirodhara

It is a method of pouring the medicated cow milk over forehead of the patient in the form of regular stream in a fixed oscillatory movement.

Duration: - 30 to 35 minute daily for 1st two weeks of 1st month then again on 4th week of 1st month, after that whole procedure repeated for 2nd and 3rd week of next five months.

***Yoga* Postures**

An asana is a physical pose, a kind of bodily gesture. In asana practice we place the body into a position that has a specific result.

***Asanas* Included in the study**

- *Bhadrasana*
- *Bhujangasana*
- *Siddhasana*
- *Shalabhasana*
- *Vajrasana*

Result & Discussion

Observations

In the present clinical study 42 patients of cerebral palsy were registered, out of which 20 patient of CP with spasticity in each group completed whole treatment for duration of 6 months.

Age-Maximum patients i.e. 21 (52.5%) were in age group 1 – 4years.Maximum number of the early age group children is good because early introduction of the therapy prevents secondary and tertiary problems associated with CP and help in inducing the drugs and procedures to combat with primary problem of balance and mobility.

Sex-Maximum numbers of cases reported were found to be males i.e. 32 (80%) while only 8 patients (20%) were female. Greater number of male patient supports the higher prevalence in male. Data is consistent with the findings of reports of Surveillance of Cerebral Palsy in Europe (Male to female ratio is**1.33: 1).**[8]

Consanguinity-History of consanguineous marriage of parents was absent in maximum i.e. 37 (92.5%) patients while it was present in 3 (7.5%) patients. Mother age of Conception in maximum i.e. 34 (85%) patients mother were having history of appropriate age of conception.

ANC (Ante-natal care) - Mother of maximum i.e. 36 (90%) patients were found to have proper ANC check up followed by 4 (10%) mother had improper ANC. The government plan of door to door ANC care and more awareness of ANC among general population were behind this maximum percentage but the Ante natal period is the important time period for the reason of cerebral palsy.

Birth Order-Maximum number of incidence of CP were found in 1st Birth order with 25 (62.5 %), followed by 10 (25%) in 2nd birth order, 5(12.5 %) in 3rd birth order. Previous study also indicated first pregnancy is associated more with CP[9].

Mode of Delivery-Maximum number of patients i.e. 32 (80%) were delivered normally, 7 (17.5%) patients by LSCS and 1 (2.5%) by Instrumental delivery. While in all over world data there is strong connection between CP and pregnancy complication and mode of delivery[10] however the increased rate of caesarean section does not change rate of cerebral palsy and perinatal deaths.

Place of Delivery-Maximum number of patients i.e. 30 (75%) were delivered at hospital while 10 (25%) patients were delivered at home.

Foetal Presentation-Maximum number i.e. 36(90%) patients had vertex presentation while 2(5%) patient had breech presentation and others 2(5%).The above consequence may be due to the maximum presentation of vertex in pregnancy however abnormal foetal presentation has strong connection with CP and breech position was found in 13.7% patients of CP as compared with 6.0% controls in a study [11].

Birth Maturity-Maximum number of patients i.e. 28 (70%) were born as full term, while 12 (30 %) babies were Pre term. In western countries, higher rate of preterm and LBW due to advanced obstetric care has contributed to higher rate of CP in these infants [10].

Birth Weight-Maximum number of patients i.e. 25 (62.5%) were having history of normal birth weight followed by 10 (25 %) patients were having Low birth weight. In addition to that 3(7.5%) cases were VLBW, and 2 (5%) cases were overweight. The prevalence of CP among very low-birth weight (VLBW) infants (<1500 g) is 40 to 100 times higher than in normal weight infants and VLBW infants, who constitute only 0.68% of newborn survivors, contribute up to 28% of children with CP[12].

Birth Asphyxia -23 patients (57.5%) had a positive history of birth asphyxia while in 11 (27.5%) patients history of birth asphyxia was absent. In 6 (15 %) patients the reports were not available. The data highlights the birth asphyxia as an important contributor to CP in India. This is similar to other studies conducted in Nigeria, Malta, and other developing countries [12].

Pre Natal Factors-Maximum number i.e. 34(85%) of mothers had history of normal health status during pregnancyhypertension (HTN) 2(5%).Eclampsia, Thyroid, HTN, Twins, Jaundice, diabetes and anemia all were 1(2.5%).Prenatal factors that have the potential of causing CP are present in a significant number of children with CP.70% of term infants present with CP have a history of one or more adverse prenatal factors [12].

Natal factors-Maximum causes contributing to CP during natal period was history of Birth Asphyxia in 23 (57.5%), Fetal Distress was found in 22 (55%) cases, prolonged II stage of labour in 21 (52.5%) cases , Prematurity in 12(30%) patients, LBW in 11(27.5 %) patients.h/o Caesarean was present in 6 (15%) cases, Meconium stained liquor in 3 (7.5%) cases, while H/o Instrumental delivery in 1(2.5%), Cord around neck in 1(2.5%) and Breech presentation in 2 (5%) cases each.

Post Natal factors-Maximum number i.e. 23 (57.5%) cases presented with respiratory distress syndrome (R.D.S.), neonatal cyanosis 12(30%). Hyperbilirubinemia 10(25%), Seizures 6 (15%), Intracranial haemorrhage 3 (7.5%), Neonatal sepsis in 3(7.5%), Hypoglycaemia 1 (2.5%).Among the various above mentioned factors, studies are available for different factors worldwide which increases the risk of CP, like gestational age less than 32 weeks 29.3%, multiple birth 6.62%, breech

position 13.7%, bleeding at any time in pregnancy 29.3%, multiple miscarriage 7.7% smoking 14.0%,drug use 3.3%.[11]

Associated problems-Maximum number of associated problem with CP werefound speech problems 28 (70%), drooling of saliva 26 (65%) and Pallor in 24(60%) patients followed by feeding problems21(52.5%) then malnutrition in 17 (60.7%) patients, eye problem in 16(40%) , sleep disturbance in 14(35%), constipation in 9(22.5%), mental retardation (MR) in 9((22.5%), contractures in5 (12.5%), Teeth problems in 1 (2.5%) and 1 (2.5%) with hearing defects. Associated problems are very common in CP according to the location of brain lesion one data shows Mental retardation was common in 25-30% of cases, epilepsy in 25-45% of cases, sensory impairment in 14% of full term infants and behavioural problems were common in 25.5% of cases[12].

Topographical Classification-Maximum number of patients i.e.25 (62.5%) were found to be Diplegic followed by 11 (27.5%) patients Quadriplegic in nature. 4 (10%) cases were found to have Hemiplegic pattern. The above results were slightly contradictory with Indian data showing spastic quadriplegia in 61% cases followed by spastic diplegia 22%[13] while world wide data nearly similar to the above data showing quadriplegia, hemiplegia, and diplegia constitute 36%, 32%, and 22% of cases, respectively[12] however due to small sample size the exact results are difficult to interpret.

Statistical Analysis

Students paired‘t’ test was applied for statistical improvement analysis in the clinical features of Cerebral palsy in single group and unpaired ‘t’ test for statistical status of intergroup differences of clinical features. The results were interpreted.

Table no. 02 showing results in Group A (after treatment)

Parameter	Mean (n=20)			%	S.D.	S.E	‘t’	‘p’	Result
	B.T.	A.T.	Diff.	Change	(±)	(±)	value	value	
GMFCS	3.850	3.050	0.800	20.77	0.523	0.117	6.839	<0.0001	E.S.
Neck Holding	3.650	4.600	-0.950	26.03	0.887	0.198	4.790	0.0001	E.S.
Sitting	2.750	4.050	-1.300	47.27	0.864	0.193	6.725	<0.0001	E.S.
Standing	1.450	2.850	-1.400	96.55	0.820	0.183	7.628	<0.0001	E.S.
Spasticity in Rt UL	1.525	0.700	0.825	54.09	0.466	0.104	7.906	<0.0001	E.S.
Spasticity in Lt UL	1.550	0.700	0.850	54.83	0.400	0.089	9.488	<0001	E.S.
Spasticity in Rt LL	1.700	0.900	0.800	47.05	0.377	0.084	9.491	<0.0001	E.S.
Spasticity in Lt LL	1.725	0.925	0.800	46.37	0.299	0.066	11.96	<0.0001	E.S.
Power in Rt UL	3.200	4.250	-1.050	32.81	0.510	0.114	9.200	<0.0001	E.S.
Power in Lt UL	3.100	4.150	-1.050	33.87	0.394	0.088	11.91	<0.0001	E.S.
Power in Rt LL	3.050	4.250	-1.200	39.34	0.523	0.117	10.25	<0.0001	E.S.
Power in Lt LL	2.950	4.150	-1.200	40.67	0.410	0.091	13.07	<0.0001	E.S.
Barthel Score	22.45	39.70	-17.25	76.83	5.270	1.178	14.63	<0.0001	E.S.

Table no. 03 showing results in Group B (after treatment)

Parameter	Mean (n=20)			%	S.D.	S.E	't'	'p'	Result
	B.T.	A.T.	Diff.	Change	(±)	(±)	value	value	
GMFCS	3.750	3.400	0.350	9.33	0.489	0.109	3.199	0.004	V.S.
Neck Holding	4.100	4.600	-0.500	12.19	0.607	0.135	3.684	0.001	V.S.
Sitting	2.950	3.500	-0.550	18.18	0.686	0.153	3.584	0.002	V.S.
Standing	1.700	2.350	-0.650	38.23	0.812	0.187	3.577	0.002	V.S.
Spasticity in Rt UL	1.400	0.850	0.550	39.28	0.394	0.088	6.242	<0.0001	E.S.
Spasticity in Lt UL	1.425	1.000	0.425	29.82	0.327	0.083	5.101	<0.0001	E.S.
Spasticity in Rt LL	1.700	1.225	0.475	27.94	0.443	0.099	4.790	0.0001	E.S.
Spasticity in Lt LL	1.725	1.200	0.525	30.43	0.379	0.084	6.185	<0.0001	E.S
Power in Rt UL	3.250	3.750	-0.500	15.38	0.513	0.114	4.359	0.0003	E.S.
Power in Lt UL	3.300	3.800	-0.500	15.15	0.513	0.114	4.359	0.0003	E.S.
Power in Rt LL	3.000	3.400	-0.400	13.33	0.502	0.112	3.559	0.002	V.S.
Power in Lt LL	3.000	3.400	-0.400	13.33	0.502	0.112	3.559	0.002	V.S.
Barthel Score	27.55	40.20	-12.65	45.91	4.295	0.960	13.17	<0.0001	E.S.

E.S.- extremely significant, V.S.- very significant

Effect on GMFCS

This is the most important scale representing the evaluation of the therapy changes in the cerebral palsy. In the above results *panchkarma* procedures & yoga postures as a standard management for cerebral palsy brought very significant results after end of the trial. However in the 2nd month they were not significant in group B. Above all group A shown extremely significant changes at the end of trial which proves that oral drug with *panchkarma* along with yoga postures were showing better result than group B.

Effect on CDC

The CDC scale was used for the comparison of gross motor milestone achievement. *Panchakarma* with *abhyanga* and *shalishastika* give a proper massage to the portion improving blood circulation and as a result power also increases .On this phenomenon oral drug along with *panchakarma* procedures& yoga postures contribute special effect of muscle relaxation makes a outcome of enhanced neck holding. Patients in both groups had already achieved neck holding. So the change in neck holding in terms of percentage is not very satisfactory.

Sitting results are very much better compared to the neck holding. *Yoga* postures can be most conveniently performed in the limb areas but trunk areas were not properly affected by it. In both groups *panchakarma* help in proper massaging of all the body muscles hence giving a additional support with yoga postures, that is why better trunk control was observed yielding a proper sitting in these groups.

Group A shows better results than group B in standing concern, due to help of stretching exercise along with *panachkarma* &oral drug having muscle relaxant and muscle strengthening property. Both Groups had subjects who were not able to stand properly or walk properly; therefore, the change seen in both groups was much better in terms of percentage.

Effect on Spasticity

In both groups *abhyanga* with *ksheerabala*

oil, *shashtika skali pinda sweda* and *shirodhara* along with proper stretching provided by *yoga postures* has contributed a good result. While group A has additional benefit of oral drug having skeletal muscle relaxant property shown best results over group B.

In the intergroup comparison the left side of both upper and lower limb shown statistically significant changes in comparison to the right side may be because of presence of right hemiplegic patients in group A who responded well toward their left side comparative to rigid right side.

Effect on Power

Lower limb muscles are most prone muscle for severe form of spasticity and the thing become more problematic due to their weight bearing nature. But from the percentage change and result significance we can say that group A is more efficacious than group-B, which proves the effectiveness of oral drug. Oral drug posses the character of nerve regeneration, synaptic reconstruction and neuronal arborisation which help in repairing the brain damage along with facilitating the effect of neuronal plasticity on the other normal nerve fibres.

Discussion on the overall results of Barthel score

Barthel score assess the child performance in daily activities. In this study most of the time, all activities become significant at the end of trial except ambulation where both group were significant at the end of 6th month and also in the chair bed transfer where none of the group was able to achieve any significant result. This variation occurred due to the increase in the power of upper limb especially in the distal parts so those performances which were performed by the distal part of the upper limb shown better result. Among these functions the intergroup comparison showed statistically significant results in group A over group B.

On the contrary of the above statement the fine works like dressing and personal hygiene were still not shown significant result while the improvements among the months are always significant.

Improvement in the bowel and bladder habit shows systemic effect of the oral drug which shows the efficacy of drug as muscle relaxant. In most of the scales tetra pelagic do not respond too much but in the bowel and bladder they improved well due to systemic effect of oral drug.

Mode of action of the oral drug

The oral drug possesses antispastic[14], effect in diskinesia[15] and ataxia[16], known to induce Neuritic regeneration and synaptic reconstruction effect[17]. Also shows Protective effect on cerebral ischemic injury [18] and smooth muscle relaxant activity [19], which is very much significant in management of cerebral palsy in children.

Mode of action of Procedures

Abhyanga

The effect of *Abhyanga* can be assumed in two way i.e. physical manipulations and the medicinal effect of the drug in the medicated oil. Physical manipulation in the form of massage increases the circulation of blood and plasma, it can stimulate and strengthen the lymphatic system and remove internal waste products. Muscles and deep connective tissues get relaxation. Nerve endings seated in skin and muscle spindles get stimulated. A study also supports the role of *ksheerbalaTaila* in neuromuscular disorders [20].

***Shali shastika pinda sweda* (SSPS)**

The procedure SSPS seems having significant *Vata Shamaka* properties along with *Abhyanga*. *Abhyanga* and SSPS (Oleation and Fomentation) are contradictory to the *Guna* of *Vata* viz. *Sheeta, Ruksha* etc. In addition medicines used in these procedures like *Shashtika Shali,* Milk*, Bala* and *Taila* also having anti Vata properties. This fact has also been supported by the findings of present study as *Abhyanga* along with SSPS provided significant relief in major symptoms of Cerebral Palsy like spasticity, exaggerated tendon reflex, diminished muscle power etc. This strengthening fomentation is used to improve muscle strength. The whole process becomes a kind of physiotherapeutic procedure.

Shirodhara

In a research study by Kazuo Ubeba et al shown that the 30 minutes per day of *shirodhara by*

tila taila, showed deep restfulness with less anxiety in the research subjects. Shirodhara induced bradycardia and the relative suppression ofLF/HF power spectrum density, which indicated lowered sympathetic tone. Expired gas analysis showed a decreased tidal volume and CO2 excretion. The EEG showed the slowing of the α wave, an increase in α and θ activity and an increase in right-leftcoherence. These metabolic, ECG, and EEG findings support the reported experiences of relaxed and low metabolic states during *shirodhara*.

Physiological changes during s*hirodhara* shows a-wave dominance in the frontal area and a decrease in heart rate and CO2 excretion. These findings indicated a change in the function of the frontal lobe, limbic system, brain stem, and autonomic nervous system. This shows the anxiolytic effect of the shirodhara showing decrease in noradrenaline ration exhibiting sympathlytic effect[21]. Further another study shown the positive effect on the balance in progressive degenerative cerebellar ataxia using *shirodhara* along with other treatment procedure [22].

Effect of *Yogic* Postures (*Asanas*) Apart from the common methods of treatment, *Yogic* Postures (*Asanas)* help to reduce high muscle tone in children with Cerebral Palsy. When the *asana* is being performed, the muscles and tendons stretch and the overall rigidity of muscles and joints is reduced. Simultaneously these *Yogic* Postures (*asanas*) provide a small amount of resistance and low muscle tone areas are also exercised. So the dual benefit of improving both low and high muscle tone is achieved. Sitting poses provide stability in the spine. Some of them create flexibility in the backs of the legs. Since most sitting postures create parasympathetic stimulation, they create a pleasant calming influence. Standing poses increase general strength and energy levels. Backbends tend to excite us (sympathetic stimulation), increase spinal extension, and create strength in the trunk elevator muscles. Relaxation poses even out and calm the energies created by our *asana* practice. All *asana*, whether in groups or individually, have their own energetic depending upon what they do to the body.

Conclusion

Role of *Vata* in causation and disease presentation; improvement with its treatment protocol puts the disease entity nearer to *Vata Vyadhi* or *Vata* predominant condition. Multi system involvement in this disorder needs multidisciplinary approach using drugs having multifactorial effect. In combined therapy group A having Oral drug, *panchkarma* procedure along with *Yoga* postures, all of them present with the synergistic effect in the management of Cerebral Palsy that is why results are more pronounced. Therefore it can be concluded that study drug *Badaradi yog* and *panchkarama procedures w*ith Yoga postures are effective treatment modalities and can be used efficiently in the management of Cerebral palsy. No any adverse effects of procedure and drug were seen in this trial.

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Clinical Study

A Clinical Study To Evaluate The Efficacy of *Vamana* And *Nasya Karma* In The Management of *Peenasa* W.S.R. To Sinusitis

*Dr. Sarmah Jayanta, **Dr. Mangal Gopesh

Abstract

Peenasa is a disease of *Kaphavata* dominance situated in *Jatrurdhva* characterized by *Kshavathu, Nasasrava, Nasanaha, Shirogourava. Acharya Sushruta* used the term *Apeenasa* to described *Peenasa.* The sign and symptoms of *Peenasa* can be correlated with sinusitis in modern system of medicine. Sinusitis is a chronic troublesome disease which is having impact on physical, financial and social aspects of life. Incidence is high both in India and abroad. In modern system of medicine there is symptomatic management with surgical correction. The worldwide incidence of Sinusitis is recorded as 31 million cases in US that is 146 per 1000 population, and in Indian incidence is estimated that 134 million Indians are suffering from chronic sinusitis. One in eight Indian suffers from chronic sinusitis caused by the inflammation of the Para nasal sinuses. Among Indians this disease is more widespread than diabetes, asthma or coronary heart disease. The study had been conducted on 30 patients of *Peenasa* (Sinusitis) which were divided in to two groups and were given treatment for 1 months and follow-up after two months. *Nasya Karma* done for 14 days with *Pathadi Taila* in Group A. *Vamana Karma* followed by *Nasya Karma* with *Pathadi Taila* in Group B. It was observed that both groups were effective in *Kshavathu, Nasasrava, Nasaavarodha, Shira Shoola ,Ashrusrava,* and *Mukhadaurgandhya* in the management of *Peenasa* (Sinusitis) as a fact improvement in all the symptoms cannot be attend only by this treatment.

Key Words: *Peenasa*, *Vatakapha Vyadhi*, *Nashya Karma, Vamana Karma.*

सारांश–

पीनस उर्ध्वजत्रुगत प्रदेश मे होने वाला क्षवथु, नासानाह, शिरोगौरव की विशेषता वाला कफवात प्रभुत्व का एक रोग हैं। आचार्य सुश्रुत ने पीनस के लिए अपीनस शब्द का प्रयोग किया है। पीनस के लक्षण चिकित्सा के आधुनिक तंत्र में साइनोसाइटिस के साथ सहसंबद्ध हो सकते हैं। साइनोसाइटिस एक जटिलतम व्याधि है जिसका प्रभाव शारीरिक, मानसिक, आर्थिक और सामाजिक सभी स्तर पर पड़ता है इसका विस्तार मधुमेह दमा और हृदरोग से भी ज्यादा है। साइनोसाइटिस के दुनिया भर में 146 रोगी प्रति 1000 जनसंख्या है, और भारतीय संदर्भ में अनुमान है कि 134 मिलियन भारतीय पुरानी साइनोसाइटिस से पीड़ित हैं अमेरिका में 31 मिलियन मामले दर्ज है। अध्ययन पीनस (साइनोसाइटिस) के 30 रोगियों जो दो समूहों में विभाजित किया गया और 1 महीने के लिए उपचार दिया और अनुवर्ती दो महीने के बाद किया गया था। नस्यकर्म समूह ए में पाठादि तैल के साथ 14 दिनों तक एवम समूह बी में वमन कर्म के बाद नस्य दिया गया था। देखा गया है कि दोनों समूह क्षवथु, नासानाह, शिरोगौरव, शिर शूल, अश्रुस्त्राव में प्रभावशाली थे और मुखदौर्गन्ध्य को भी कम किया। लेकिन पीनस (साइनोसाइटिस) का प्रबंधन, सभी लक्षणों में सुधार इस अकेले उपचार से नहीं हो सकता है।

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Clinical Study

A Clinical Study To Evaluate The Efficacy of *Vamana* And *Nasya Karma* In The Management of *Peenasa* W.S.R. To Sinusitis

Dr. Sarmah Jayanta, Dr. Mangal Gopesh

Introduction

Vata, Pitta and *Kapha,* the three basic pillars of *Ayurveda* and body. Any disturbance in their normal physiology produces diseases. *Peenasa* is described as *Vatakaphaj Vyadhi*. *Acharyas* mentioned that *Peenasa* is a *Krichasadhya Vyadhi*. *Ayurveda* has broadly clarified treatment into three parts i.e. *Nidan Parivarjana*, *Shodhan* and *Shaman Chikitsa*. *Acharya Sushruta* used the term *Apeenasa* to described *Peenasa*.[1] *Acharaya Charak* had specially designed a peculiar treatment for it. The description of *Peenasa* can be interpreted with sinusitis. Modern medical science attributes this condition as inflammation of the paranasal sinuses, which may be due to infection, allergy, or autoimmune issues. Sinusitis is the inflammation of the mucosa of any one or all of the paranasal sinuses. When all sinuses are involved it is called as pansinusitis. In modern medicine the treatment of sinusitis is as general and local management. In general management use of antibiotics, decongestants, analgesics, and anti-histamines are used. As local treatment use of nasal decongestant drops, steam inhalation, fomentation or short wave diathermy, adrenaline may be applied in the region of middle meatus to decongest the mucosa, and antoral puncture. With advent of modern drugs, the pattern of disease has grossly changed, where the drugs only assuage the symptoms temporarily and the underlying pathology goes on progressively to worsen the condition. Though ample research is being carried out for alleviating the disease and new avenues are being explored for treating early stage of the disease. Therefore, the *Ayurvedic* therapeutics has attracted considerable glamour for providing safe and effective remedies. Numerous researches have been done time and again to reprove the worth of these medicaments. Yet there is a necessity for perusing further research to find out some safe, effective and cheap remedy.

Need of Study

The clinical condition similar to *Peenasa* in modern medical science is described by the term sinusitis. The worldwide incidence of sinusitis is recorded as 31 million cases in US, that is 146 per 1000 population, and in Indian incidence is estimated that 134 million Indians are suffering from chronic sinusitis. One in eight Indian suffers from chronic sinusitis caused by the inflammation of the Para nasal sinuses. Among Indians this disease is more widespread than diabetes, asthma or coronary heart disease. Taking all the above points into consideration, its poor prognosis and nature of chronicity, the disease was selected, to find a measure that could help in restoring quality in life of patients. Although a number of projects have been carried out using the principle of *Charaka* at various research institutes, we have evolved a different pattern of treatment which falls under the principles boundaries of *Acharya Sushruta* in which *Shodhana* i.e. *Vamana Karma* and *Acharya Charaka* mentioned about *Nasya Karma* with *Pathadi Taila*.

A sincere effort has been made to evaluate the combined effect.

Aims And Objectives

- ⇨ To evaluate the efficacy of *Nasya Karma*.
- ⇨ To evaluate the efficacy of *Vamana Karma* and *Nasya Karma* in *Peenasa*.

Materials And Methods

The present study was carried out in two parts, i.e. literary and clinical. For literary part different textbooks of both school of medicine were utilized. The *Ayurvedic* concepts were understood on the basis of the authentic classical texts, while for modern aspect, various textbooks on E.N.T, reference books and various journals were referred.

Various sites on the internet related to the subject were also surfed.

A) Patients:- Patient fulfilling all the section (inclusion & exclusion) criteria visiting NIA OPD, IPD, P.G. department of Panchakarma, National Institute of Ayurveda, Jaipur.

B) Laboratory:- Assistance was taken from central lab of NIA hospital.

C) Drug:- Drug used in the trial was prepared in the pharmacy of NIA Jaipur.

Inclusion Criteria

- Age between 18 to 65 years.
- Presence of cardinal features of *Peenasa* (sinusitis).
- History of at least 4 episodes in last 1 year.
- Patients fit for *Nasya* and *Vamana Karma*.

Exclusion Criteria

- Age below 18 years and above 65 years.
- Patients suffering from other infectious diseases.
- Patients suffering from severe systemic disorders like HTN, D.M, cardiac and respiratory pathology, renal pathology etc.
- Patients who are not fit for *Nasya* and *Vamana Karma*.

Discontinuation Criteria

- Patients not willing to continue treatment.
- Patients developing life threatening complication during treatment.
- Any other acute illness.

Duration - One month duration for treatment and follow-up after two months.

Management Of Patients:

After diagnosis, the patients were randomly divided into following two groups,

Two groups :-

Group A: The patients of this group were treated by *Nasya Karma*[2] with *Pathadi Taila for 14* days, with proper *Abhyanga* and *Swedana of the* supra clavicular region prior to *Nasya*.

Group B: The patients of this group were also treated *Vamana Karma*[3] then advised *Samsarjan Krama* followed by *Nasya Karma* with *Pathadi Taila* for[4] 14 days.

***Poorva-karma* includes**

Deepan - Pachana - It was done to brought in the normal condition of appetite of the patient.

Snehana-Pana[5] – It was done with *Go-ghrita* up to the appearance (duration of minimum 3 to maximum 7 days) of *Samyaka Snigdha Lakshana*.[6] During this time period patients were instructed to follow special code and conduct, which include *Ahara* and *Vihar* both.

Ahara[7] – *Drava, Usna, Ana-abhisyandi, Na-ati-sankirna* and *Snigdha Bhojana*, warm water.

Vihar[8] – *Bramha-chari jeevana*, avoid day sleep, not arresting natural urges, avoiding heavy exercise, loud speak, anger, depression, too much cold, hot and airy places.

Abhyanga – Swedana – After completion of *Snehapana*, patients had under gone with *Abhyanga* with *Doshmool Tail* & *Swedana* with *Dashmool- kwath steam* for 3 days.

Pradhana-karma[9] -

On 3rd days they were conduct *Vamana Karma*, conduct with *Madanphal Pippali* early in the morning after *Abhyanga* and *Swedana*.

Paschata-karma[10] -

According to the *Vaigaki,* and *Antaki Lakshana*[11] patients were advised for *Samasarjana Krama*.[12]

Investigations Performed

Following investigations were advised to exclude the cases as per the exclusion criteria's as mentioned earlier.

1. Blood for TLC, DLC, ESR, Hb %, AEC.
2. X-ray PNS.

Criteria For Assessment:

A) Subjective Improvement

Improvement in the following subjective sign and symptoms were assessed.

1. *Kshavathu* (Sneezing)
2. *Nasa Srava* (Nasal Discharge)
3. *Nasa Avarodha* (Nasal Blockage)
4. *Shirogourava* (Heaviness of head)
5. *Shirashoola* (Headache)
6. *Ashrusrava* (Lacrimation)
7. *Mukha Dourgandhya*. (Halitosis)

Observations And Results:

For the clinical study, 30 clinically diagnosed and confirmed cases of *Peenasa* (Sinusitis) were registered on the basis of a specially designed performa prepared for the purpose. No any cases were dropped out from the study in the initial phase of trial and the study was carried out by following complete protocol in 30 cases. All the patient treated *Vamana Karma* and *Nasya Karma* with *Pathadi Taila* were very well and no side or toxic effects in was trial were observed. *Peenasa* involves *Vatakapha Doshas*, which makes the disease *Krichra-Sadhya*. The results were assessed in regard to the clinical signs and symptoms, functional capacity of the patient, degree of disease activity and the overall improvement. The overall effect of therapy was assessed in terms of major improvement, minor improvement and unimproved or progression. Observation and results are described below.

The observations made on the 30 patients of *Peenasa* of this series showed that maximum number of patients 56.6 % were in the age group of 20-30 years, male and female were 66.67 % and 33.33 % respectively, majority of patients, were *Hindu* i.e. (83.33%), maximum 56.67 % were student. 43.33 % were from lower middle socio-economic status, maximum 56.67% were living in urban area, Maximum number of patients i.e. 53.33% had positive family history of allergy. Maximum number of patients i.e. 83.33% were *Niramisha* food habit, maximum number of patients i.e. 50% were having history of *Vishamashana*, Dominant *Rasa* wise maximum number of patients i.e. 50% were having preference of *Madhura Rasa*. Appetite wise 50% had good appetite. Maximum number of patients i.e. 67.67% was giving history of regular bowel habit. 83.33% had Sound sleep. Bathing habit wise maximum number of patient's i.e. 70% had habit of cold water bathing, Nature of work wise maximum number of patients i.e. 50% had history of moderate work. Distribution of patients according to *Prakriti* of the patient, most of the patients of the study group belonged to *Vatakaphaja Prakriti* i.e 63.33%, *Manas Prakriti* wise maximum number of patients i.e. 76.67% were of *Rajasika Prakriti*, Sara wise distribution maximum number of patients i.e. 73.33% were o*f Madhyam Sara*, *Kostha* wise 36.67% were *Madhyam Kostha*.

Fifteen patients were given *Snehapana* in group B prior to *Vamana Karma* and *Samyak Snigdha* wise distribution in 4-6 days i.e. 66.67%. Fifteen patients were conduct *Vamana Karma* and *Veigiki Suddhi* wise distribution of patient maximum eight *Vegas* were observed in 66.67% of patient. Maximum number of patients i.e. 73.33% had *Madhyaabhyavaharana Shakti*. 36.67% patient had history of aggravating of disease in dusty environment.

Table no 1. Clinical improvement in the symptoms of *Peenasa* (Sinusitis) in Group-A

Symptoms	B.T.	A.T.	Diff.	%	S.D.	S.E.	t	P
Kshavathu	2.66	2	0.73	27.5	0.45	0.11	6.20	<0.001
Nasasrava	2.2	1.53	0.66	30.30	0.61	0.15	4.18	<0.001
Nasa Avarodha	2.6	1.73	0.86	33.33	0.51	0.13	6.5	<0.001
Shiro Gourava	1.6	1.26	0.33	20.83	0.61	0.15	2.09	<0.05
Shirashoola	1.73	1.13	0.6	34.61	0.50	0.13	4.58	<0.001
Ashrusrava	0.86	0.4	0.46	23	0.51	0.13	3.5	<0.05
Mukha dourgandh	0.4	0.26	0.13	33.33	0.35	0.09	1.46	>1

Highly significant results were obtained in *Kshavathu, Nasasrava, Nasaavarodha* and *Shirashoola* i.e. p<0.001. Significant results were obtained in *Shirahgourava* and *Ashrusrava* and insignificant result found in *Mukhadaurgandhya* i.e. P >1.

Figure no 1

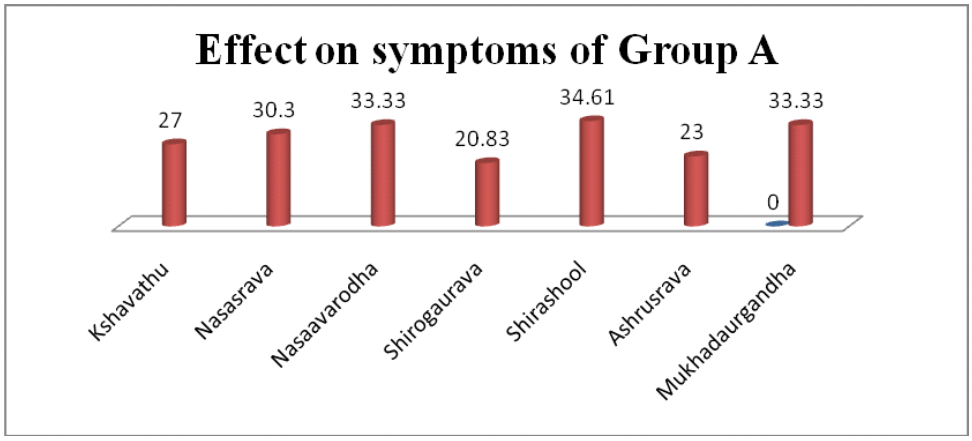


Table no-2 Clinical improvement in the symptoms of *Peenasa* (Sinusitis) in Group-B

Symptoms	B.T.	A.T.	Diff.	%	S.D.	S.E.	t	P
Kshavathu	2.2	0.8	1.4	63.63	1.24	0.32	4.36	<0.001
Nasasrava	2.8	1	1.8	64.28	0.86	0.22	8.08	<0.001
Nasa Avarodha	2.86	1.4	1.46	51.16	0.51	0.13	11	<0.001
Shiro Gourava	2.4	0.8	1.6	66.66	1.05	0.27	5.8	<0.001
Shirashoola	1.53	0.4	1.13	73.91	0.83	0.21	5.26	<0.001
Ashrusrava	0.33	0.13	0.2	60	0.41	0.10	1.87	<0.05
Mukha dourgandh	1.4	0.53	0.86	61.90	0.91	0.23	3.66	<0.005

Effect on associated symptoms of group B – Highly significant results were obtained in *Kshavathu, Nasasrava, Nasa avarodha, Shira gourava, Shirashoola* i.e. p<0.001. Significant result was found in *Mukhadaurgandhya* i.e. p<0.005 and insignificant result was obtained in *Ashrusrava* i.e.p<0.05.

Figure no-2

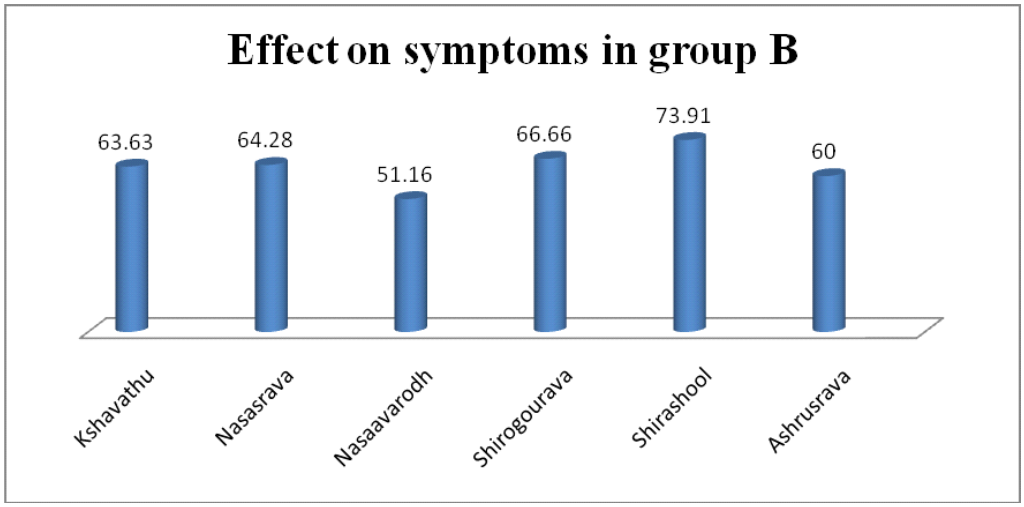
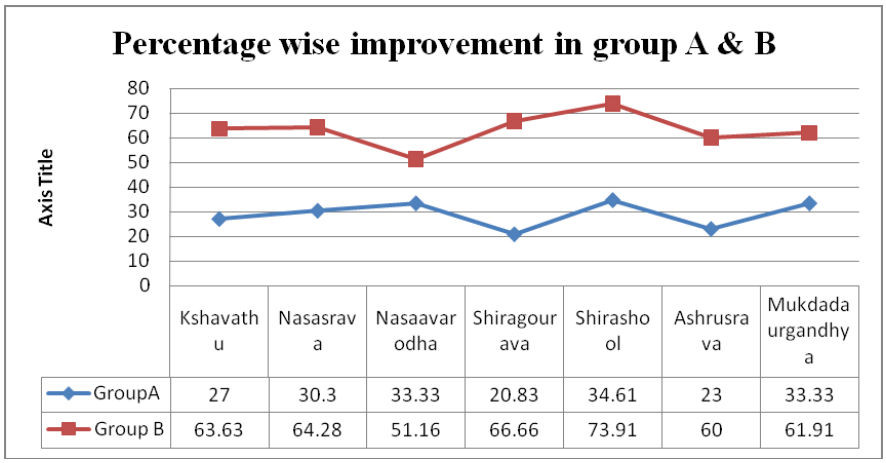


Figure no-3, Comparison of percentage wise improvement in group A & group B



Discussion:

Probable Modes Of Action Of Therapy

1. *Abhyantara Snehapana* (internal oleation) with *Go-ghrita*. *Ghrita* is best known for its *Vata*, *Kapha* and *Pitta Shamak* property, which helps to migrate the vitiated *Doshas* from *Shakhas to Kostha*.

2. *Swedana* (*Sarvanga Swedana*) (Fomentation/Sudation Therapy) *Swedana* removes *Stambha* (stiffness), *Gaurava* (Heaviness), *Shita* (coldness) and produces sweating indicating different effects achieved by *Swedana*. *Swedana* causes sweating, dilates the *Srotas* (micro channels) and helps to cleanse the *Srotas* as well as brings the adhering *Ama Dosha* to *Kostha* for *Shodhana*.

3. Nasya Karma- The *Panchakarma* procedure where medicaments administered through nose is called as *Nasya*, Best method to eliminate and alleviate the vitiated *Doshas* of *Urdhvanga*.

***4. Vamana Karma* (Medicated Emesis)** *Charak* defined *Vamana* as a process in which morbid *Dosha* are eliminated through upper channels[13] i.e. mouth. *Chakrapani* mentions *Urdhavabhaga* as *Urdhavamukha*. *Bhavaprakasha* also has same opinion for *Urdhva as Mukhamarga*. *Vamana* is a process in which *Apakva Pitta* and *Kapha* are removed forcefully through upper channels.[14]

***5. Sansarjan Krama* (Post Procedure diet and regimen:** *Vamana Karma* temporarily diminishes the *Kosthagni* (Digestive fire). *Peyadi Samsarjan Krama* was given as post *Shodhana* regimen to regulate the ignited *Agni*.

Probable mode of action of *Nasya*

Nasa being door way to *Shira*,[15] the drug administrated through nostrils reaches *Sringataka*, a *Siramarma* by *Nasa Srota* and spreads in the *Murdha* (Brain), taking routes of *Netra* (eyes), *Shrotra* (ears), *Kantha* (throat) *Sira and Mukhas*[16] the morbid *Doshas in Urdwajatru* and extract them from *Uttamanga*. We are using the *Mridu Paka* for the drug preparation for *Pathadi Taila* which means that the *Nasya* medicine should contain water soluble as well as fat soluble active principles. The aqueous part of the active principle will be easily absorbed through mucous membrane (Nasal mucosa, olfactory mucosa) and fat soluble active principle can be easily assimilated through nerve endings (Trigeminal and olfactory). The preoperative procedures (*Poorvakarma*) of *Nasya Karma* play a major role in the access of the drug into the body. The lowering of the head, elevation of lower extremities and fomentation of face seems to have an impact on blood circulation of the head and face. As the efferent vasodilator nerves are spread out on the superficial surface of the face, receives stimulation by fomentation and it may engender the increased blood flow to the brain. Lowering of head plays a major role in the spread of medicine to the sinus ostia.

The drugs used in the preparation of '*Pathadi Taila*'[18] are *Patha, Haridra, Daruharidra, Murba, Pippali, Dantimool* and *Jatipallav* they are dominance of *Laghu, Teekshna* in *Guna* and *Katu,*

Tikta Rasa, Katu Vipaka and *Ushna* in *Veerya*. All these drugs having *Kapha Vata Nasak* and *Srotoshodhak* properties .

As we know from the above study that *Peenasa is a Kaphavata* predominance disease and the property of *Pathadi Taila* is opposite to the quality of *Kaphavata* as its local effect of elimination of vitiated *Doshas* from *Nasa Marga* and gives relief from *Peenasa*.

Probable mode of action of *Vamana*

In *Peenasa*, *Vata and Kapha* are the main vitiated *Doshas* involved. Therefore *Acharya Susruta* and specially mentioned the role of *Vaman Karma*[19] in the management *of Peenasa*. *Vaman Dravyas* are having the properties *Vyavayi* and *Vikasi* by virtue of *Veerya* (Potency) they get quickly circulate into large and small capillaries of the body.[20] It pervades all over the body. By virtue of its *Ushna* and *Teekshna* properties, the accumulated *Doshas* get liquefies and breakup into small pieces at cellular level. *Doshas* started melting in the body due to *Ushna Guna,* we can observe the perspiration (*Swede Pradurbhava*) on patient's forehead or sometimes whole body.[21] Because of its *Vikashi Guna*, it detaches the *Malas* from *Dhatus*. Owing to the presence of *Sukshma Guna* and *Anupravana* properties the *Malas* or *Doshas* float because already body has got *Smayak Snigdhata* (internal oleation) and pass through smallest capillaries and ultimately *Malarupi Kapha* reaches to stomach from *Nasa Marga*. *Vamana Karma* is radical therapy to treat *Kapha* disease. *Vamana karma* which corrects the pathology by eliminating disease causative factor *Kapha* from its main site of accumulation. *Vamana* cleanses the different types of toxic materials from the body.

Conclusion

In *Ayurvedic* classics, the term *Peenasa* covers a broad spectrum of nasal and paranasal infections. Regarding the prognosis of *Peenasa* different opinions are available. *Acharya Susruta* described it as *Krichrasadhya*, *Vagbhata as Yapya* and *Charaka* and *Madhavakara* opined it as *Asadhya*. Majority of ingredients of *Pathadi taila* are having *Laghu, Trikshna* in *Guna* and *Katu, Tikta Rasa, Katu Vipaka* and *Ushna* in *Veerya*. All these drugs having *Kapha Vata Nasak* and *Srotoshodhak* properties. Finally it can be concluded that combined therapy of *Vamana Karma* and *Nasya Karma* with *Pathadi Taila* was more effective in the management of *Peenasa*(Sinusitis) as compared to the individual treatments.

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Clinical Study

Acute toxicity Study of *Sanjeevani Vati* according to OECD Guideline 420

**Dr. Arun Kumar Dutta, **Dr. Richa Sharma, ***Dr. R. K. Sharma (Chulet)*

Abstract

The Present Study was planned to assess the acute toxicity of *Sanjeevani Vati*. Rats were orally administrated single dose of rate of 22.5 mg, 45 mg, 225 mg, 450 and 675 mg/kg of aqueous extract of *Sanjeevani Vati*. Mortality, signs of toxicity, body weight, food consumption and gross findings were observed for 14 days post treatment of *Sanjeevani Vati*. Results from the present study have elucidated that treatment of *Sanjeevani Vati* exerts no significant signs of toxicity at any dose level used in the study. Physical, biochemical as well as hematological parameters was unaltered throughout the study. The results of study have suggested there was no obvious toxicity observed with the treatment of *Sanjeevani Vati*.

Keywords: Toxicity, *Sanjeevani Vati*, Mortality etc.

सारांश :

संजीवनी वटी की तीव्र विषाक्तता को जांचने हेतु यह अध्ययन किया गया। चूहों को संजीवनी वटी की एकल मात्रा 22.5 मि.ग्रा. प्रतिकि.ग्रा., 45 मि.ग्रा. प्रतिकि.ग्रा., 225 मि.ग्रा. प्रतिकि.ग्रा., 450 मि.ग्रा. प्रतिकि.ग्रा., 675 मि.ग्रा. प्रतिकि.ग्रा. के परिमाण में मुख द्वारा दी गई। मृत्युदर, विषाक्तता चिन्ह, शरीर भार, खाने का परिमाण एवं अन्य बातों का संजीवनी वटी सेवन के 14 दिन पश्चात तक अवलोकन किया गया। प्रस्तुत अध्ययन में इस नतीजे पर पहुंचा गया कि संजीवनी वटी, अध्ययन में प्रयुक्त किसी भी मात्रा की सीमा में विषाक्त प्रभाव नहीं पाये गये। भौतिक, जैवरासायनिक एवं रक्तगत परीक्षण के आधार पर इनमें कोई परिवर्तन नहीं देखा गया। अत: संजीवनी वटी से चिकित्सा करने पर कोई विषाक्त प्रभाव नहीं पाये गये है।

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Clinical Study

Acute toxicity Study of *Sanjeevani Vati* according to OECD Guideline 420

Dr. Arun Kumar Dutta, Dr. Richa Sharma, Dr. R. K. Sharma (Chulet)

Introduction

Acute toxicity is usually defined as the adverse change(s) occurring immediately or a short time following a single or short period of exposure to a substance or substances or as adverse effects occurring within a short time of administration of a single dose of a substance or multiple doses given within 24 hr. An adverse effect is any effect that results in functional impairment and/or biochemical lesions that may affect the performance of the whole organism or that reduce the organ's ability to respond to an additional challenge.[1] If the dose dependent lethality incidence is determined in a precise manner, it is usually expressed as an LD_{50}. This is defined as the statistically derived dose that, when administered in an acute toxicity test, is expected to cause death in 50% of the treated animals in a given period.[2] The purposes of acute toxicity testing are to obtain information on the biologic activity of a chemical and gain insight into its mechanism of action. Long-term studies usually start with a dose-finding exercise under acute conditions. Furthermore, the information on acute systemic toxicity generated by the test is used in hazard identification and risk management in the context of production, handling, and use of chemicals.

Sanjeevani Vati is most popular ayurvedic formulation for pyrexia or *Sannipatik Jwar* among all ayurvedic practitioners. It is included in all books of medieval India known as *Madhya Kaleen Sangraha Granthas* and *Sharangadhar Samhita*[3] is one of them. In some books this formulation has been termed as *Jeevani Vati*[4] and in some books it has been described as *Sanjeevani* with common *Prabhava* of *Sanjeevayati manavam* while the formulation is same means ingredients and ratio of ingredients is same. It is classical example of dose related effect of one medicine in various diseases.

As per *Punarvasu Aatreya* doses are important to know the effect of drug independently or in combination along with method of use, *anupan – sahapana*, proper diagnosis etc. for the treatment. *Sanjeevani Vati* is classic example of such combination where quantity based or dose related indications are described as stated in *Shrangadhar samhita*:

Sanjeevani Vati has been indicated-

— 1 pill of one gunja weight in *Ajeerna*

— 2 pills of one gunja weight each in *Visuchi*.

— 3 pills of one gunja weight each for snake bite

— 4 pills one gunja each in *Sannipaat* or *sannipatik Jwar*.

Sanjeevani Vati is an antipyretic formulation which consist of ten drugs namely *Amalaki* (Embelica officinalis), *Bibhitaki* (Terminalia bellerica), *Haritaki* (Terminalia chebula), *Shunthi* (Zinngiber officinale), *Pippali* (Piper longam), *Vidang* (Embelia ribes), *Vacha* (Acorus calamus), *Guduchi* (Tinospora cardifolia), *Shudha Vatasanab* (Aconitum ferox) and *Shudha Bhallatak* (Semecarpus anacardium).[6]

Aims and objectives:

Acute toxicity study of *Sanjeevani Vati* according to OECD Guideline 420

Inclusion criteria:

- Adult healthy albino rats of either sex.
- Rat weighing 100-150gms.
- Albino rats between 90-120 days were included.

Exclusion criteria:

- Unhealthy albino rats.
- Weight below 100gms and above 150gms.
- Albino rats of below 90 days and above 120 days were excluded.

Materials and Methods:

Preparation of *Sanjavani Vati* Suspension in Gum Acacia[7] 5 % for test Group.

Suspension was prepared by levigation the *Sanjeevani Vati* (963mg, 4904mg, 9400 mg, 10935 mg, 315 mg, 720 mg, and 1080 mg) in 20 ml. Gum Acacia 5 %. Successive portion of the vehicle are used to wash the mortar, to transfer the suspension quantitatively in volume make up 100 ml. The preparation may be homogenized to ensure a uniform final dispersion. Six test sample was stored in a suitable and sterile labeled (a, b, c, d, e, f) containers.

Experimental Animals

The experiment was carried out on albino rat of either sexes, weight of rat 100 to 150 gm. Number of Animals – 36. The study was approved by the Institutional Animal Ethics Committee (IAEC) of Arya College of Pharmacy, Kukas, Jaipur, India and according to CPCSEA guideline. Registration no: 1013/P0/c/CPCSEA. The rats were acclimatized to the laboratory conditions for at least five days prior to commencement of the experiments. Animals were kept in polypropylene cages with paddy husk bedding. The temperature in the experimental room was around 24^{0}C. Lighting was natural, the sequence being 12 hours dark, 12 hours light. They were provided standard food pellets and water ad libitum.[8]

Acute toxicity

An experimental study with the objective to evaluate the acute toxicity of *Sanjeevani Vati*, was done as per toxicity guidelines, the OECD guidelines 420 (OECD, 2001). Albino rats (n = 6) of either sex were treated with single dose, while the control group received saline (5 ml/kg). The *Sanjeevani Vati* preparation were administered orally at the single dose rate of rate of 22.5 mg, 45 mg, 225 mg, 450 and 675 mg/kg body weight. The animals were observed for the clinical symptoms for 30 minutes, at hourly intervals for next 24 hours and thereafter for total 14 days. The animals were observed for signs of convulsions, tremors, circling, depression, excitement and mortality. No mortality was observed in any of the rats. Body weight was recorded at 0, 7th and 14th day and plasma total protein, albumin; aspartate amino transferase & alkaline phosphatase (SGOT & SGPT) were measured to evaluate the toxicity of the preparation. Two animals are terminally sacrificed for gross necropsy findings.

Haematological studies

The blood samples before centrifugation that were collected into heparinised tubes were used for the estimation of hematological parameter. All blood parameters like heamoglobin, red blood cells (RBC), white blood cells (WBC), packed cell volume (PCV), platelets, polymorphs, lymphocytes and eosinophils were found to be normal in *Sanjeevani vati* treated group. All values are similar to normal saline treated control and there were no marginal difference occurs. These biochemical and haematological parameters were measured at the diagnostic laboratory of the Arya College of Pharmacy, Kukas, Jaipur, India.

Histopathological Study

There is no any toxicity seen in above parameter so, we sacrified two rats of test group (*Sanjeevani vati* 675mg). The histopathological study was done by Dr.M.L.Yadav at Gaurav Diagnostic laboratory, Jaipur. There were no pathological changes as shown in table lll and table IV.

Results and Discussion

Experimental screening method is imperative in order to establish the safety and efficacy of traditional and herbal products and also to set up the active components of the herbal products (Baghel et al., 2011). All the animals were carefully observed for development of any toxic signs or symptoms at different time intervals of 0, 30 minutes, 1, 2, 4, 6, 8, 12 hrs and then daily for period of 14 days. No abnormal sign and symptoms were observed in any of the animal with test group (*Sanjeevani Vati)* at the dose rate of 22.5 mg, 45 mg, 225 mg, 450 and 675 mg/kg body weight. No mortality was observed in any animal indicating its safety. Hence, from the present study it can be concluded that the *Sanjeevani Vati* is non toxic at the limit dose of 675 mg/kg body weight. No adverse effect was seen on the body weight gain and no significant changes in the biochemical parameters from those of normal values of these parameters were observed as compared to control, indicating no adverse effect on the lipid profile at experimental dose rats. No adverse effect was seen even at a higher limit dose of 675 mg/kg. All heamatological parameters like

heamoglobin, red blood cells (RBC), white blood cells (WBC), packed cell volume (PCV), platelets, polymorphs, lymphocytes and eosinophils were found to be normal in *Sanjeevani Vati* treated group. All values of hematological examination are similar to normal saline treated control and there were no marginal difference occurs. Clinical examination of all the rats were normal and necropsy findings does not show any remarkable findings (Table lll & lV).

Summary and Conclusion

Therefore, it is concluded that the administration of *sanjeevani vati* is safest & has no adverse effect on growth related and biochemical parameters. Acute toxicity study has shown that LD_{50} of *Sanjeevani vati* was greater than 675 mg/kg. Hence $1/10^{th}$ of dose was taken as an effective dose (67.5 mg/kg body weight). It is also inferred that '*Sanjeevani vati*' being safe at a higher limit dose, belongs to class 5 or unclassified substances as per Globally Harmonized Classified system (GHC) for chemical substances and mixture indicative of very high LD_{50} value. Hence, it can be recommended as a safe product to replace synthetic methionine in poultry ration and for supplementation in basal diet for regular usage.

Table I showing the group of albino rat with dose in acute toxicity

Group No.	Group Name	Dose
1.	Control group	Administer 5% gum acacia (5ml/ Kg)
2.	1^{st} test group	*Sanjeevani Vati* (22.5 mg/kg)
3.	2^{nd} test group	*Sanjeevani Vati* (45 mg/kg)
4.	3^{rd} test group	*Sanjeevani Vati* (225 mg/kg)
5.	4^{th} test group	*Sanjeevani Vati* (450 mg/kg)
6.	5^{th} test group	*Sanjeevani Vati* (675 mg/kg)

Table ll showing mean weight (mg) chart of rats of different groups

Groups days)	Before Treatment (Average body wt. 0 day)	After Treatment (Average body wt. after 14^{th}
Control group	113.75 mg	114.98 mg
Test group 1	123.00 mg	138.67 mg
Test group 2	114.25 mg	127.70 mg
Test group 3	118.25 mg	116.22 mg
Test group 4	103.50 mg	121.89 mg

Figure 1 Graph showing body weight (gm.) difference between before and after treatment.

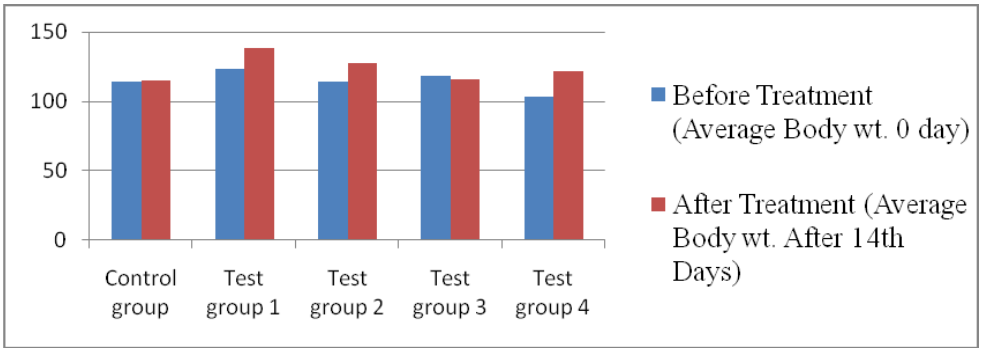

Table No. lll - Shows histopathology acute toxicity study of *sanjeevani vati* at 675mg/Kg (Slides labeled HB from sacrificed albino rat 1)

Organs	Findings
Liver	Section shows normal hepatic architecture. No evidence of degeneration of necrosis could be seen.
Kidney	Sections show normal glomeruli and tubules. No evidence of degeneration of necrosis could be seen
Spleen	Sections show normal red and white pulp. No evidence of degeneration of necrosis could be seen
Heart	Sections shows normal cardiac muscles. No evidence of degeneration of necrosis could be seen.
Brain	Sections show normal cerebral and cerebral tissue. No evidence of degeneration of necrosis could be seen.

Table lV Shows histopathology acute toxicity Study of *sanjeevani vati* at 675mg/Kg (Slides labeled HB from sacrificed albino rat 2)

Organs	Findings
Liver	Section shows normal hepatic architecture. No evidence of degeneration of necrosis could be seen.
Kidney	Sections show normal glomeruli and tubules. No evidence of degeneration of necrosis could be seen
Spleen	Sections show normal red and white pulp. No evidence of degeneration of necrosis could be seen
Heart	Sections show normal cardiac muscles. No evidence of degeneration of necrosis could be seen.
Brain	Sections show normal cerebral and cerebral tissue. No evidence of degeneration of necrosis could be seen.

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Clinical Study

Role of *Agnikarma* in the Management of Plantar Fasciitis

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Abstract -

Introduction: Plantar Fasciitis is a common painful heel syndrome. It is due to inflammation of plantar fascia causing pain and disability, as in prolonged standing. The overall prevalence rate of Plantar Fasciitis is 1-3%. It has become a challenging medical condition nowdays because it affects the daily routine activities of a person. **Materials and Methods**: Total 100 diagnosed cases having signs and symptoms of plantar fasciitis were enrolled for the study and randomly divided in two groups. 50 patients in Trial Group were treated with 4 sittings of *Agnikarma* with an interval of 7th days between the consecutive sittings. Similarly 50 patients in Standard Group were treated with 3 sittings of local infiltration of Local Anaesthetic 1 ml (2% plain) mixed with *Triamcinolone* 1 ml (40mg) with an interval of 7 days between the consecutive sittings. **Results**: Both the selected interventions i.e. *Agnikarma* and LATC (Local anaesthetic and triamcinolone) gave statistically significant results in their own groups but intergroup comparison revealed that steroidal infiltration has an upper edge in relieving the symptoms. **Conclusion**: LATC is better than *Agnikarma* in providing immediate relief.

Key Words: *Agnikarma, Vata kantaka,* plantar fasciitis.

सारांश–

प्रस्तावना – एड़ी में दर्द होना एक सामान्य दर्द युक्त एड़ी सिंड्रोम है। यह लम्बे समय तक खड़े रहने के कारण पैरों के तलवें में स्थित फेशिया में सूजन होने के कारण होता है। इसका सामान्य प्रचलन दर 1–3 प्रतिशत है। वर्तमान समय में यह एक चुनौतीपूर्ण चिकित्सा संबधी स्थिति है क्योंकि यह व्यक्ति की दिनचर्या को प्रभावित करती है। **संसाधन और विधि**– कुल 100 रोगी जिनमें एड़ी के दर्द के चिन्ह और लक्षण उपस्थित थे उनका पहचान कर उन्हें बेतरकीब ढंग से दो वर्गों में बांटा गया। 50 रोगियों को अग्निकर्म की 4 सिटिंग दी गई तथा बीच में 7 दिन का अंतराल रखा गया। उसी तरीके से दूसरे मानक समूह के रोगियों को स्थानीय निश्चेतक 1 मिली.(2% plain) को ट्राइएमसीनोलोन 1 मिली. (40 mg.) में मिलाकर 7 दिनों के अंतराल से स्थानीय इन्फिल्ट्रेशन की 3 सिटिंग दी गई। **परिणाम** – दोनों ही चुने गए समूहों अग्निकर्म और स्थानीय निश्चेतक और ट्राईएमसीनोलोन में परिणाम सांख्यकीय दृष्टि से महत्वपूर्ण मिले लेकिन दोनों वर्गों के बीच में तुलना करने पर पाया गया कि स्टीरॉइड इन्फिल्ट्रेशन से लक्षणों में ज्यादा आराम आया। **निष्कर्ष**–LATC, अग्निकर्म की तुलना में तुरन्त आराम देने में अधिक उपयोगी है।

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Clinical Study

Role of *Agnikarma* in the Management of Plantar Fasciitis

Dr.Pooja Arya, Dr.Rahul Sharma, Prof. Sanjeev Sharma, Prof. Hemant K. Kushwah

Introduction

Heel pain is a common clinical entity which usually affects the routine activities of an individual of any age. There are various conditions causing heel pain in different age groups. In children, Sever's disease is observed mostly in boys which is type of 'traction osteochondritis'. In adolescent girls calcaneal knob is uncommonly observed. In adult women bursitis is common and acute plantar fasciitis may be found[1]. In patients belonging to middle- aged groups, bony spur and chronic plantar fasciitis is commonly observed[2]. The exact pathology of plantar fasciitis is not known but it is more often seen in men between 40 to 60 years of age who are more prone for ill fitting footwear [3]. There is an early morning stiffness, restricted movement and pain below the calcaneum[4]. As far as management is considered, initially conservatively a soft pad may be used just below the tender area. If this does not help, local injection of Triamcinolone should be made at the most tender spot. If this fails then lastly division of the plantar fascia is indicated[5]. Moreover, they do not give permanent cure for the disease and very uneconomical for a common man to afford all these costly measures. According to *Acharya Sushruta*, Plantar Fasciitis can be correlated with *Vata kantaka* which is caused by vitiated *Vata Dosha* due to constant standing and walking on uneven surface[6]. *Acharya Sushruta* also mentioned that the disease *Vatakantaka* is *Snayu-Asthi-Sandhi aashrit Vyadhi* and such diseases should be treated with oleation, poultice, *Agni Karma*, Bandaging and massage up to a considerable relief from pain[7]. *Agni Karma* seems to be more effective in providing distinct relief if it is done perfectly and disease does not recur[8]. Present study is a sincere effort to find out an effective *Ayurvedic* treatment modality for Plantar Fasciitis in the form of *Agni-Karma* therapy, a para-surgical procedure mentioned for the treatment of *Vata Vyadhi* and *Snayu Vikara* in the classics of *Ayurveda*[9]. *Agnikarma* (Thermal cauterisation) is in practice as a therapeutic measure since *Vedic* period and gained supremacy during the period of *Acharya Sushruta*. Even in *Charaka Samhita*, which is a main treatise of medicine, *Agni Karma* has been employed for various ailments as a line of treatment [10] .

Aims and Objectives

1. To evaluate the efficacy of *Agni Karma* in Plantar fasciitis.
2. To provide a better modality of treatment to the patients suffering from Plantar fasciitis.

Materials and methods

Total 100 patients fit under inclusion criteria attending the O.P.D. of Shalya Tantra Department of Rajiv Gandhi Govt. Post Graduation Ayurvedic College & Hospital, Paprola H.P. were selected and registered.

Ethical Clearance

Proposed protocol was submitted to the Institutional Ethics Committee and the clearance of the IEC obtained before starting the trial.

Inclusion Criteria

Willing patients for trial between the age of 25-60 years of either sex having heel pain, tenderness over the medial aspect of heel, painful plantar fascia stretching and extremely painful initial steps at morning time with normal x-ray finding.

Exclusion Criteria

Non-willing patients, below 25 years and above 60 years of age, *Pitta* dominating *Prakriti, Alpa Satva, Antah Shonita, Vranita,* Unfit for *Svedana,* with *Anuddhrita Shalya*, *Avara Samhanana*, *Bhiru* and pregnant women. [11] Patients having joint disorders (viz. RA, OA, GA), Tuberculosis, Diabetes or having associated with some other constitutional disorders etc, calcaneal spur, Recent H/O trauma/fracture/dislocation/ manipulation/immobilization/surgery of the affected

foot, Recently healed/treated calcaneal fractures, old mal-united fractures of the calcaneus, Limping or lurching gate due to any disease and patients who walk bare footed were excluded.

Subject with drawl Criteria

Voluntary withdrawal by the research subject with or without information, patients showing gross side effects or complications of the procedures, appearance of any ailment/s during the trial requiring medical or surgical intervention, which is likely to affect/discontinue/interrupt the trial, interruption of the trial for more than four days or missing of one sitting of Agni karma or Local Anaesthetic with Triamcinolone and uncooperative patient.

Investigations

Laboratory investigations were done only to exclude certain relevant disorders. There are no available particular investigations to diagnose Plantar Fasciitis. It is diagnosed only on the basis of clinical presentation. However, some investigations carried out as routine and some others for the differential diagnosis purpose.

Blood - TLC, DLC, ESR, Hb, and Blood sugar (F), S. creatinine, S. uric acid and RA factor (if required).

Urine - Routine and microscopic

X-rays - Chest PA view (if required) and Calcaneum Lat. view

Selection of Remedy

Due to *Vata Kapha shamaka* effects of *Agni* and indication of Agni karma in Snayu Vikara by our Acharyas, the *Agni karma* was selected for the management of Plantar fasciitis.

Null Hypothesis (H_0)

Agni Karma is not effective in the treatment of Plantar fasciitis.

Alternate Hypothesis (H_1)

Agni Karma is as effective as local infiltration of Local anesthetic with Triamcinolone.

Confidence Level - At 95% level.

Study Design - Patients included in the study were divided in two groups and assessment was done on the basis of the specified parameters (before and after the treatment). Sample size was 100 patients i.e. 50 patients in each group i.e. *Agni karma* and LATC respectively.

Interventions

a) *Agni karma* (Trial group)

Total 4 sittings of *Agni Karma* were done with the interval of 7 days. Seven *Bindu* type of therapeutic *Dagdha* was done in rosette manner.

b) LATC (Standard Group)

Standard treatment of Plantar Fasciitis i.e. Local Anaesthetic with Triamcinolone was given to the patients in 3 sittings. The interval between subsequent visits was of 7 days.

Management

After the diagnosis, patients were randomly categorized into two groups:

a) *Agnikarma* Methodology:

Agnikarma is a para-surgical measure and requires all the principles to be observed carefully which are mentioned in ancient Ayurvedic texts. However, in present study some modifications have been done in the procedure as well as in instrumentation without departing from the basic classical principles. Every step of the procedure was standardized to produce uniform *Dagdha* in all the patients. Care of dietetics, season as well time of the day has been taken properly. No Agni karma done on *Durdin* i.e. on the day when it was raining, thundering and was stormy or deep clouds in the sky. However, thin and silent clouds with bright sun were not the criteria to defer or postpone the procedure. Following schedule observed uniformly in all the patients:

i *Purva Karma* (Pre-operative preparation): Patients and attendants were counseled and explained about the procedure. Fresh consent of the patients for each sitting of *Agnikarma* obtained. All the required instruments, emergency drugs and equipments arranged. Most tender spot was thoroughly cleansed and gentle *Abhyanga* was done with *murchhit til-taila* for 10 minutes. Patients were advised to take some *Pichhila* (unctuous) diet.

ii) *Pradhana Karma* (Main procedure): Patients were kept in Supine position before starting the procedure. Electric cautery was then heated up to red-hot and *Bindu* type *dagdhas* were made on the most tender spot, till the *samayaka twaka dagdha lakshanas* appeared i.e. *shabda pradurbhava, durgandhata*. During the procedure patients kept being consoled and held comfortably by the assistants. In case patient got frightened or did not co-operate the procedure was terminated and case was withdrawn from the study.

iii) *Pashchata karma* (Post Operative measures): Immediately after completion of the procedure *Ghritkumari pulp* applied over the *vrana* and gauge impregnated with *Madhuyasti churna* kept and bandaged. Patient was advised to take rest for about 10 minutes on the operation table and not to get up promptly just after the completion of the procedure.

b) Intra lesional steroidal injection (Local Anaesthetic with Triamcinolone) methodology:

This group was managed with standard modern treatment i.e. Local Anesthetic with Triamcinolone local infiltration. Total 3 sittings of Local Anesthetic with Triamcinolone infiltration were given and interval between subsequent visits was of 7^{th} days *i. e.* on the 8^{th} post procedure day the same was repeated.

i. Pre-procedure preparation: Consent of the patients and attendants were obtained. History of sensitivity to lignocain was also taken. All the required instruments, emergency drugs and equipments were arranged. Most tender spot was located and marked on the surface with marker. Prior to the procedure, proper scrubbing done by the investigator. Hands were washed properly and sterile disposable gloves worn. The part was thoroughly cleansed with three anti septic solutions viz. Savlon, Betadine and Spirit.

ii. Main procedure: Triamcinolone acetate 40mg/ml (1ml) lignocain HCL 2% 21.3mg/ml (1ml) were taken and mixed in 5cc disposable syringe with 23 gauge hypodermic needle. Air in the syringe well evacuated. Infiltration done at required depth sparing the important structures viz. tendons and neurovascular structures. A care was taken not to inject it subcutaneously for the fear of discoloration of skin. During the procedure of infiltration needle was withdrawn and reinserted time and again depending on the requirement and area to be infiltrated. On completion of the procedure needle taken out from the site. Area covered with gauze soaked in betadine solution. Dressings held with sterile cotton bandages. The subject was called after 7 days for next sitting of Local Anesthetic with Triamcinolone.

Concomitant Medication

Medication permitted during the study period: During the study occasional use of *(maximum up to twice a week)* NSAIDs in case of pain not controlled by the study procedures, anti hypertensive drugs, antilipidemic drugs, short term medication for systemic disorders like viral, bacterial fever, Gastro-enteritis etc. (except NSAID's and steroids) and antibiotics

Medication not permitted during the study period: Any skeletal muscle relaxant viz. Benzodiazpines, Tizanidine, Chlorzoxazone, Chlormezanone, Methacarbamol, Carisoprodol, Anticholinergic agents, Baclofen, Eperisone, Lornoxicam, Thiocholchicoside, Eperisone etc. Neuromuscular blocking drugs (Succinyl choline, Pancuronium, Atracuronium etc.), Cholinergic drugs (Neostigmine, Pyridostigmine etc.), Systemic or tropical steroids in any form, *Guggulu* and *Ahiphen* derived or mixed drugs, Ayurvedic *Shothhara* Drugs, Locally acting oil, gel, ointment or liniments.

Follow-Up

On the completion of the trial patients were followed up for three months at monthly visits.

Treatment Compliance

Patients were convinced to complete the trial as per the protocol. Subjects, who failed to get the due procedure done (*Agni karma* or Local Anaesthetic with Triamcinolone) on the scheduled time, were categorized as *non-compliant* and were withdrawn from the study. Such withdrawn or dropout patients were replaced by new trial subject. For the withdrawal or drop out purpose Major protocol violation was considered as the determining

factor as per the following definition:

Major Protocol Violation: Defined as:

1. All drop outs due to any reason.
2. Patients who were withdrawn from the study due to some adverse event.
3. Failure of the patients to follow up the successive visits.
4. Any complication arising due to the interventions under study (ADRS).
5. Intervention delayed for more than four days due to any reason.

Minor Protocol Violation: Defined as:

1. Patients who have delayed the intervention for less than 4 days. Such patients will be the part of study.

RESULTS - Comparative Study

Table No. 1 Table showing the comparative study of the results in both groups

Sr. No.	Assessment parameter	Trial Group			Standard Group		
		Mean score		%age relief	Mean Score		%age relief
		BT	AT		BT	AT	
1.	Pain *(Heel)*	3.20	0.46	85.62	3.28	0.22	93.29
2.	Tenderness	2.56	0.26	89.84	2.70	0.12	95.56
3.	Painful plantar fascia stretching	3.16	0.34	89.24	3.2	0.26	91.88
4.	Painful walking	2.66	0.26	90.23	2.72	0.16	94.12
5.	VAS (Visual Analog Scale)	7.82	1.30	83.38	8.16	0.44	94.61
6.	VDS (Visual Descriptive Scale)	4.08	0.64	84.31	4.2	0.32	92.38

Table No. 2 Table showing the comparison of study in both the groups

Sr. No.	Assessment parameter	Trial Group				Standard Group			
		+SD	+SE	't'	'P'	+SD	+SE	't'	'P'
1.	Pain *(Heel)*	0.852	.120	22.724	<0.0001	.585	.082	36.931	<0.0001
2.	Tenderness	0.580	.082	28.027	<0.0001	.498	.070	36.591	<0.0001
3.	Painful plantar fascia stretching	0.747	.105	26.676	<0.0001	.651	.092	31.893	<0.0001
4.	Painful walking	0.571	.080	29.698	<0.0001	.540	.076	33.485	<0.0001
5.	VAS	1.034	.146	44.549	<0.0001	.833	.117	65.456	<0.0001
6.	VDS	0.812	.114	29.951	<0.0001	.711	.100	39.145	<0.0001

Table No. 3 Table showing the comparative means score of assessment criteria

Sr. No.	Assessment parameter	Mean scores AT		'z'	'P'
		TG	SG		
1.	Pain *(Heel)*	0.46	0.22	2.37	0.0178
2.	Tenderness	0.26	0.12	1.22	0.2225
3.	Painful plantar fascia stretching	0.34	0.26	2.97	0.0030
4.	Painful walking after getting up from the bed	0.26	0.16	5.05	0.0001
5.	VAS	1.30	0.44	1.79	0.0735
6.	VDS	0.64	0.32	0.86	0.3898

Discussion (Inter group comparison)

i. Pain: In the Trial Group %age of relief was 85.62% in comparison to 93.29% in Standard Group (SG). Percentile improvement is less in Trial Group however; both the results are statistically significant at 1% level in their own groups. But inter group comparison reveals the real difference i.e. "z" score is 2.27 (p = 0.0178) and alternate hypothesis (H_1) is rejected.

ii. Tenderness: In the TG relief was 89.84% in comparison to 95.56% in SG. Percentile improvement was less in TG however; both the results are statistically significant at 1% level in their own groups. But inter group comparison does not reveal the real difference i.e. "z" score is 1.22 (p = 0.2225) and alternate hypothesis (H_1) is accepted.

iii. Painful Plantar Fascia Stretching: In TG %age of relief was 89.24% in comparison to 91.88% in SG Percentile improvement is less in trial group however; both the results are statistically significant at 1% level in their own groups. But inter group comparison reveals that the difference is real i.e. "z" score is 2.97 (p = 0.0030) and alternate hypothesis (H_1) is rejected.

iv. Painful walking: In the TG %age of relief was 90.23% in comparison to 94.12% in SG Percentile improvement is less in trial group however; both the results are statistically significant at 1% level in their own groups. But inter group comparison reveals that the difference is real i.e. "z" score is 5.05 (p = 0.0001) and alternate hypothesis (H_1) is rejected.

v. Visual Analog Scale: In the TG improvement was 83.38% in comparison to 94.61% in SG. Percentile improvement is less in TG however; both the results are statistically significant at 1% level in their own groups. Inter group comparison reveals that the difference is not real i.e. "z" score is 1.79 (p = 0.0735) and alternate hypothesis (H_1) is accepted.

vi. Verbal Descriptive Scale: In the TG improvement was 84.31% in comparison to 92.38% in SG. Percentile improvement is more in trial group however; both the results are statistically significant at 1% level in their own groups. But inter group comparison reveals that the difference is not real i.e. "z" score is 0.86 (p = 0.3898) and alternate hypothesis (H_1) for this variable is accepted.

It is revealing the fact that the local steroidal infiltration is more effective than *Agnikarma*.

Discussion on Follow-up examination

In the first follow-up visit there was stability in the features i.e. no further increase or decrease in the symptoms was recorded. On 2nd visit an increase or recurrence in the features was noted in some patients and it was more in trial group than standard group. On the third visit also there was further increase in the features in both the groups but comparatively more in trial group. This reveals the fact that recurrence of features by both the treatments was there. Literature of modern medical science also says that recurrence after steroidal injection is common. But recurrence after *Agni Karma* is contrary to the textual references that

"diseases cured by *Agni Karma* do not recur". Hence, some sort of modification in the procedure, oral medication and prevention of the causative factors is essentially required. Hence, it can strongly be stated that this therapeutic procedure not only subsides the symptoms but also cures the disease.

Conclusion

Plantar fasciitis is a disease caused by Vitiated *Vata* affecting the *Kandaras* (a type of *Snayu*) situated near heel area. Statistically both the therapies are equally effective in the management of plantar fasciitis. No untoward effect of either *Agni Karma* or LAHC could be recorded. This disease is more common in people involved in occupation involving prolonged walking, standing, bare foot walking on hard floor, improper footwear, females and age group 36-40 yrs. They should adopt such measures so that the disease can be prevented. It can be concluded that LAHC is better than *Agnikarma* in immediate results but later can provide a better modality of management of plantar fasciitis if some modifications are done in the technique and oral medication is also included.

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Pharmaceutical Study

Pharmaceutical and Analytical Study of *Mehakulanthaka Rasa*

*Dr.Sakhitha K.S., **Prof. P.Suresh, ***Prof. K. Shankar Rao

Abstract

Mehakulanthaka Rasa (MKR) is an Ayurvedic herbomineral compound formulation used in the intervention of *Prameha*. It was prepared by the trituration of ingredients *Abhraka Bhasma* ,*Vanga bhasma*, *Parada, Gandhaka, Shilajatu* and around 15 herbal ingredients. An attempt was made to validate the pharmaceutical preparation of *Mehakulanthaka Rasa*. Each of the *bhasma* was prepared according to the norms of Ayurvedic classical texts and by employing Electric Muffle Furnace as heating device for incineration. To ensure the proper preparation of *Bhasmas*, standard tests (*Bhasma Pariksha*) were employed. MKR was prepared and analysed for physiochemical constants and phytochemical constituents.It was found that the formulation was having a pH of 3.90, hardness 3.5 to 4.0 kg/cm^2 and disintegration time 60.0 min to 65.0 min while the phytochemical analysis revealed the presence of flavanoids, glycosides etc in the sample.

सारांश:

मेहकुलान्तक रस प्रमेह चिकित्सा में प्रयुक्त किया जाने वाला रसयोग है। प्रस्तुत शोध कार्य में इस अद्वितीय योग के मापदण्ड निर्धारित करने का प्रयास किया गया है। चयनित योग में अभ्रक भस्म, वंग भस्म, पारद, गंधक, शिलाजतु एवं 15 काष्ठौषधियों का समावेश किया गया है। प्रत्येक घटक द्रव्य को शास्त्रानुसार तैयार किया गया है तथा भस्म निर्माण के लिए विद्युतीय भ्राष्ट्री का प्रयोग किया गया है। भस्म परीक्षा के लिए निश्चित मापदण्डों का अनुसरण किया गया है। मेहकुलान्तक रस का भौतिक रसायनीय एवं पादप रसायनीय घटकों के लिए विश्लेषण किया गया जिसमें Flavanoid एवं Glycosides की उपस्थिति पाई गयी।

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Pharmaceutical Study

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Dr. Sakhitha K.S., Prof. P.Suresh, Prof. K. Shankar Rao

Introduction

Diabetes is one of the world's major diseases, currently affecting an estimated 285 million people worldwide[1]. Oral hypoglycemic agents form a primary part of treatment of diabetes but prominent side effects of such drugs are the main reason for a number of people seeking alternative therapies that may have less severe or no side effects. *Rasa Yogas*, the organo metallic formulations of *Ayurveda* have been in use in the treatment of diabetes with their excellence for centuries. *Mehakulantaka Rasa* is one such excellent herbo mineral preparation described in the *Pramehadhikara* of one of the prominent *Rasashastra* texts of 19th century; *Bhaishajya Ratnavali*[2].

As for the classics, the formulations stand already standardized. In fact what we mean by standardization is validation of the existing processes. Since a lot of innovations and expertise has been inculcated in to the *Ayurvedic* pharmaceutics, pharmaceutical study of formulations utilizing the tools and technique available at present has become essential for producing quality drug as well as revalidating the claim of ancient *acharyas*. Considering the above facts an attempt has been made to standardize the pharmaceutical preparation of *Mehakulanthaka Rasa*.

Materials And Methods:

The raw materials for the preparation of *Mehakulanthaka Rasa* were procured from the pharmacy attached to National Institute of Ayurveda, Jaipur. Ingredients and their various proportions are mentioned in table 1.

Table 1: Ingredients of *Mehakulanthaka Rasa* and their proportion.

Sl No.	Ingredients	Proportion	Sl No.	Ingredients	Proportion
1.	*Vanga bhasma*	1 part (3 g)	11.	*Hareetaki*	1 part (3g)
2.	*Abhraka bhasma*	1 part (3 g)	12.	*Amalaki*	1 part (3g)
3.	*Shudha parada*	1 part (3 g)	13.	*Vibheetaki*	1 part (3g)
4.	*Shudha gandhaka*	1 part (3 g)	14.	*Trivrit*	1 part (3g)
5.	*Shudha shilajatu*	4 part(12 g)	15.	*Rasanjana*	1 part (3g)
6.	*Bhunimba*	1 part (3 g)	16.	*Vidanga*	1 part (3g)
7.	*Pippalimula*	1 part (3 g)	17.	*Musta*	1 part (3g)
8.	*Sunthi*	1 part (3 g)	18.	*Bilva*	1 part (3g)
9.	*Maricha*	1 part (3 g)	19.	*Gokshura*	1 part (3g)
10.	*Pippali*	1 part (3 g)	20.	*Dadima*	1 part (3g)

Preparation of *Mehakulanthaka Rasa*

Pharmaceutical processes carried out during the preparation of *Mehakulanthaka Rasa* was dealt under various sections as follows:

- *Shodhana* of *Parada*[3]
- *Shodhana* of *Gandhaka*[4]
- Preparation of *Kajjali*
- Preparation of *Vanga bhasma*[5]

- Preparation of *Abhraka bhasma*
- *Shodhana* of *Shilajatu*
- Preparation of powders of crude drugs
- Preparation of *vati*

Details of *shodhana* of various ingredients like *Parada, Gandhaka, Vanga, Abhraka* and *Shilajatu* are depicted in the table 2.

Table 2: Details of *shodhana* of various ingredients of *Mehakulanthaka Rasa*

Sl.No	Name of the drug	Method of *Sodhana*
1.	***Parada***	***Mardana* using *lashuna, sudha* and *saindhava lavana***
2.	*Gandhaka*	Melted along with ghee and poured in to *godugdha*.
3.	*Vanga*	*Samanya shodhana- Dalana* in *Kanji, Takra, Gomutra, Kulattha Kwatha, Tila Taila.* *Vishesha Sodhana - Dalana* in *nirgundi patra swarasa* mixed with *haridra churna.*
4.	*Abhraka*	Heated to red hot and quenched in *triphala kwatha*
5.	*Shilajatu*	Dissolved in *triphala kwatha* and then decanted and reduced to semi solid consistency and dried.

Kajjali was prepared by triturating equal amount of *shudha parada* and *shudha gandhaka* until a black coloured fine powder was obtained[6]. *Jarana* of shodhita *vanga* was carried out using *apamarga (Achyranthes aspera) panchanga* churna[7]. For preparation of *vanga bhasma bhavana* of *kumari swarasa(Aloe barbadensis)* was given to the *jarita vanga* and *puta* was given in an electric muffle furnace. The details of *vanga marana* is depicted in table 3. *Dhanyabhraka* was prepared from *shodhita abhraka* as per the reference of *Ayurveda Prakasha*[8]. For the *marana* of *abhraka; arka ksheera(*latex of *Calotropis procera), arka patra rasa*(juice of *Calotropis* leaves*), kadali kanda rasa(*juice of *Musa paradisiaca* tuber*)* and *vata jata kwatha* (decoction of *Ficus bengalensis* root)were utilized[9]. The details of *marana* are mentioned in table 4.

Table 3: Numerical summary of various parameters obtained during the pharmaceutical process of *Marana* of *Vanga*.

Order of *puta*	Weight of *vanga*	Amount of *bhavana dravya*	Max. temp given	*Chakrika*			
				Wt.before *puta*	Wt. after *puta*	Colour	Consis-tency
1.	95 g	50 ml	500	95.6 g	95 g	Greyish white	hard
2.	95 g	50 ml	500	96 g	95.3g	Greyish white	hard
3.	95.3 g	50 ml	550	96.0 g	95.6 g	Dull white	soft
4.	95.6 g	50 ml	550	96.4g	96.0 g	Dull white	soft
5.	96.0 g	50 ml	600	97.2g	96.4 g	Dull white	hard
6.	96.4 g	50 ml	600	97.6 g	97.0 g	Dull white	soft
7.	97.0 g	50 ml	650	97.8 g	97.2 g	Dull white	Soft
8.	97.2 g	50 ml	650	98.5 g	97.6 g	Dull white	Soft
9.	97.6 g	50 ml	700	99.0 g	98.1 g	White	Soft
10.	98.1 g	50 ml	700	99.3 g	98.5 g	white	Softer

Table 4: Summary of various parameters obtained during the pharmaceutical process of *Marana* of *Abhraka*.

No. of *Puta*	Name & Quantity of *Bhavana* Drava	Weight of material Temp.			Colour Given *Puta*	*Chan-* After	*drika*
		Before *Puta*(g)	Dried Pellets (g)	After *Puta*(g)			
1	*Arka kshira* (70 ml)	100	130	94	750 °c	Brownish golden	Less
2	*Arka kshira*(70 ml)	94	128	95	750 °c	Brownish	Lesser
3	*Arka kshira*(70 ml)	95	128	95	750 °c	Brownish red	Lesser
4	*Arka kshira*(70 ml)	95	126.5	95.7	750 °c	Brownish red	Lesser
5	Arka kshira(70 ml)	95.7	126	96.1	750 °c	Light brick red	Lesser
6	*Arka kshira*(70 ml)	96.1	128.5	96.6	750 °c	darker brick red	Lesser
7	*Arka kshira*(70 ml)	96.6	126	97	750 °c	Light brick red	Lesser
8	*Arka patra swarasa* (50ml)	97	117	97	750 °c	Brick red	Lesser
9	*Arka patra swarasa* (50ml)	97	117	97.3	750 °c	Brick red	Lesser
10	*Arka patra swarasa* (50ml)	97.3	116.5	97.7	750 °c	Brick red	Lesser
11	*Arka patra swarasa* (50ml)	97.7	118	98	750 °c	Brick red	Lesser
12	*Arka patra swarasa* (50ml)	98	118.5	98.2	750 °c	Brick red	Lesser
13	*Arka patra swarasa* (50ml)	98.2	116.1	98.5	750 °c	Brick red	Lesser
14	*Arka patra swarasa* (50ml)	98.5	117.4	99	750 °c	Brick red	Lesser
15	*Vata Jata Kwatha* (50ml)	99	113	99.2	750 °c	Brick red	Lesser
16	*Vata Jata Kwatha* (50ml)	99.2	113.5	99.2	750 °c	Brick red	Lesser
17	*Vata Jata Kwatha* (50ml)	99.2	115	99.5	750 °c	Brick red	Lesser
18	*Vata Jata Kwatha* (50ml)	99.5	113.5	99.7	750 °c	Brick red	Lesser
19	*Vata Jata Kwatha* (50ml)	99.7	115	100	750 °c	Brick red	Lesser
20	*Vata Jata Kwatha* (50ml)	100	115	100.4	750 °c	Brick red	Lesser
21	*Vata Jata Kwatha* (50ml)	100.4	114.5	100.7	750 °c	Brick red	Noticeable in light
22	*Kadali kanda swarasa* (50ml)	100.7	120	101	750 °c	Brick red	Noticeable in light
23	*Kadali kanda swarasa* (50ml)	101	120	101.5	750 °c	Brick red	Noticeable in light

24	*Kadali kanda swarasa* (50ml)	101.5	121	102.1	750 °c	Brick red	Noticeable in flash of light
25	*Kadali kanda swarasa* (50ml)	102.1	121.4	102.7	750 °c	Brick red	Noticeable in flash of light
26	*Kadali kanda swarasa* (50ml)	102.7	121	103	750 °c	Brick red	Noticeable in sunlight
27	*Kadali kanda swarasa* (50ml)	103	121.5	103.4	750 °c	Brick red	Noticeable in sunlight
28	*Kadali kanda swarasa* (50ml)	103.4	121.3	103.9	750 °c	Brick red	Ocasionaly seen on movement
29	*Arka kshira* (70 ml)	103.9	132	104.4	750 °c	Brick red	None
30	*Arka kshira* (70 ml)	104.4	132	104.7	750 °c	Brick red	None

All the herbal ingredients were powdered and sieved through 120 mesh. The prepared mineral drugs were taken in a porcelain mortar, powders were added to it and triturated well. *Bhavana* was given with *gopalakarkati mula swarasa*. (*Melothria moderaspatana* root*)* Hand made pills of 250 mg were made and stored in air tight glass bottle.

Analysis of *Mehakulanthaka Rasa*

Physico chemical constants like LOD, Acid insoluble ash, water soluble and alcohol soluble extractives were carried out along with screening for phytochemical constituents and microbial contamination.

Results

Results of the analytical studies carried out for the formulation are depicted in the following tables(tables 5-8).

Table 5: Organoleptic characters of *Mehakulanthaka Rasa*

Sample	Colour	Taste	Odour	Texture
Mehakulanthaka rasa (vati)	Blackish brown	Bitter	Not specific	Smooth

Table 6: Physico chemical constants of *Mehakulanthaka Rasa*

S.No.	Parameters	Value
1.	Moisture content (%w/w) / LOD	4.86
2.	Total Ash (%w/w)	19.4
3.	Acid insoluble Ash (%w/w)	5.24
4.	Alcohol soluble extractive (%w/w)	18.32

5.	Water soluble extractive (%w/w)	27.12
6.	pH 5% w/v sol. in water	3.90
7.	Average weight	0.260 g
8.	Diameter	0.5cm
9.	Hardness	3.5 to 4.0 kg/cm^2
10.	Disintegration Time	60.0 min to 65.0 min

Table7: Qualitative phytochemical screening of *Mehakulanthaka Rasa*

Sl. No.	Test	Result
1.	Alkaloids	Negative
2.	Carbohydrates	Positive
3.	Steroids	Positive
4.	Tannins	Positive
5.	Saponins	Negative
6.	Starch	Negative
7.	Flavanoids	Positive
8.	Coumarins	Positive
9.	Carboxylic acids	Negative

Table 8: Test report of microbial contamination of *Mehakulanthaka Rasa*

S.No.	Microbes	Values
1.	*Escherichia coli*	Absent/gm
2.	*Salmonella*	Absent/gm
3.	*Pseudomonas aeruginosa*	Absent/gm
4.	*Staphylococcus aureus*	Absent/gm

Discussion

For *samanya shodhana* of *Vanga* the common method of the *dhatu shodhana* was adopted. However the order of quenching was *Kanchi, Takra, Kulatha Kwatha, Gomutra* and *Tila taila* as per the reference of *Rasatarangini*[10]. The order of quenching is mentioned differently by different *Acharyas*. The various liquids used for quenching served the basic purpose of acidic or alkaline medias which were necessary to bring about the desired changes in the metal. Tin purified by the general method was melted and poured in to *Nirgundi patra swarasa* (juice of *Vitex nigundo* leaves) mixed with *Haridra* (*Curcuma longa*) powder[11].

For the *jarana* procedure *vishesha shodhita vanga* was taken in an iron pan, heated at the temperature 600°C - 700°C. *Apamarga panchanga* coarse powder was added little by little and rubbed with back of ladle with pressure. The process continued till it turned to powder form completely. The purpose of *putiloha* is to increase the melting point. With out *jarana marana* of *putiloha* is not possible[12].

For preparation of *bhasma* electric muffle furnace was used instead of classical puta method because a better control of temperature is possible by electric muffle furnace. It took 10 *putas* to obtain the *bhasma* which complied with classical *bhasma parikshas*.

Shodhana procedure selected for *Abhraka* was *nirvapa* which was done in *triphala kwatha* for 7 times[13]. *Shodhana* of *abhraka* is more a size reduction process while separating the physical impurities. The process of *dhanyabhrakeekarana* produces granular form of purified *abhraka,* destroying its lattice form and giving better chance of exposure to maximum particles of it. The small size of particles procured after this process helps in early conversion to *bhasma,* as more surface area is exposed for reaction. To make *abhraka bhasma* free from *chandrika* is a tedious job but the *marana* of *abhraka* with the help of *arka ksheera* proved very much beneficial. About 60% of *Chandrika* disappeared in the 1st *puta* itself and thereafter decrease was very gradual. It took 30 putas for

complete removal of *chandrika*. The weight gain can be attributed to the addition of organic matter of *bhavana dravya*. Brick red colour of *bhasma* was noticed from 5th *puta* onwards which became darker with further *puta*.

The classical reference selected for *parada shodhana* contained *sudha*(lime), *lashuna*(*Allium sativum)* and *saindhava lavana*(rock salt). It was observed that when *Parada* was triturated with *sudha,* it was converted to powder form which may be referred as Grey powder. It is difficult to procure whole amount of *parada* by *vastra-galana* process (filtration through cloth) as mentioned in classics. So it was washed with hot water. During this procedure loss of *parada* with water should be checked. *Lashuna* contains organic sulphur, which reacts with mercury to give black colour. Studies have shown the effectiveness of garlic in reducing the trace elements present in mercury[14].

Process of *Gandhaka shodhana* was carried out as per AFI part-I (quoting the reference of Rasamritam) by taking one fourth *ghrita* and *godugdha* four times the weight of *gandhaka*. *Mandagni* was given to avoid burning of sulphur. Cloth was smeared with ghee to avoid sticking of *gandhaka* to the cloth. *Godugdha* was boiled and then cooled. The formation of granules were facilitated by slightly shaking the vessel of *godugdha* as well as pouring the molten *gandhaka* in to the vessel through a large area. After each *dhalana, gandhaka* was thoroughly washed with hot water to remove fat contents of milk and ghee. Each time, fresh *godugdha* was taken to facilitate detoxification of *gandhaka*.

Samaguna kajjali was prepared taking equal quantity of *shuddha parada* and *shuddha gandhaka*. It took average 24 hours to form proper *Kajjali*.. As the triturating continued, the *kajjali* became fine and had a tendency to be spilled out of the *khalva yantra*. Hence, sprinkling of water was done to avoid this phenomenon. Completion tests of *kajjali* indicated its complete formation i.e. *Nishchandrata* indicated no free mercury and *Rekhapurnata* indicated its fineness.

Shilajatu shodhana with *triphala kwatha* was done as per the reference of the text *Rasa Tarangini* where the amount of *triphala kwatha* was taken double that of Shilajatu[15]. But the amount seemed insufficient for dissolving *shilajatu* and it was found that the solution became very thick. Hence equal amount of hot water was added .After sedimentation, the supernatant liquid was decanted and to the residual matter again hot water was added to extract remaining *shilajatu*. The supernatant portion was collected and was evaporated to collect the *shuddha shilajatu*.

***Gopala karkati mula* (root of *Melothria moderaspatana*) ,the bhavana drug is specially indicated for *Prameha* in *Raja Nighantu*[16]. During mixing of ingredients mineral drugs in the order *kajjali, vanga bhasma, abhraka bhasma* were added first and triturated well. Then the herbal ingredients were added one by one and triturated. *Shilajatu* which was in the maximum quantity was added in the last.**

Regarding organo leptic characters, the colour of *Meha kulanthaka rasa* (MKR) was blackish brown and it was odourless. Colour can be attributed to blackish *kajjali* and *shilajatu* apart from brown coloured herbal ingredients. The taste of MKR was *tikta, kashaya* due to the presence of herbal ingredients which were having *tikta, kashaya* rasa predominance especially *Bhunimba*. MKR was smooth in touch since the powders were very fine. Average weight of the *vati* was 260.0 mg. Both hardness and disintegration time interfere with the bioavailability of drug. MKR was found to have 3.5-4 kg/cm² hardness and 60-65 min disintegration time. Moisture content should be minimum to prevent degradation of product. Excess of water in drug encourage microbial growth, presence of fungi or insects and deterioration following hydrolysis.MKR contained 4.86% w/w moisture showing that the tablet should be protected from humid atmosphere as climatic changes affect the tablet. Ash values are the criteria to judge the identity and purity of crude drug, where water soluble acid insoluble and total ash are considered.MKR contained 19.4% w/w of total ash. The water soluble and alcohol soluble extractives of the sample were 27.12 % w/w and 18.32 % w/w respectively indicating that the drug is having good solubility in water. The pH value is one of the main factors influencing the quality of medicine. It always

controls many chemical and microbiological reactions. The pH of MKR 5% w/v solution in water was found to be 3.90.

By their origin, herbal drugs are subject to contamination by microorganisms from soil, air and water which can be potentially pathogenic to human. However analysis for specific pathogens like salmonella, e coli, pseudomonas and staphylococcus were found nil in the sample. Phytochemical screening of drug revealed the presence of steroids, carbohydrates, tannins, flavanoids, and coumarins. In earlier studies steroids and terpenoids have been reported to possess antidiabetic activity[17]. Flavonoids and their related natural compounds are also known to encompass antidiabetic potential, demonstrated in various animal models[18].

Conclusion

The present effort to develop an SOP for the preparation of *Mehakulanthaka Rasa* as well as to develop its analytical profile serve as a preliminary step towards standardization of the formulation. Further study is necessary to explore other parameters related to standardization to be carried out in different batches to set the limit for reference standards for the quality control and quality assurance of *Mehakulanthaka Rasa*.

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Pharmaceutical Study

Pharmaceutical Standardization of *Manjishthadi Tailam*

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Abstract:

Ayurvedic dosage forms are very exclusive in its pharmaceutics and therapeutics. *Sneha Kalpana* is a group of products of medicated *Taila* and *Ghee*, These drugs are treating very wide range of diseases among patients of all age groups. In context of *Sneha Kalpana taila* and *ghrita* are supposed to undergo the process called *Murchchana samskar* through which better therapeutic value can be incorporated in to the raw material which is easily absorbable into the biological systems. The *Taila* acts not only as base or vehicle but class I preservative also.

In Present study detailed Pharmaceutical process of *Manjishthadi Tailam* preparation and observations with changes observed in physiochemical parameters have been discussed here.

Key Words: *Aja Dugdha, Kshudra Roga, Manjishtadi Taila, Murchchhana, Sneha Kalpana.*

सारांश :

आयुर्वेदीय औषध कल्पना का चिकित्सा विज्ञान में बहुत विशिष्ट महत्व है। स्नेह कल्पना तैल और घृत के उत्पादों से निर्मित एक औषधीय समूह है, जिसकी सहायता से सभी आयु-वर्ग के रोगियों की बहुत विस्तृत श्रृंखला की चिकित्सा की जाती है। विभिन्न तकनीकों का प्रयोग करते हुए,जो कि स्नेह कल्पना के संदर्भ में संस्कार प्रक्रिया है, जिसके माध्यम से औषध द्रव्यो के रस-गुण-विपाकादि का स्नेह में आधान किया जाता है। जो कि जैविक प्रणालियों में आसानी से अवशोषित हो जाता हैं। तैल ना केवल द्रव्य के आधार रूप है बल्कि यह द्रव्य के गुणों का वाहक और क्लास वन प्रिजर्वेटिव का कार्य भी करता है।

प्रस्तुत शोध कार्य में मंजिष्ठादि तैल की निर्माण विधि का विस्तृत अध्ययन एवं फिजियोकेमिकल विश्लेषण किया गया है।

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Pharmaceutical Study

Pharmaceutical Standardization of *Manjishthadi Tailam*

Dr. Dattatray Dighe, Dr. Sanjay Kumar

Introduction:-

Sneha Kalpana may be defined as "A pharmaceutical process to prepare oleaginous medicaments from the substances like *Kalka* (Herbal paste of different parts of botanicals), *Sneha*, *Kwatha* (specifically prepared decoction in accordance of *Ayurvedic* principles) or *Drava Dravya* (any other liquid such as milk, self expressed juices, meat juice, etc.) taken in specific proportion and by subjecting them to unique heating pattern and duration to fulfill certain pharmaceutical parameters, according to the need of therapeutics.

Aims And Objectives: -

Sneha Kalpana is a unique dosage form in Ayurveda. Aim of this dosage form is mass transfer of the aqueous and lipid-soluble active principles of all treated herbal drugs and material of animal and mineral origin, if any, in accordance of established formulae quoted in authoritative text books of *Ayurveda* which should serve therapeutic objectives as per indications of the classical treatise of *Ayurveda*.

Main aims and objectives were:-

1. To carry out *Tila Taila Murchchhana*[1] as part of *Sneha Kalpana* preparation for better quality oleaginous medicinal substance.
2. To prepare *Manjishthadi Tailam* as per the guidelines of the classical literature. *Manjishthadi Tailam* was prepared in three batches with similar conditions to standardize the SOPs & SMP and has been assessed by organoleptic method, Physico-Chemical characters, and Chromatographic Parameters.

Material And Methods: -

All the raw drugs enumerated in this preparation were procured from the N.I.A, pharmacy, except *Matulunga*. Drugs for *Tila Taila Murchchhana* were procured from local market of Jaipur and identified by expert of *Dravyaguna* department of NIA Jaipur. Goat milk procured from local person at the time of procedure. Pharmaceutical study was conducted in the *Rasashastra* and *Bhaishajya Kalpana* practical laboratory, NIA, Jaipur.

Tila Taila Murchchhana was carried out as a part of *Sneha Kalpana* process. In M.D thesis of Rao K.S. et al. it was mentioned that *Murchchhana* process for oils is beneficial for the human health. This process helps in decreasing the percentage of composition of saturated fatty acids and at the same time it found increased in the percentage composition of unsaturated fatty acids.

Table No. 1: Showing Ingredients of *Manjishthadi Tailam* *(Chakradutta Kshudra Roga Chikitsa[2])*

Dravya	Latin Name	Family	Proportion
Manjishtha	*Rubia cordifolia*	Rubiaceae	*1 Karsha*
Madhuka	*Glycyrrhiza glabra*	Fabaceae	*1 Karsha*
Laksha	*Laciffer lacca*	Lacciferridae	*1 Karsha*
Matulunga	*Citrus medica*	Rutaceae	*1 Karsha*
Sayashtikam	*Glycerrhiza glabra*	Fabaceae	*1 Karsha*
Taila (Tila)	*Sesamum indicum*	Pedaliaceae	*1 Kudava*
Aja- Dugdha	*Capra aegagrus*	Bovidae	*2 Kudava*

Table No. 2: Specifications of *Kalka Dravya* used in *Manjishthadi Tailam* Preparation.

	Sample (M.T-1)	Sample (M.T-2)	Sample (M.T-3)
Time required to convert dry herbs in *Yavakuta* form	150 min.	150 min.	130 min.
Weight of Dry *Kalka Dravyas*	400 g	400 g	400 g
Water added for *Kalka Nirmana* in dry herbs	1200 ml	1200 ml	1200 ml
Time required for *Kalka* preparation	50 min.	40 min.	45 min.
Weight of prepared *Kalka Dravyas*	1500 g	1600 g	1540 g
Colour of the *Kalka Dravya*	Reddish-Brown	Reddish-Brown	Reddish-Brown
Taste of *Kalka*	*Kashaya-Tikta*	*Kashaya-Tikta*	*Kashaya-Tikta*
Consistency of *Kalka*	Smooth	Smooth	Smooth
Equipment for *Kalka Nirmana*	Mixer Grinder	Mixer Grinder	Mixer Grinder

M.T-1: *Manjishthadi Tailam* Sample 1; M.T-2: *Manjishthadi Tailam* Sample 2;
M.T-3: *Manjishthadi Tailam* Sample 3

Table No. 3: Specifications of *Sneha Dravya* used in *Manjishthadi Tailam* Preparation.

	Sample (M.T-1)	Sample (M.T-2)	Sample (M.T-3)
Type	*Murchchhit Tila Taila*	*Murchchhit Tila Taila*	*Murchchhit Tila Taila*
Colour	Red	Red	Red
Odour	Pleasant	Pleasant	Pleasant
Taste	*Tikta-Kashaya*	*Tikta-Kashaya*	*Tikta-Kashaya*
Quantity	1600 ml	1600 ml	1600 ml
Equipments for weighing	Electronic Weighing Machine	Electronic Weighing Machine	Electronic Weighing Machine

Table No. 4: Specifications of *Drava Dravya* used in *Manjishthadi Tailam* Preparation.

	Sample (M.T-1)	Sample (M.T-2)	Sample (M.T-3)
Type of *DravaDravya*	Water and milk	Water and milk	Water and milk
Ratio of *Drava Dravya* to *Sneha*	Water - 4:1 Milk - 2:1	Water - 4:1 Milk - 2:1	Water - 4:1 Milk - 2:1
Quantity of *Drava* Dravya	Water: - 6.4 Ltr. Milk: - 3.2 Ltr.	Water: - 6.4 Ltr. Milk: - 3.2 Ltr.	Water: - 6.4 Ltr. Milk: - 3.2 Ltr.

After the *Tila Taila Murchchhana* the *Murchchhita* oil was subjected to next procedure i.e. *Manjishthadi Tailam* preparation. Three batches (1.6 kg. each) of *Manjishthadi Tailam* has been prepared with intention to establish SOPs & SMP. In Manjishthadi Tailam preparation total 4 drugs were taken for *Kalka* preparation. Each drug was taken 100 g in its dry form except *Matulunga* fruit which was taken fresh at the time of *Kalka* preparation. *Yashtimadhu*[3] was taken doubles the quantity i.e. 200g. because in the classical reference both *Madhuka* and *Sayashtikam* are mentioned as an ingredients which are the synonyms of *Yashtimadhu*.

Laksha was mentioned in *Kalka Dravyas* but it was not added at the time of *Kalka* preparation instead of that it was utilized in the form of *Laksha Rasa*. *Laksha Rasa* has been prepared according to the reference of *Acharya Yadavaji Trikamji*. 100 g *Laksha Pottali* was suspended in 600 ml water and by *Dolayantra* method the water was reduced upto ¼ th and prepared *Laksha Rasa* was used in *Taila Paka*.

All the *Kalka Dravyas* were made in *Yavakuta* form and soaked in water separately one day before *Taila Paka*. Soaked *Dravyas* were converted in fine paste form in Mixer grinder separately; because it was observed that during *Yashtimadhu Kalka* preparation lots of froth appeared in it. Stainless steel vessels having capacity of 16 ltr has been taken. For the process for 1.6 kg *Taila Paka* it is quite sufficient as total 6.4 ltr water and 3.2 ltr goat milk, means total 11.2 ltr material was in the vessel.

Murchchhita Taila was subjected to heat on mild fire; the maximum temperature of oil observed was within range of 140°-150° C. After slight cooling *Kalka* was added in *bolus* forms; at that time temperature of oil ranges between 95°-105° C. Froth appears only for initial 2-5 minute after addition of first 2 to 3 *bolus* after that froth disappear completely. No mark able change in color was observed; but final colour of the prepared sample was slightly darker as compared to *Murchchhita Taila*. Goat milk was added in *Sneha* in its boiling stage. Goat milk was also subjected to heat and added in its hot stage. Temperature of Goat milk was observed 83°-88° C during addition of milk in Sneha Paka.

In classics it is mentioned that when we use milk in *Sneha Paka*, the *Paka* should be carried out for two days. In present study 2-3 days required in all the three samples to complete the *Sneha Paka* and average time duration taken to complete the Sneha Paka was 17-18 hrs. *Sneha Paka* was carried out on *Mandagni*. During the *Paka* maximum temperature observed of water was 95°-100° C and that of oil was 85°-90° C in initial stage and 90°-97° C in final stage of *Paka*. Temperature of oil at the time of filtration was 60°-65° C. Average loss of oil observed after completion of *Sneha Paka* was 3.12%;

Table No. 5: Showing the *Sneha Siddhi Lakshana* of *Manjishthadi Tailam*[4] *(Sh.M.Kh. 9/12-13)*

Sneha Siddhi Lakshana	***Kalka***	***Taila***
Sanyav Eve Niryase	+	-
Madhye Darvi Vimunchati	+	-
Shabda Hino Agni Nikshipta	-	+
Phenodgama	-	+
Gandh, Varna, Rasotpatti	-	+

Table No. 6: Showing Comparative Observational study of Manjishthadi Tailam

	Sample (M.T-1)	Sample (M.T-2)	Sample (M.T-3)
Enviromental condition during *Sneha-Paka*	Room-Temp: - 28.2° C Humidity: - 54 %	Room-Temp: - 28.7° C Humidity: -65 %	Room-Temp: - 28.5° C Humidity: - 43 %
Initial quantity of Oil	1600 ml	1600 ml	1600 ml
Time required for Oil to get moisten free and max. temp. observed	Time: - 30 min. Temp: - 150° C	Time: - 30 min. Temp: 144° C	Time: - 30 min. Temp: 140° C
Temp. at the time when *Kalka* added	100° C	104° C	98° C
Temp. at the time when Water added	86° C	84° C	88° C
Temp. at the time when Goat milk added	Water: - 100 C Milk: - 96° C	Water: - 100 C Milk: - 94° C	Water: - 100 C Milk: - 95° C
Time Required to complete *Sneha-Paka*	18.20 hrs.	19.10 hrs.	17.45 hrs.
Temp. of *Taila* at the time of Filtration	65° C	62° C	64° C
Loss of Oil After completion of *Sneha-Paka*	Yield: - 1560 ml Loss: -40 ml 2.5 %	Yield: - 1540 ml Loss: -60 ml 3.75 %	Yield: - 1550 ml Loss: -50 ml 3.12 %

Analytical Study: -

For the Physico chemical analysis of medicated oil the parameters laid down by CCRAS[5] were selected. In analytical study following observations were obtained.

Table No. 7: Physio chemical analysis of Five Samples of *Manjishthadi Tailam* according to Parameters Laid down by CCRAS

Oil Sample	LOD %	S.G	R.I	Acid value	Sap. value	Ester value	Iodine value	Peroxide value	Free Fatty Acid	Total fatty matter % w/w	Unsap. Matter % w/w
Normal	1.520	0.92233	1.4720	2.115	138.050	135.935	84.897	27.434	1.063	99.121	1.123
Murchit	0.012	0.92305	1.4725	2.132	166.560	164.428	81.718	5.353	1.072	98.315	1.211
M.T-1	0.051	0.92692	1.4720	2.157	169.400	135.935	83.471	10.874	1.084	98.553	1.336
M.T-2	0.063	0.92386	1.4715	2.110	167.840	165.730	79.330	10.495	1.060	99.496	1.555
M.T-3	0.084	0.93430	1.4715	2.117	168.700	1166.583	101.014	10.109	1.064	96.616	1.510

Discussion: -

The rationality behind taking oil as a base is presumably to extract or hold lipid soluble active fractions from the ingredients used. Average time duration taken to complete the *Sneha Paka* was 17-18 hrs. Time variation in completion of *Sneha Paka* may depend upon intensity of heat source, different environmental conditions and some manual error like consistency in continuous stirring which affect on evaporating rate of the liquid media. *Sneha Paka* was carried out on *Mandagni*. Average loss of oil observed after completion of *Sneha Paka* was 3.12%; the loss was quite minimum may be due to addition of fat content from goat milk.

Conclusion: -

ñ *Manjishthadi Tailam* formulation *Yashtimadhu* was taken in double quantity because *Madhuka* & *Yashtika* are the synonyms of *Yashtimadhu*. After completion of *Taila Paka*, obtained Red coloured oil having *Tikta- Kashaya Rasa* with pleasant smell but not distinguished exact in nature. In Pharmaceutical process average loss of oil observed after completion of *Sneha Paka* was 3.12%. In analytical study an attempt was made to compare the changes in pharmaceutical process of *Murchchhita Taila* and prepared *samples of Manjishthadi Tailam* on different parameters laid down by CCRAS; which showed that there has been a definite change observed in every parameter; that may be due to process of *Taila Paka*.

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Conceptual Study

Adiponectin: A potential biomarker in *Madhumeha* (Type 2 Diabetes Mellitus)

*Dr. Amita, **Prof. Pawankumar Godatwar, ***Dr. Bal Krishan Sevatkar

Abstract –

Background: *Madhumeha* (Type 2 Diabetes Mellitus) has been a global problem and well established in the ancient Indian classics. With the changing life style and sedentary habits of the modern era, incidence of Diabetes Mellitus is increasing day by day. **Aim and objective:** To assess the consistency of the association of adiponectin levels and risk of type 2 diabetes. **Material & Methods:** This article is based on a review of *Ayurvedic* texts and modern texts. Materials related to adiponectin, and other relevant topics have been collected. This article reviews the current understanding about the structure, function of adiponectin and provide insight into its potential clinical relevance with special reference to *Madhumeha* (Type 2 Diabetes Mellitus). **Conclusion:** It can be concluded from this study that Adiponectin is a potential biomarker in prediction of *Madhumeha* (Type 2 Diabetes Mellitus). *Prameha* is described as a complication of *Sthaulya* by *Acharya*. Adiponectin is a collagen-like plasma protein secreted by adipocytes. Adiponectin appears to be a major modulator of insulin action and its levels are reduced in type 2 diabetes.

Keywords: Adiponectin, *Madhumeha*, Insulin resitance, Diabetes, Cardiovascular disease.

सारांश–

पृष्ठभूमि एवं उद्देश्य–मधुमेह (टाइप–2 डायबिटीज मेलायटस) का वर्णन प्राचीन भारतीय शास्त्रों से ही पूर्ण रूप से उपलब्ध है,जो एक वैश्विक समस्या बन चुका है। बदलती जीवन शैली और आधुनिक युग की आसीन आदतों के कारण, मधुमेह की घटनाओं में दिन प्रतिदिन वृद्धि हो रही है। वर्तमान अध्ययन का उद्देश्य,एक नए बायोमार्कर– एडिपोनेक्टिन की सहायता से बहुत ही प्रारंभिक अवस्था में रोग जांच करने के विषय मे समीक्षा करना है। **सामग्री एवं विधि:** यह लेख एडिपोनेक्टिन की वर्तमान संरचना, कार्य के बारे में समीक्षा के साथ साथ टाइप–2 मधुमेह के विशेष संदर्भ में, इसकी संभावित चिकित्सीय प्रासंगिकता के बारे अंतर्दृष्टि प्रदान करेगा।

उपसंहार: प्रस्तुत समीक्षात्मक अध्ययन से यह निष्कर्ष निकाला जा सकता है कि एडिपोनेक्टिन, मधुमेह (टाइप–2 डायबिटीज मेलायटस) की भविष्यवाणी में एक संभावित बायोमार्कर है। आचार्य द्वारा प्रमेह का वर्णन स्थौल्य के एक उपद्रव के रूप में किया गया है। एडिपोनेक्टिन एडिपोसाइट्स द्वारा स्रावित कोलेजन की तरह एक प्लाज्मा प्रोटीन है जो इंसुलिन कार्रवाई का– एक प्रमुख अधिमिश्रक (modulator) प्रतीत होता है और इसका स्तर मधुमेह (टाइप–2 डायबिटीज मेलायटस) में कम हो जाता है।

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Conceptual Study

Adiponectin: A potential biomarker in *Madhumeha* (Type 2 Diabetes Mellitus)

Dr. Amita, Prof. Pawankumar Godatwar, Dr. Bal Krishan Sevatkar

Introduction:

Ayurvedic texts suggest to diagnose the disease first and then to think over treatment. At the same time *Ayurvedic* texts also describes that health and healthy living is the prime motto of all the human beings. Now a days, to predict this dreadful disease *Madhumeha*, in a very early stage has become a demand of time. So, here is an attempt to understand the relation between Adiponectin and *Madhumeha* (Type 2 Diabetes Mellitus) in its early detection. Adiponectin, alternately named Adipocyte complement-related protein of 30 kDa (Acrp30), adipoQ, adipose most abundant gene transcript 1 (apM1), and gelatin-binding protein of 28 kDa (GBP28), is an adipocyte-specific, secreted protein with potential roles in glucose and lipid homeostasis. Circulating Adiponectin levels are high, accounting for approximately 0.01% of total plasma protein[1-4]. It is a hormone of adipocyte origin that is involved in the homeostatic control of circulating glucose and lipid levels.[5,6] Adiponectin is a 147 amino acid protein that is similar in sequence and structure to the C1q complement factor. Adiponectin has been postulated to play an important role in the modulation of glucose and lipid metabolism in insulin-sensitive tissues in both humans and animals. Low adiponectin levels have also been strongly implicated in the development of insulin resistance in mouse models of both obesity and lipoatrophy.[7] In humans, plasma levels of adiponectin are significantly lower in insulin-resistant states including type 2 diabetes.[8] Plasma adiponectin levels in diabetic subjects with coronary artery disease (CAD) are lower than in diabetic patients without CAD, suggesting that adiponectin may have anti-atherogenic properties.[9] The association of low adiponectin levels with obesity, insulin resistance, CAD, and dyslipidemia indicates that this novel protein may be an important new marker of the metabolic syndrome.

Currently, the prevalence of type 2 diabetes in the United States and many other countries in the world has reached epidemic proportions.[10] Various signaling molecules secreted by adipocytes have been implicated in the development of insulin resistance and type 2 diabetes, based on results from animal models and metabolic studies in humans.[11] Epidemiologic studies can provide insight into the potential importance of these signaling molecules as determinants of the incidence of type 2 diabetes in human populations. In addition, these studies can identify biological markers that may be useful for the prediction of type 2 diabetes and the identification of high-risk groups. Till date, no systematic review has been conducted that evaluates the available evidence for an association between adiponectin levels and risk of type 2 diabetes.

Aim and Objective: To assess the consistency of the association of adiponectin levels and risk of type 2 diabetes.

Material and Methods: This article is based on a review of *Ayurvedic* texts and modern texts. Materials related to adiponectin, and other relevant topics have been collected. The main *Ayurvedic* texts used in this study *Charaka Samhita*, *Sushruta Samhita*, *Astanga Hridaya* and available commentaries on these. We have also referred to the modern texts and searched various websites & reports to collect information on the relevant topics.

Adiponectin: A Review

Adiponectin is a 244-amino-acid-long polypeptide. There are four distinct regions of adiponectin. The first is a short signal sequence that targets the hormone for secretion outside the cell; next is a short region that varies between species; the third is a 65-amino acid region with similarity to collagenous proteins; the last is a globular domain. Overall this gene shows similarity to the complement 1Q factors (C1Q).

However, when the 3-dimensional structure of the globular region was determined, a striking similarity to TNFá was observed, despite unrelated protein sequences.[12] Adiponectin is a protein hormone that modulates a number of metabolic processes, including glucose regulation and fatty acid oxidation.[13] Adiponectin is exclusively secreted from adipose tissue (and also from the placenta in pregnancy[14]) into the bloodstream and is very abundant in plasma relative to many hormones. Levels of the hormone are inversely correlated with body fat percentage in adults, [15] while the association in infants and young children is less clear. Transgenic mice with increased adiponectin show impaired adipocyt differentiation and increased energy expenditure associated with protein uncoupling.[16] The hormone plays a role in the suppression of the metabolic derangements that may result in type 2 diabetes,[15] obesity, atherosclerosis,[13] non-alcoholic fatty liver disease (NAFLD) and an independent risk factor for metabolic syndrome.[17] Adiponectin in combination with leptin has been shown to completely reverse insulin resistance in mice.[18]

Adiponectin is secreted into the bloodstream where it accounts for approximately 0.01% of all plasma protein at around 5-10 ìg/mL. Plasma concentrations reveal a sexual dimorphism, with females having higher levels than males. Levels of adiponectin are reduced in diabetics compared to non-diabetics. Weight reduction significantly increases circulating levels.[19]Adiponectin exerts some of its weight reduction effects via the brain. This is similar to the action of leptin,[20] but the two hormones perform complementary actions, and can have synergistic effects.

Methods of measurement of Adiponectin:

Measurements of adiponectin can be performed with the help of Cell Culture Supernates, Serum or plasma by ELISA method. This assay employs the quantitative sandwich enzyme immunoassay technique. A monoclonal antibody specific for the Adiponectin globular domain has been pre-coated onto a microplate. Standards and samples are pipetted into the wells and any Adiponectin present is bound by the immobilized antibody. After washing away any unbound substances, an enzyme-linked monoclonal antibody specific for the Adiponectin globular domain is added to the wells. Following a wash to remove any unbound antibody-enzyme reagent, a substrate solution is added to the wells and color develops in proportion to the amount of Adiponectin bound in the initial step. The color development is stopped and the intensity of the color is measured.

Discussion:

Madhumeha is one of the types of *Vatika Prameha* described by different *Acharyas* in classical *Ayurvedic* texts. *Kapha Dosha* is the prime *Dosha* which plays an important role in the manifestation of the disease, it is considered as *Madhumeha-arambhaka Dosha*. *Medas* vitiation is common and it is dominant *Dushya* in the pathogenesis of *Prameha*. In *Prameha Medas* is vitiated in two ways – *Abaddha* and *Bahutva*.[21] Concept of *Bahudrava Kapha* and *Abaddha Medas* may be compared with abnormal fat metabolism. Diabetes has been described as complication of obesity due to insulin resistance caused by fat globules. *Acharya Charaka* also describes *Prameha* as a complication of *Sthaulya*. The obesity accompanying with Type 2 Diabetes Mellitus, particularly in a central or visceral location, is thought to be pathogenic process. The increased adipocyte mass lead to increased levels of circulating free fatty acids and the other fat cell products; for example: adipocytes secrete a number of biological products (nonesterified free fatty acids, retinal binding protein 4, leptin, TNF-a, resistin and Adiponectin). In addition to regulating body weight, appetite and energy expenditure, adipokines also modulate insulin sensitivity. Type 2 diabetes results from an interaction between genetic and environmental factors. Genome-wide scans have mapped a susceptibility locus for type 2 diabetes, metabolic syndrome, and coronary heart disease to chromosome 3q27, where the gene encoding adiponectin is located.[22, 23] A study has been shown that genetic variations resulting in reduced serum adiponectin levels are associated with increased risk for type 2 diabetes in the Japanese population. In another study, Japanese subjects carrying a mis-sense mutation in the adiponectin gene associated with hypoadiponectinemia exhibited the phenotype of the metabolic syndrome, including insulin

resistance and coronary artery disease.[24] Thus genetic polymorphisms of the adiponectin gene that result in lower production and secretion of adiponectin may be responsible, at least in part, for the pathogenesis of the insulin resistance syndrome and diabetes. Conversely, increased baseline concentrations of adiponectin may be associated with a reduced risk of developing type 2 diabetes.[25] Reduced insulin sensitivity is a key factor in the development of type 2 diabetes. The main insulin-sensitizing action of adiponectin results from decrease in hepatic gluconeogenesis and increase in muscle glucose transport and, secondly from enhancement of energy consumption and fatty acid oxidation in peripheral tissues with the aim of increasing ATP production.[26]

Replenishment of adiponectin might represent a novel treatment strategy for insulin resistance and type 2 diabetes. Adiponectin might have several therapeutic advantages over antidiabetic drugs now used clinically. First, in addition to hypolipidemic and antidiabetic effects, adiponectin has potential anti-inflammatory properties that might prevent or retard atherogenesis. Second, adiponectin appears to exert these effects without increasing body weight.[27] Adiponectin might have therapeutic implications as an anti-obesity drug as well, although there have been no studies in humans so far.

Conclusion:

This work opens new *Ayurveda* inspired holistic approach to the early detection and prevention of *Madhumeha* (Diabetes Mellitus). The view of the adipocyte as simply a storage depot for fat is no longer tenable. Among the various "adipocytokines," adiponectin, which is an abundant circulating protein synthesized solely in adipose tissue, appears to play a very important role in carbohydrate and lipid metabolism and vascular biology. Adiponectin appears to be a major modulator of insulin action and its levels are reduced in type 2 diabetes, which could contribute to peripheral insulin resistance in this condition. It has significant insulin-sensitizing as well as anti-inflammatory properties. The protein has been found to be decreased in cases of insulin resistance, diabetes, atherosclerosis, and coronary artery disease.[28]

Numerous important questions about adiponectin await further study. The mechanisms by which adiponectin is synthesized and secreted need to be elucidated, as do the signals that reduce adiponectin expression in adipocytes with increasing adiposity.

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Conceptual Study

Ayurvedic Management In Diabetic Retinopathy (*Prameha Janya Netra Rogas)*

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Abstract :

Sedentary life style and enormous amount of stress have created a strong platform for good number of life style disorders including Diabetes Mellitus (DM), which affects almost every system in the body. It is associated with long term complications involving eyes, kidneys, nerves and blood vessels. In eyes Diabetic retinopathy (DR) is one of the major vascular complications of DM. Eye is unique structure of the body and its anatomical and physiological frame work is said to be unique. Due to modern life style, number of diseases increasing day by day. Diabetic Retinopathy is an ocular manifestation of the systemic disease and sight-threatening disease. The treatment of modern system of medicine, focal laser therapy, anti-vascular growth factor drugs. These treatment modalities have side effects. The aim of this conceptual study to manage the diabetic retinopathy or *Prameha janya Netra Rogas* by means of *Ayurvedic* adaptation like *Shodhana, Shamana* and *Sthanika Netra Chikitsa* and to reduce the further complications of diabetic retinopathy.

Keywords: Diabetes retinopathy, *Prameha janya Netra Rogas*, *Ayurvedic* adaptation, *Sthanika Netra Chikitsa.*

सारांश–

वर्तमान समय में जो जीवन शैली संबन्धित व्याधियाँ है जिसमें डायबिटिज मेलाइटस भी है, उनका एक प्रमुख कारण विलासता पूर्ण जीवन तथा अत्यधिक तनाव है। यह व्याधि दृष्टि, वृक्क, तन्त्रिका तथा रक्त वाहिनीयों पर घातक असर डालती है। डायबिटिज रेटिनोपैथी भी लम्बे समय तक डायबिटिज के परिणामस्वरूप होती है।

आधुनिक जीवन शैली के कारण दिन प्रतिदिन व्याधियों की संख्या बढ़ती जा रही है। डायबिटिक रेटिनोपैथी एक दृष्टि के लिए घातक व्याधि है। आधुनिक चिकित्सा विज्ञान में इसकी चिकित्सा फोकल लेजर थैरेपी, एंटी वेस्कूलर ग्रोथ कारण औषध है। इस चिकित्सा उपक्रम के साइड इफेक्ट भी है।

इस अध्ययन का मुख्य उद्देश्य आयुर्वेदीय चिकित्सा उपक्रम शोधन, शमन, स्थानिक नेत्र चिकित्सा द्वारा डायबिटिज, रेटिनोपैथी के होने वाले घातक परिणामों को कम करना है।

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Conceptual Study

Ayurvedic Management In Diabetic Retinopathy (*Prameha Janya Netra Rogas)*

Singh Karan, Mishra Pramod Kumar, Soni Anamika, Sharma Brahmanand

Introduction:

Every living organism has unique features in its anatomical and physiological framework so that it can sustain to a large extent from the challenges of external hazards. Being the most developed link in the revolutionary chain human have best possible defense mechanism and adaptation power against many number of external challenges. Diabetes Mellitus is a common metabolic disorder in which there is high blood sugar level over a prolonged period and occurs in one of two forms: Type1 or Insulin Dependent Diabetes Mellitus (IDDM) and Type2 or Non-Insulin Dependent Diabetes Mellitus (NIDDM). Diabetic retinopathy is most common and serious complication of Diabetes and changes in the retina are observed by 10 years of Diabetes history or even earlier due to modified lifestyle in present era. This disease results in generalized macro and micro vascular complications linked to glycaemic control and affect theses resulting in poor vision or even blindness. Despite of better understanding of its pathogenesis, satisfactory treatment is yet to be established. *Ayurveda* is well recognized for its role in preventing the disease, but as such no description is available in text which clarifies the progression of *Prameha* to loss of vision. So *Ayurvedic* treatment purely lies on the basis to pacify the pathological changes which occurs in eye as a result of diabetes according to modern parameters.

Ayurvedic descriptions about *Prameha* show very much resemblance with that of diabetic mellitus both in aetiopathogenesis and management aspects. *Ayurvedic* science has grouped *Prameha* under *mahagadas* as it is.

Diabetic Retinopathy Diabetic Retinopathy has been variously classified. Presently followed classification is as follows[1]

I. Non Proliferative Diabetic Retinopathy (NPDR)

- Mild NPDR
- Moderate NPDR
- Severe NPDR
- Very severe NPDR

II. Proliferative Diabetic Retinopathy (PDR)

III. Diabetic Maculopathy

IV. Advanced Diabetic eye diseases Diabetic Retinopathy are a microangiopathy which affects the retinal precapillary arterioles, capillaries and venules. This microangiopathy causes:

(1) Microvascular leakage

(2) Microvascular occlusion.

1. **Microvascular leakage**:- Normally capillaries are lined by single layer of endothelial cells and basement membrane. But in retinal capillaries, they are also lined by Pericytes. These pericytes are responsible for structural integrity of vessel wall. These pericytes are specifically lost early in diabetic retinopathy. Physical weakening of capillary walls due to loss of pericyte result in localized saccular out pouching of vessel wall,termed microaneurysm. It appears as a small red spot. Some of the thin walled microaneurysms and fragile retinal capillaries may rupture and cause retinal haemorrhages, results in deep haemorrhages (dot and blot haemorrhages) and superficial haemorrhages (flame shaped). In addition there is breakdown of blood retinal barrier due to many factors, especially as a result of opening of tight junction between adjacent microvascular endothelial cell processes. Break down of blood retinal barrier causes leakage of plasma constituents in the retina and form hard exudates and retinal oedema. Hard

exudates are deposits of plasma proteins and lipids. All the lesions often occur more near macula and optic disc.[2]

2. Microvascular occlusion:- Due to prolonged diabetes mellitus there occurs thickening of capillary basement membrane, capillary endothelial cell damage and proliferation, changes in R.B.C's (i.e elasticity of R.B.C reduced) and increased stickiness and aggregation of platelets. All together leads to microvascular occlusion which in turn lead to retinal hypoxia, results in retinal ischaemia, which initially develops in the mid retinal periphery. Appearance of ischaemic areas due to occlusion of capillaries may manifest as "cotton wool spots" or soft exudates. These are microinfarct of nerve fibre layer of retina. Venous dilation, beading and looping of the veins occurs secondary to Ischaemia.[3]

Prameha janya netra roga:-

In the context of *Shalakya Tantra* there is no direct reference is told by detailing about the diabetic retinopathy or for *Pramehaja Netra Rogas*, though there are credible references about affections of *Prameha* in sense organs. It is also told clearly that those *Indreeya Dourbalyatha* will occur by the progress of disease. In *Prameha* the major *Samprapti ghataka* is *Kleda* which contributes much to the *Upadrava Rogas*. It has been mentioned in classics "*Hrinnetra jihwa sravanopadeha*[4]" which gives direct clue regarding the involvement of vital organs like eye in *Prameha Samprapti*. It can be understand that any alterations in the mechanism of *Dhatu Parinamakriya* (metabolism) can lead to combinations of various symptoms. The *Poshaka Dhatus* (nutrients) for *Dhatuparinama Kriya* is supplied by *Rasa-Rakta Dhatus* through various *Srotas* to various organs of the body. The *Dhatus* undergo *Upapachaya Pravarthanas* through *Brahmana-Langhana Kriyas*. Any disruptions in any of the mentioned steps will alter the homeostatic balance of the whole *Parinama Kriya*. It finally leads to *Vaigunya* of *the Rasa-Rakta Dhatus* and its functions. The vitiated *Doshas* will get *Sthana Samsraya* in *Netra* and will lead to various pathological processes and the pathology can be given name as *Pramehajanya Netra Vyadhi* or diabetic retinopathy.

Netra is *Tejo Mahabhoota Pradhana* with definitely *Pitta Pradhana*. Any organ with *Pitta* origin if it is get *Avrutha* by *Kapha Dosha* will lead to *Srotoavarodha*. If we deeply analyses the pathogenesis of NPDR and PDR we can clearly see the involvement of all type of *Sroto Dusti* ie, *Atipravruthi, Sanga, Siragranthi, Vimarga Gamanam*. Retinal vessel occlusion to *Sanga*, development of aneurysms can be correlated to *Siragranthi*, retinal hemorrhage to *Vimarga Gamana* and neo vascularization to *Ati Pravruthi*. Each of these *Srothodustis* are present in various stages of retinopathy. *Sopha Samprapti* can also give special attention over here.

Classification:-

On the basis of involved *Doshas Kapha-pitta Pradhana Vata-pitta Pradhana* On the basis of *samprapti*.[5]

Kapha-Avaranavasta - Simple background retinopathy

Raktapitta Prakopavasta - Diabetic maculopathy

Urdwaga Raktapittavasta - Pre-proliferative Diabetic retinopathy

Vataja Linganasham - Proliferative Diabetic retinopathy

Kapha-Avaranavasta **-**

Kapha Dosha in *Dravavasta* produces *Srothodusti* in the eye and leads to *Dhatwagni Vaigunya*. The *Raktadhatwagni Vaigunya* leads to *Rakta Srothovaha Vaigunyata* and cause deposition of *Samakapha* in the minute channels. The result is *Khavaigunyata* of the *Srothas*.

Treatment-

The treatment mentioned in *Prameha, Raktapitta, Kaphaja Timira, Abhishyanda* can be *ayurvedic* adaptation as the treatment modality for the different condition of DR. *Samanya Netra Roga Prathishedha* along with *Kaya Shodana* and *Shamana Chikitsa* can be adopted for the management of DR.

Shodhana **therapy:-**

Kaya Shodana should be done for eliminating the *Amadosha* from the *Shareera*. *Snehapana* with *Triphala Gritha, Maha Triphala Gritha* followed by *Virechana (*depending upon *Doshavastha)*.

***Shamana* therapy:-**

Shamana can be given for those who are not fit for undergoing *Shodana* therapy. *Shamana Oushadi* should be *Pramehahara* as well as *Chakshushya* in action. *Ropana, Sthambana, Sheeta* drugs can be preferred. *Triphala* formulation is a better drug of choice in all conditions and stages of DR. In *Kapha-Avarana Avastha* drugs like *Lajjalu, Khadira, Bilwa, Haridra, Ashwagandha* give a better result. In stage of *Rakta-Pitta, Vasa, Lodhra, Musali, Yashti, Manjista, Sariva, Chandana* drugs can give a better result. *Pratimarsha Nasya* can be with *Anu Taila* and *Shadbindu Taila*. *Saptamritha Loha, Asanadi Gana Kashaya, Sameera Panchaka Kashaya, Guduchyadi Kashaya*.

Stahnika netra chikitsa: -

In *Sthanika Chikitsa, Kriya Kalpa* procedures can be adopted like *Seka, Aschotana, Tarpana* and *Shirotalam*. *Seka* can be given with *Vasa, Amalaki, Lodhra, Yashti Kashayas* etc drugs. *Aschotana* with *Triphala Ghrita, Maha Triphala Gritha* etc. *Tarpana* with *Triphala Ghrita, Maha Triphala Ghrita, Jeevanthyadi Gritham* etc. *Shirotalam* with *Vasa Churna, Yashti Churna, Amalaki Churna, Lodhra Churna* etc can be adopted according to the stage of *Vyadhi*.

Ayurvedic adaptation for Life style Along with these treatment:-

1 *Dinacharya*[9] and ***Ritucharya***- getting up in "*Brahmi Muhurta*" sets the biological clock properly and this is the equilibrium of the *Doshas* to work in the right way. Appropriate habit of diet, exercise, meditation.

- life style which helps to maintain control the blood sugar level Practicing *Siroabhyanga* (head massage), *Anjana*.
- *Padabhyanga*(foot massage), *Pratimarsha Nasya*, *Pada Trana Dharana* (footwear) and *Chatra Dharana* (umbrella) will help in maintaining the health of eye. Adopt suitable measure according to *Ritu* and *Dosha* like avoiding day sleep except in summer season.

2 *Achara Rasayana Sevana:-* Following the ethical regimen and eight codes of conduct provides peace of mind and balance.

Conclusion -

Prameha janya Netra Roga or diabetic retinopathy can be controlled or aggravated according to one's life style and control over blood sugar levels. It is the leading cause of blindness in elderly subjects. As no satisfactory treatment is available for diabetic retinopathy, new approaches are needed to slow the progression and limit the damage caused by this disease. *Ayurveda* provides a better management for diabetic retinopathy compared to modern medicine. *Ayurvedic* treatment helps to manage blood sugar levels and the same time *Chakshushya* in nature helps to maintain the vision which detoriates according to the stages of diabetic retinopathy. Changes in life style, diet habit, exercise, meditation and following daily regimen and ethical regimen plays important role.

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Literary Review

Concept of *Viruddha Ahara*: A Review

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Abstract:

In *Ayurvedic* classics, *ahara* (food) is mentioned as one among the three *upasthambas* (sub-pillars of body) which supports the three main *sthambas* (pillars) of the body. *Ahara* is considered to be vital for a human body as it provides the basic nutrients, which are very essential to carry out the basic activities of digestion and metabolism. *Ayurveda* emphasizes on consuming healthy and nutritious diet. Unwholesome diet (*viruddha ahara*) is a unique and important concept described in *Ayurveda*. The diet, which disturbs the balance among the body elements, is called as *viruddha ahara*. Consumption of *viruddha ahara* gives rise to various disturbances of mild to violent nature and disease of acute to chronic nature including the eight *maharogas*, genetic disturbances and even sometimes causes death of the person. Therefore ayurveda have given keen attention on concept of wholesome *ahara* and unwholesome *ahara*. Correspondingly intake of incompatibility food is much increases in present era. The article details about variety of incompatible food consumed in today's day to day life style and also enlists the hazardous effects on health.

Keywords: *viruddha ahara; amavisha; agnimandya;* incompatible diet.

सारांश–

आयुर्वेदिक संहिताओं में आहार का वर्णन तीन उपस्तंभों में सर्वप्रथम किया है जो शरीर के तीन महत्वपूर्ण स्तंभ (वात, पित्त और कफ) को उत्पन्न करता है। मनुष्य शरीर के लिये आहार प्रधान माना गया है क्योकि आहार से जो पोषक तत्व प्राप्त होते है वो पाचन क्रिया के लिये अत्यावशक होती है। आयुर्वेद में स्वास्थ्य के लिये हितकर और पोषण युक्त आहार का उपदेश किया है। विरूद्ध आहार ये एकमेव और महत्वपूर्ण विषय का वर्णन हमारें शास्त्रों में मिलता है। जो आहार शरीर घटकों को प्रभावित करता है उसे विरूद्ध आहार कहते है। विरूद्ध अन्न के सेवन से आशुकरी स्वभाव तथा चिरकारी स्वभाव के रोग उत्पन्न होते है जैसे, आठ महारोग, आनुवांशिक व्याधियाँ और विरूद्ध अन्न का सेवन मृत्यु का कारण हो सकता है। इसीलिये हितकर और अहितकर आहार का वर्णन हमारे संहिताओं में मिलता है। आज के आधुनिक काल में विरूद्ध अन्न का सेवन बढ़ता ही जा रहा है। इसीलिये सामान्य मनुष्य को इस विरूद्ध आहार से परिचित करना जरूरी है। प्रस्तुत लेख में आज के दैनन्दित जीवन में सेवन किये जाने वाले विविध प्रकार के विरूद्ध अन्न और उनका स्वास्थ्य पर हानिकारक प्रभाव का वर्णन किया है।

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Literary Review

Concept of *Viruddha Ahara*: A Review

Dr. Talekar Manisha, Dr. Mandal Sisir Kumar, Dr. Sharma Reetu

Introduction:

For healthy living, ayurveda emphasizes on consuming right kind of diet which is healthy and nutritious. In ayurveda, food is considered not only as mixture of the basic ingredients like proteins, vitamins, fats and carbohydrates, but it directs to avoid those food articles which are having opposite attributes to be used at same time as per ayurveda. This sort of food may induce the accumulation of toxins in the body which may end up in chronic and grave diseases like cancer, immune disorders. Diet is considered to be vital for a human body as it provides the basic nutrients, which are necessary to carry out the basic activities of digestion and metabolism. Ayurveda has categorized food into three types based on its basic quality-the *satvik* or spiritual quality, *rajasik* or active quality, and *tamasik* or material quality. It is said that whatever food we eat affects our mind in accordance with its basic quality. *Satvik* food is enriching and elevating the level of energy for mind and soul, while *rajasik* food has a basic tendency to provoke man to a materialistic and selfish way of living. *Tamasik* food is one, which leads to a devilish streak in a person.[1]

Attributes of Food-

1. *VARNA* (Colour and complex)
2. *PRASADA* (Pleasure)
3. *SUKHAM* (Comfort and Health)
4. *TUSHTI* (Satisfaction)
5. *SAUSVARYAM* (Tone)
6. *PUSHTI* (Nourishment)
7. *PRATIBHA* (Skill)
8. *MEDHA* (Intellect)
9. *BALA* (Strength and immunity)

Viruddha ahara **:** The Destroyer Of Health

Etymology:

The word *Viruddha* is originated from the root "*Rudhir Avarni*" by applying the Prefix "VI". This leads to two factors i.e. on combining two, three things; the stronger one shades or overpowers the weaker ingredients. This has been accepted principally in ayurveda also. It has been stated that in a combination of so many opposite qualities the majority of the power packed qualities overpower the weaker qualities.[2]

Definition of *Viruddha ahara*:

According to *Acharya Charaka*, all kinds of foods which aggravate (increase) the *doshas* but do not expel them out of the body and all of them become unsuitable or unhealthy for body is called as *viruddha*.[3] The food articles by which the *doshas* are going to be provoked and spread or diffused from their place but these *doshas* are not eliminated from the body. So these food articles become unwholesome. According to *Acharya Sushruta*, *viruddha ahara* not only provokes the *doshas* but that also aggravate the *dhatus*.[4] "*Viruddha*" word here denotes opposition. The combination of any two or more factors out of 18 mentioned below, when used, may create harmful effects on the health. They act opposite to the above mentioned 9 attributes of food which are desired.

Classification of *Viruddh Ahara* :

There are 18 types of *viruddha ahara* described by *Acharya Charaka*. Among them some of these types can be correlated with causes of various diseases like-

1. *Desha Viruddha* - The use of dry (*ruksha*) and acute (*tikshna*) and other food substances of similar qualities in an arid region (*jangala desha*) and the use of unctuous and cold and other food substances of similar qualities in a wet region (*anupa desha*) are examples of incompatibility of diet with reference to *clime* - *Desha Viruddha*.

2. *Kala Viruddha* - The use of cold, dry and similar things in winter and the use of pungent, hot and similar things in summer season are called incompatibility of diet with reference to season - *Kala Viruddha*.

3. Agni Viruddha - One should take diet (food - *ahara*) after considering four types of *agni* respectively. If food has not been taken in accordance to the respective thermal intensity (*jatharagni bala*) then it will become *agni viruddha*. Some examples of *agni viruddha* diseases like *Grahaniroga Nidana*[5], *Sannipatodara Nidana*[6] etc.

4. Matra Viruddha -This group includes those substances which possess the property of *viruddh ahara* only on combination in specified amount. Some example of *matra viruddha,* as given in classics are -

- Honey + ghee in equal quantity,
- Honey + rain water in equal quantity,
- Honey + water in equal quantity etc.

5. Satmya Viruddha - Intake of sweet and cold food substances or articles by a person to whom only pungent and hot substances are homologous is an example of incompatibility of diet with reference to homologation. Various acharyas have mentioned *Satmya viruddha ahara* as a causative factor in different diseases. Viz.

Kustha Nidana : Satmya Viruddha[7]

Krimi Nidana : Satmya Viruddha [8]

Atisara Roga Nidana : Satmya Viruddha[9]

6. Dosha Viruddha- The use of articles of diet (food), drugs and procedures, which are similar in quality to that of the respective (susceptible) body humours, is called (*vatadi viruddha*) humoral incompatibility. Various acharyas have mentioned *dosha viruddha ahara* as a causative factor in different diseases. Viz.:

- *Gulma Nidana* : *Vata* provoking diet in *vata prakriti*.[10]
- *Pittaja Atisara* : *Amla, lavana, tikshna, katu* food substances in *pitta prakriti*.[11]

7. Sanskara Viruddha -This includes the consumption of substances prepared in a particular way which produces poisonous effects. Multiple examples have been given of this type, some of important ones of which are :

- Indian Spinach (*Yorksaka*) prepared with *tila* paste causes *atisara*.
- *Ghrita* kept for ten night duration in a bell metal (*kansya*) vessel.
- Meat of sparrow, peacock etc. roasted on castor spit and heated honey etc.

8. Veerya Viruddha -It is the usage of substances with opposite potencies such as an *ushna veerya* (a hot potency) *dravya* (substances) used with a *sheeta veerya* (cold potency substances) *dravya*. eg. fish+milk

9. Koshtha Viruddha -It is the usage of diet and drugs not in accordance with the bowel for example – Administration of mild purgative in a small dose to a person with *krura koshtha* (constipated bowel) or vice - versa.

10. Avastha Viruddha -It is the consumption of substances having qualities contradictory to the state of health. for example – An old age person consuming less amount of food or food which is dry in nature (*ruksha*), cold in potency (*sheeta veerya*) and easy to digest or consumption of *kapha* aggravating factors by a person after sleep.

Classical example- *Swarbheda Nidana*: Intake of meal after speech or *adhyayana*.[12]

11. Krama Viruddha -Taking meals not following the correct pattern for example –intake of food without clearance of bowel or bladder , intake of food when not hungry, not taking food when hungry and so on. Various acharyas have mentioned *krama viruddha ahara* as a causative factor in different diseases. Viz.:

- *Hikka Nidana - Ushna sevana* after *sheeta sevana,* & vice-versa*, snigdha* after *ruksa* & vice-versa *, manda* after *tikshna*[13]
- *Kushtha nidana – Sheeta-ushna krama viruddha sevana*[14]

12. Parihara Viruddha- In diseased condition, intake of food substances, which are mentioned as *apathya* - unwholesome in that particular disease is called *parihara viruddha*. Similarly, in healthy conditions, after intake any type of meal, one should avoid those food substances, which are similar in quality with previous meal. Various acharyas have mentioned *parihara viruddha*

ahara as a causative factor in different diseases. Viz.:

- *Vataja Gulma Nidana:* Drinking fresh water in excess quantity after meal[15]
- *Kaphaja Gulma* : Excess drinking of water after excess intake of meal[16]
- *Kamala :* Taking of *pittaja nidana* after *panduroga*[17]
- *Udararoga* : *Mithya ahara* in *samsarjana karma* after *vamana – virechana*[18]
- *Vata vyadhi : Ruksha bhojana*[19]

13. Upachara Viruddha -Intake of substances in contradiction to the prescriptions such as –

- Intake of cold things after taking ghee.
- Intake of hot things after taking pig meat.
- Intake of hot water after taking *madhu* (honey)

14. Paka Viruddha -This type includes consumption of substances which are not properly cooked – may be undercooked or overcooked or burnt during the process of preparation etc. In recent era processed food also one of the causative factors of various disease.

15. Samyoga Viruddha -This is the consumption of two such substances which on combination have deleterious or poisonous effects, for example – fruit salad or milk + banana. It is seen practically in research work of Psoriasis that intake of milk+ khichadi (*lavana rasa*), milk+ onion/garlic, fish+ milk etc as causative factor found in maximum patients which are clear examples of *samyoga viruddha*[20]. Also it is stated by charaka that taking of milk and fish together can lead to *kushtha roga*[21] and taking of milk + *rohini shaka* together can lead to *raktapitta*.[22] Among all types of *viruddha* which are mentioned by several acharyas, *samyoga* or *veerya viruddha* is the most important or more dangerous than others.

16. Hrit Viruddha -*Hrit* here refers to the like and palatability of the person, so this type includes the consumption of those substances which are not liked by the person or are not palatable to him.

17. Sampat Viruddha -Consumption of food substances which are not having their proper qualities for example – intake of substances that are not matured, over matured or putrefied. It is seen practically that fruits and vegetables available in market are mostly synthetically made ripe which soon loses its qualities leading to formation of *ama*.

18. Vidhi Viruddha -This includes the diet and drug pattern not in accordance with the rules of eating. *Ajirnashana* is already stated in *kushtha nidana* by *acharya charaka*[23] which is also seen practically in patients of psoriasis during research.[24] For example – Taking meals in public, Food intake immediately after eating, consuming curd at night.

Diseases due to *viruddha ahara*

Viruddha Ahara (unwholesome diet) produces various types of diseases. Charaka advocating this matter gives one more verse specially regarding to *ahara* and its causativeness for diseases. Body is the result of nourishment by food ingested in the four-fold manner i.e. eaten, drunk, licked up and masticated and similarly the diseases that afflict this body are equally the result of food that is also eaten, drunks, licked up and masticated. It is the distinction between the use of wholesome diet and that of unwholesome diet that is responsible for the distinction between health and disease in the body.[25] *Agnimandya* is source of several diseases. *Viruddha ahara* causes the vitiation of *agni* by *abhojana, ajirnatibhojana, vishamashana, asatmya, ati ruksha* and *sheeta, sansrusta bhojana*. Thus the *agni* mostly gets vitiated by *viruddhahara*. This vitiated *jatharagni* does not digest even the lightest of food substances, resulting in indigestion (*ajirna*). This undigested food material turns sour and acts like a poison, which is called *ama visha* in ayurvedic terminology. Following are the diseases mentioned in *Ayurvedic* texts as a result of *viruddha ahara*[26].

- *Klaibya* (Impotency)
- *Andhatva* (Blindness)
- *Visarpa* (Erysipelas)
- *Jalodara* (Ascitis)
- *Unmada* (Insanity)
- *Bhagandara* (Fistula in ano)

- *Murcha* (Coma/fainting)
- *Aadhmana* (Abdominal distention)
- *Galgraha* (Obstruction in throat)
- *Pandu roga* (Anaemia)
- *Ama* (Endogenous toxin)
- *Kilasa* (Leucoderma)
- *Kushtha* (Various skin disorders)
- *Grahani* (Sprue)
- *Shotha* (Swelling or oedema)
- *Amlapitta* (Acidity)
- *Jwara* (Fever)
- *Pinas* (Allergic Rhinitis)
- *Santana Dosha* (Infertility problem)
- *Mrutyu* (Death)

Food combinations must be avoided:

Many food combinations are given in the texts as incompatible with proper explanation[27,28] for e.g.

- Fish (specially *chilchim* fish) should not take along with milk because both substances are *madhura* (sweet) in taste and sweet after digestion. This combination is *abhishyandi* (produce more moisture in the tissue and causes obstruction of various channels). Second reason is that both have opposite (incompatible) in potency. Fish being hot in potency and milk is of cold potency. This opposite potencies causes great vitiations of three *doshas* i.e. *vata, pitta* and *kapha doshas*.
- *Dadhi* (curd) should not be consumed in the night. Because curd is acidic in nature. It aggravates *pitta* and *kapha doshas* which later on produces a lot of heat in the stomach. A curd is heavy, slow to digest and produces constipation. It can be best digested at lunch time when the digestive abilities are the strongest.
- Warm honey should not be consumed by the person suffering from heat exhaustion or sun stroke. Because after heated honey becomes poison and this can cause death.
- Avoid consuming cold water immediately during or after a meal hot tea or coffee. Because it diminishes the *agni* and causes various digestive problems.
- Avoid eating bananas with milk. Because it can diminish *agni*, change the intestinal flora producing excess toxins in the body. The combination may also cause cold, cough and even produce allergies.
- After consuming green leafy vegetables, drinking of milk should be avoided.
- Avoid consuming meat of animals of marshy and domestic region with *masha*/black gram (*Phaselolus radiatus* Linn), honey, radish, milk, germinated grains and jaggery. Because it leads to deafness and blindness, trembling, loss of intelligence, loss of voice and nasal voice and even cause death.
- One should not consume *pushkara mula* (*Nelumbo nucifera* Gaertn) or *rohini shak* or meat of *kapota* (pigeon) fried in *sarshapa taila* along with milk and honey. Because this obstructs channels of circulation and causes dilation of blood vessels, *apasmara* (epilepsy), *shankhaka* (temporal headache), *galaganda* (scrofula), *rohini* (diphtheria) or even death.
- After eating *muli* (radish), *lasuna* (garlic), *tulsi* (basil) one should not be consumed milk because of the risk of skin disorders (leprosy).
- All Sour substances are incompatible with milk.
- Ghee (Clarified butter) kept for more than ten consecutive days in a bronze vessel should be avoided as unwholesome.
- Avoid eating melons and grains together. Melons digest quickly whereas grains take more time. This combination will upset the stomach. Melons should be eaten alone or left alone. Sweet and sour fruits should never be combined as in a fruit chat. Individual fruits should be eaten as such and as a different meal.
- Milk and melons both should not be consumed at a same time. Because both are *sheet* (cold) in nature, but milk is *saraka* (laxative) and melon is *mutrala* (diuretic). Milk takes longer time to

digest. Moreover the action of hydrochloric acid in the stomach causes the milk to curdle. For this reason ayurveda advises against taking milk with sour fruits.

- Avoid eating raw and cooked foods together. One can have the salad first and then proceed for dinner after a short gap.
- Likewise honey and ghee in equal quantity, hot water after taking honey are antagonistic.
- Combination of fruit salad with milk and banana should be avoided.
- *Upodika* should not be cooked with paste of *tila* (Sesame). Because it causes diarrhoea.
- *Pippali* (*Piper longum*) processed with fish fat is fried should be rejected.
- Similarly also the meat of *tittira* (black partridge), *Patradhya* (peacock), *godah* (iguana lizard) *lava* (common quail), *kapinjala* (gray pigeon) cooked over by the fire of wood of *eranda* (*Ricinus communis*) plant and processed with fried in its oil castor oil.

Exceptional cases for consuming *viruddha ahara* :

Food though incompatible do not produce disease if an individual is habituated to the intake of unwholesome drugs or diet or if they are taken in small quantity or taken by a person having strong digestive power or by a young person (adult) or by the one who has undergone oleation therapy or who is strong physique due to regular physical exercise. The unwholesomeness of various diets does not have any effect.[29]

Discussion:

It may be hypothesized that *viruddhaharas* cause imbalance among the various bodily humours, body channels & body tissues leading to the manifestation of various diseases and also causing death. The scientific basis is that when we mix certain types of protein together, digestion becomes difficult in some people. This leads to the deposition of toxic residue called *ama*, which can block channels and thus lead to skin infections and other diseases. The concept of *ama* and *agni* has an important role in disease manifestation. Proper eating habits helps in proper digestion and assimilation and thereby no production of *ama* (free radicals). It has been described that majority of diseases are due to uncontrolled or wrong dietary controls, lack of exercise and environmental factors. Regarding treatment aspect, most of diseases could be managed only by changing diet and life style.[30]

Conclusion:

From the above discussion, it is clear that *viruddha ahara* is an important aspect of today's improper dietary habits. This can lead to several hazardous diseases unknowingly to the patients. Therefore, it is important to enlist the causative incompatible dietary factors and train the patients to avoid such etiologic factors. The article also opens a new research window in the field of ayurvedic dietetics to research upon a variety of incompatible factors to observe the effect.

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Literary Review

The Utility of *Dugdha Chikitsa* (Milk Therapy) in *Udara* (Ascites)

Dr. Londhe P. D.

Abstract:

Udara being *Srotorodha pradhana vyadhi*, the treatment necessarily comprises of *Shodhana* through *Virechana*. After *Virechana*, diet possessing the ability to kindle digestive fire and consequently preventing further *Srotorodha* should be administered. Consequently *Pathya* plays vital role to maintain equilibrium of *Dosha*, strength of the patient and revert the catabolic changes occurred in tissues. It is mandatory to achieve water and salt restriction in *Udara*. So, the diet plan should include drugs having *Dipana*, *Pachana*, *Laghu* and *Kapha* alleviating property. Milk, by virtue of its *Satmya, Balya, Preenana* and *Rasayana* properties becomes highly beneficial in *Udara.* Milk also performs *Doshashodhana* and *Shamana* at the same time, by ascertaining its quantity and *Samskara*. Milk is beneficial in complications of *Udara* such as *Trishna*, *Raktapitta*, *Shotha* etc. Hence it could be said that *Ksheeraprayoga* is an inseparable part of treatment in *Udara* with multi dimensional utility in various stages and manifestations of disease.

Key words: *Udara, Pathya*, Milk, *Virechana, Srotorodha*, Hypoproteinemia.

सारांश–

उदर रोग (Ascites) मुख्यतया स्रोतोरोध प्रधान व्याधि है इसकी चिकित्सा में मुख्य रूप से संशोधन चिकित्सा में विरेचन का वर्णन किया है। विरेचन के बाद, संसर्जन क्रम (पथ्य पालन) करने से अग्नि की रक्षा होती है और पुनः स्रोतोरोध होने से रोका जा सकता है। पथ्य का हमारे शरीर में दोषों का साम्य तथा रोगी के बल को बनाए रखने में मुख्य स्थान है, संशोधन से शरीर के ऊतकों में चयापचय से संबन्धित परिवर्तन होते है। इसलिए पथ्य के लिए औषधियाँ जो कि दीपन, पाचन, लघु और कफ गुण वाली होती है, उनका प्रयोग किया जाना चाहिए। दूध उसके सात्म्य, बल्य, प्रीणन और रसायन गुणों की वजह से उदर में बहुत लाभदायक है। संस्कारित दूध के द्वारा दोषों का शोधन व शमन किया जाता है। दूध उदर रोग के उपद्रवों तृष्णा, रक्तपित्त, शोथ आदि में उपयोगी है। इसलिए यह कहा जा सकता है कि दूध का उदर रोग की विभिन्न अवस्थाओं की चिकित्सा में बहु आयामी उपयोगिता है।

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Literary Review

The Utility of *Dugdha Chikitsa* (Milk Therapy) in *Udara* (Ascites)

Dr. Londhe P. D.

Introduction

Udara is predominantly a *Srotorodha-pradhana vyaadhi* which means blockade of *Srotas* plays a vital role in its pathogenesis. Hence its treatment necessarily comprises of *Shodhana* or biopurification of channels through *Virechana*. *Virechana* facilitates elimination of vitiated "*Apdhatu"* or free fluid in abdominal cavity. After *Shodhana* by *Virechana*, diet possessing the ability to kindle digestive fire and consequently preventing further *Srotorodha* should be administered.

The therapeutic utility of *Dugdha* or *Ksheera* is specifically beneficial in *Udara* patients who are debilitated due to long term consumption of medicines, chronic nature and *Prabhava* of the disease.

Udara is considered as *Achikitsya*[1] (difficult to cure) *Vyadhi*. On the part of physician, it is extremely difficult to maintain the *Doshic* equilibrium, maintain *Bala* or strength of the patient and revert the catabolic changes occurred in tissues. *Shodhana* aids in removing blockade in *Srotas* and facilitating *Mala Shodhana*, haulting the *Aama* production process and thereby kindling the *Agni*.

In *Udara,* it is mandatory to avoid water consumption[2] in patients, as *Udakapaana* leads to *Udakadhatuvruddhi* as per basic principle of *Ayurveda-Samanena Samanasya Vruddhi* which further worsens the condition.

Also it is important to avoid use of diet and medicines having *Ushna guna, Amla, Lavana Rasa* and *Guru guna*. Diet plan should comprise of *Dipana, Kapha* alleviating property is recommended. Normal diet, if heavy in nature (*Guru Guna*) should not be administered immediately after *Shodhana*.

Milk, by virtue of its *Satmya* property (suited since birth) is extremely beneficial to maintain *Agnibala, Doshaanubandha* (equilibrium of body humors), strength and integrity of bodily tissues.

The administration of milk helps in *Shodhana* as well as *Shamana*. But this therapeutic administration of milk should strictly be made after ascertaining the quantity and *Samskara*. Milk, if administered in *Alpa* and *Satmya Matra*, alleviates *Dosha* and if administered in excess quantity, facilitates *Shodhana* (biopurification).

A unique property of milk is that it performs *Doshashodhana* and *Brimhana*; at the same time helps in building body tissues thereby maintaining the *Bala* of patient.

Milk has *Madhura Rasa, Madhura Vipaka* and *Sheeta Veerya* and possesses *Preenana*, *Brimhana*, *Vrishya, Medhya* and *Utsahavardhaka* property. Milk by virtue of its properties is highly beneficial in *Udara, Shwasa, Kasa, Raktapitta, Pandu, Shosha, Amlapitta, Gulma, Mootralpata* etc.[3]

In *Udara* due to vitiation of *Udakavahasrotasa*[4], *Trishna* or excessive thirst is seen in patients. Milk by virtue of its *Preenana Karma* and *Sheetaveerya*, helps in thirst allevation.

In *Udara, Raktapitta* is a major complication noted in many cases. In the pathogenesis of *Udara, Pitta Dosha* undergoes qualitative increase in *Ushna guna*. As a result, *Dhatu paaka* occurs and *Drava guna* of *Rakta dhatu* increases. If this pathogenesis continues, tissues undergo breakdown (*Ksharana*) and *Rakta* vitiation gradually increases and *Rakta* is eliminated in *Udara*. To curb this pathogenesis, *Madhura Rasa*, *Madhura vipaka* and *Sheeta*, *Raktpittaghna* milk therapy should be initiated from the very beginning and thereby complication like *Raktapitta* can be prevented. Also milk posseses *Sandhankara* property by virtue of which, it facilitates *Sandhana* of broken or damaged *Sira* in *Raktapitta* thereby aiding in stopping bleeding.

In *Udara, Sarvangashotha* and *Padashotha* are manifested; perhaps *Udara* is a type of *Shotha*[5].

Milk is highly beneficial in *Shotha*[6]. If administered in large quantity, its *Saraguna* reduces the *Grathitatwa of stools* and helps in easy/smooth elimination of *Malas*.

Practically, in ascites, *Virechana*, medicines and *Pathyasevana* confer good relief to patients. But the formation of vitiated ascitic fluid and accumulation continues. To curb this vicious cycle, milk acts by virtue of its dual properties *Shodhana* and *Shamana*. When administered in sufficient *Matra* as per dictum- *UdaramNityamevaVirechayet*[7], milk promotes *Nityavirechana* and acts as *Rasayana* (rejuvenator) which prevents recurrence. It also does *Balaadhana* (confers strength) to patient after *Virechana*[8].

Milk being a '*Saar' Dravya* since birth can be easily transformed by hepatic digestion into body tissues (*Dhatus*). This eventually reduces hepatic load and augments regeneration of damaged hepatocytes.

TABLE[9]

Cow's milk (Nutritional value per 100 g) :-

Energy 60 Cal					
1.	Carbohydrates	5.26gm		Histidine	0.075 gm
2.	Fat	3.25gm		Alanine	0.103 gm
	Saturated	1.865gm		Aspartic acid	0.237 gm
	Monounsaturated	0.812gm		Glutamic acid	0.648 gm
	Polyunsaturated	0.195gm		Glycine	0.075 gm
3.	Protein	3.22gm		Proline	0.342 gm
	Isoleucine	0.165gm		Serine	0.107 gm
	Cystine	0.017gm	4.	Minerals	
	Theronine	0.143gm		Calcium	11%
	Tryptophan	0.075gm		Magnesium	03%
	Phenylalanine	0.147gm		Potassium	03%
	Tyrosine	0.152gm		Sodium	02%
	Valine	0.192gm		Zinc	03%
	Arginine	0.075 gm	5.	Water contain	88.329

Calcium present in milk has greater bioavailability than calcium derived from other vegetable sources.

As per modern medicine, in Liver disorders and particularly in Ascites, vitamin and other nutritional deficiency is seen in patients. While treating such cases, it is important to replenish these vital nutrients. All such vital nutrients are present in ample quantity in milk.

In *Udara*, hypoproteinaemia is the commonly found trait. But while replenishing these proteins, care should be taken. Proteins, if not given in sufficient quantity, directly augment catabolic processes and thereby deterioration in *Bala* of patient occurs. On the contrary, if proteins are administered in excess quantity, major complications like hepatic encephalopathy[10] may manifest. In this context, milk therapy has a vital role. Milk being a daily food article, aids in assimilation of required quantity of proteins which eventually helps in a complication free treatment. But in hepatic

encephalopathy stage, usage of milk should be avoided otherwise it may aggravate the condition. Once patient recovers from hepatic encephalopathy, to treat liver cirrhosis with ascites, milk diet is best indicated as it helps in protein – zinc supplementation which helps early recovery in this stage.

In *Udara*, salt restriction in diet should be followed and milk being deficient in *Lavana Rasa*, makes it easy for its therapeutic utility.

Milk has a unique role in *Udarachikitsa*, its therapeutic usage should be made considering the suitability of patient. In cases having aversion towards milk, *Ksheeraprayoga* should be done after convincing the patient and adjusting the quantity of milk to be administered. Practically, patients can consume up to 3 litres of milk daily. Modern medicine recommends 1.2 gm/kg/day proteins and 2000 cal energy in *Udara*. This can be easily fulfilled by this 2-3 litre milk administration[11]. While administering this *Ksheeramatra*, blood pressure, pulse, urine output, Liver Function Tests, Renal Function Tests, *Virechanavega* should be assessed. Also it should be seen that this *Ksheeramatra* is not insufficient as compared to the body built of the patient.

Udara being an *Udakavaha srotas vyaadhi*, always manifests with *Trishna* (excessive thirst) as the principal symptom. Naturally patient has tendency to consume water to pacify thirst. Milk which comprises of 88% water is capable of supplementing this water needed for daily metabolic processes in body and its *Trushnanashaka guna* helps in quenching the thirst of patient. This makes it convenient for patient to restrict water intake and administer only *Ksheera*. It is also easy to fortify milk with medicinal herbs as per *Dosha* like *Mustasiddhaksheera, Sunthi Maricha Pippali Siddha Ksheera, Shilajatu Siddha Ksheera* etc.

The diet schedule recommended by classics in *Udara*[12]

Upto 6 months	- only milk diet
7 months to 9 months	- *Ksheerapeya*
9 months to 12 months	- *Ksheeraodana*

Majority of *Udara* cases are due to Alcoholic Liver Disease. In *Madatyaya Chikitsa*, *Charaka* has endorsed the therapeutic use of *Ksheera* to prevent recurrence of disease.

Ksheera prayoga is an inseparable part of treatment in *Udara vyaadhi* with multi dimensional utility in various stages.

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In the interests of fairness and to keep correspondence within manageable proportions, journal may want to set time limits for responding to articles and correspondence, and for debate on a given topic. Journal has also set policy with regard to the archiving of unedited correspondence that appears on line. These policies should be published both in print and electronic versions of the journal.

III.F. Supplements, Theme Issues, and Special Series

Supplements are collections of papers that deal with related issues or topics, are published as a separate issue of the journal or as part of a regular issue, and are usually funded by sources other than the journal's publisher. Supplements can serve useful purposes: education, exchange of research information, ease of access to focused content, and improved cooperation between academic and corporate entities. Because funding sources can bias the content of supplements through the choice of topics and viewpoints, this journal adopts the following principles. These same principles apply to theme issues or special series that have external funding and/or guest editors.

1. The journal editors take full responsibility for the policies, practices, and content of supplements, including complete control of the decision to publish all portions of the supplement. Editing by the funding organization will not be permitted.
2. The journal editors will retain the authority to send supplement manuscripts for external peer review and to reject manuscripts submitted for the supplement.
3. The journal editors will approve the appointment of any external editor of the supplement and take responsibility for the work of the external editor.
4. The sources of funding for the research, publication, and the products the funding source make that are considered in the supplement should be clearly stated and prominently located in the supplement, preferably on each page. Whenever possible, funding should come from more than one sponsor.
5. Secondary publication in supplements (republication of papers previously published elsewhere) will be clearly identified by the citation of the original paper. Supplements will avoid redundant or duplicate publication. Supplements will not republish research results, but the republication of guidelines or other material in the public interest might be appropriate.

IV. Manuscript Preparation and Submission

IV.A. Preparing a Manuscript for Submission

Editors and reviewers spend many hours reading manuscripts, and therefore appreciate receiving with manuscripts that are easy to read and edit. Much of the information in journals' instructions to authors is designed to accomplish that goal in ways that meet each journal's particular editorial needs. The guidance that follows provides a general background and rationale for preparing manuscripts for any journal.

IV.A.1.a. General Principles

The text of observational and experimental articles is usually (but not necessarily) divided into sections with the headings Introduction, Methods, Results, and Discussion. This so-called "IMRAD" structure is not simply an arbitrary publication format, but rather a direct reflection of the process of scientific discovery. Long articles may need subheadings within some sections (especially the Results and Discussion sections) to clarify their content. Other types of articles, such as case reports, reviews, and editorials, are likely to need other formats.

Publication in electronic formats has created opportunities for adding details or whole sections in the electronic version only, layering information, cross-linking or extracting portions of articles, and the like. Authors need to work closely with editors in developing or using such new publication formats and should submit material for potential supplementary electronic formats for peer review.

Double spacing of all portions of the manuscript including the title page, abstract, text, acknowledgments, references, individual tables, and legends-and generous margins make it possible for editors and reviewers to edit the text line by line, and add comments and queries, directly on the paper copy. If manuscripts are submitted electronically, the files should be double spaced, because the manuscript may need to be printed out for reviewing and editing.

During the editorial process reviewers and editors frequently need to refer to specific portions of the manuscript, which is difficult unless the pages are numbered. Authors should therefore number all of the pages of the manuscript consecutively, beginning with the title page.

IV.A.1.b. Reporting Guidelines for Specific Study Designs

Research reports frequently omit important information. The general requirements listed in the next section relate to reporting essential elements for all study designs. Authors are encouraged in addition to consult reporting guidelines relevant to their specific research design. For reports of randomized controlled trials authors should refer to the CONSORT statement. This guideline provides a set of recommendations comprising a list of items to report and a patient flow diagram.

IV.A.2. Title Page

The title page should carry the following information:

1. The title of the article. Concise titles are easier to read than long, convoluted ones. Titles that are too short may, however, lack important information, such as study design (which is particularly important in identifying randomized controlled trials). Authors should include all information in the title that will make electronic retrieval of the article both sensitive and specific.
2. Authors' names and institutional affiliations.
3. The name of the department(s) and institution(s) to which the work should be attributed.
4. Disclaimers, if any.
5. Corresponding authors. The name, mailing address, telephone and fax numbers, and e-mail address of the author responsible for correspondence about the manuscript (the "corresponding author;" this author may or may not be the "guarantor" for the integrity of the study as a whole, if someone is identified in that role. The corresponding author should indicate clearly whether his or her e-mail address is to be published.
6. The name and address of the author to whom requests for reprints should be addressed.

7. Source(s) of support in the form of grants, equipment, drugs, or all of these.
8. Word counts. A word count for the text only (excluding abstract, acknowledgments, figure legends, and references) allows editors and reviewers to assess whether the information contained in the paper warrants the amount of space devoted to it, and whether the submitted manuscript fits within the journal's word limits. A separate word count for the Abstract is also useful for the same reason.
9. The number of figures and tables. It is difficult for editorial staff and reviewers to tell if the figures and tables that should have accompanied a manuscript were actually included unless the numbers of figures and tables that belong to the manuscript are noted on the title page.

IV.A.3. Conflict of Interest Notification Page

To prevent the information on potential conflict of interest for authors from being overlooked or misplaced, it is necessary for that information to be part of the manuscript. It should therefore also be included on a separate page or pages immediately following the title page.

IV.A.4. Abstract and Key Words

An abstract should follow the title page. The abstract should provide the context or background for the study and should state the study's purposes, basic procedures (selection of study subjects or laboratory animals, observational and analytical methods), main findings (giving specific effect sizes and their statistical significance, if possible), and principal conclusions. It should emphasize new and important aspects of the study or observations.

Because abstracts are the only substantive portion of the article indexed in electronic database and the only portion many readers read, authors need to be careful that abstracts reflect the content of the article accurately.

3 to 10 key words or short phrases that capture the main topics of the article. These will assist indexers in cross-indexing the article and may be published with the abstract. Terms from the Medical Subject Headings (MeSH) list of Index Medicus should be used; if suitable MeSH terms are not yet available for present terms may be used.

IV.A.5. Introduction

Provide a context or background for the study (i.e., the nature of the problem and its significance). State the specific purpose or research objective of, or hypothesis tested by, the study or observation; the research objective is often more sharply focused when stated as a question. Both the main and secondary objectives should be made clear, and any pre-specified subgroup analyses should be described. Give only strictly pertinent references and do not include data or conclusions from the work being reported.

IV.A.6. Methods

The Methods section should include only information that was available at the time the plan or protocol for the study was written; all information obtained during the conduct of the study belongs in the Results section.

IV.A.6.a. Selection and Description of Participants

Describe your selection of the observational or experimental participants (patients or laboratory animals, including controls) clearly, including eligibility and exclusion criteria and a description of the source population. Because the relevance of such variables as age and sex to the object of research is not always clear, authors should explain their use when they are included in a study report; for example, authors should explain why only subjects of certain ages were included or why women were excluded. The guiding principle should be clarity about how and why a study was done in a particular way. When authors use variables such as race or ethnicity, they should define how they measured the variables and justify their relevance.

IV.A.6.b. Technical information

Identify the methods, apparatus (give the manufacturer's name and address in parentheses), and procedures in sufficient detail to allow other workers to reproduce the results. Give references to established methods, including statistical methods see below; provide references and brief descriptions for methods that have been published but are not well known; describe new or substantially modified

methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

Authors submitting review manuscripts should include a section describing the methods used for locating, selecting, extracting, and synthesizing data. These methods should also be summarized in the abstract.

IV.A.6.c. Statistics

Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). References for the design of the study and statistical methods should be to standard works when possible (with pages stated). Define statistical terms, abbreviations, and most symbols. Specify the computer software used.

IV.A.7. Results

Present your results in logical sequence in the text, tables, and illustrations, giving the main or most important findings first. Do not repeat in the text all the data in the tables or illustrations; emphasize or summarize only important observations. Extra or supplementary materials and technical detail can be placed in an appendix where it will be accessible but will not interrupt the flow of the text; alternatively, it can be published only in the electronic version of the journal.

When data are summarized in the Results section, give numeric results not only as derivatives (for example, percentages) but also as the absolute numbers from which the derivatives were calculated, and specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid non-technical uses of technical terms in statistics, such as “random” (which implies a randomizing device), “normal,” “significant,” “correlations,” and “sample.”

Where scientifically appropriate, analyses of the data by variables such as age and sex should be included.

IV.A.8. Discussion

Emphasize the new and important aspects of the study and the conclusions that follow from them. Do not repeat in detail data or other material given in the Introduction or the Results section. For experimental studies it is useful to begin the discussion by summarizing briefly the main findings, then explore possible mechanisms or explanations for these findings, compare and contrast the results with other relevant studies, state the limitations of the study, and explore the implications of the findings for future research and for clinical practice.

Link the conclusions with the goals of the study but avoid unqualified statements and conclusions not adequately supported by the data. In particular, authors should avoid making statements on economic benefits and costs unless their manuscript includes the appropriate economic data and analyses. Avoid claiming priority and alluding to work that has not been completed. State new hypotheses when warranted, but clearly label them as such.

IV.A.9. References

IV.A.9.a. General Considerations Related to References

Although references to review articles can be an efficient way of guiding readers to a body of literature, review articles do not always reflect original work accurately. Readers should therefore be provided with direct references to original research sources whenever possible. On the other hand, extensive lists of references to original work on a topic can use excessive space on the printed page. Small numbers of references to key original papers will often serve as well as more exhaustive lists, particularly since references can now be added to the electronic version of published papers, and since electronic literature searching allows readers to retrieve published literature efficiently.

Avoid using abstracts as references. References to papers accepted but not yet published should be designated as “in press” or “forthcoming”; authors should obtain written permission to cite

such papers as well as verification that they have been accepted for publication. Information from manuscripts submitted but not accepted should be cited in the text as "unpublished observations" with written permission from the source.

Avoid citing a "personal communication" unless it provides essential information not available from a public source, in which case the name of the person and date of communication should be cited in parentheses in the text. For scientific articles, authors should obtain written permission and confirmation of accuracy from the source of a personal communication.

Some journals check the accuracy of all reference citations, but not all journals do so, and citation errors sometimes appear in the published version of articles. To minimize such errors, authors should therefore verify references against the original documents. Authors are responsible for checking that none of the references cite retracted articles except in the context of referring to the retraction. For articles published in journals indexed in MEDLINE, the ICMJE considers PubMed the authoritative source for information about retractions.

IV.A.9.b. Reference Style and Format

The Uniform Requirements style is based largely on an ANSI standard style adapted by the National Library of Medicine (NLM) for its databases. For samples of reference citation formats, authors should consult National Library of Medicine web site.

References should be numbered consecutively in the order in which they are first mentioned in the text. Identify references in text, tables, and legends by Arabic numerals in parentheses. References cited only in tables or figure legends should be numbered in accordance with the sequence established by the first identification in the text of the particular table or figure. The titles of journals should be abbreviated according to the style used in Index Medicus.

This Journal requires that the references from the Ayurvedic classics should be cited within parentheses in the text, i.e. (Cha. Soo. 25/40).

IV.A.10. Tables

Tables capture information concisely, and display it efficiently; they also provide information at any desired level of detail and precision. Including data in tables rather than text frequently makes it possible to reduce the length of the text.

Type or print each table with double spacing on a separate sheet of paper. Number tables consecutively in the order of their first citation in the text and supply a brief title for each. Do not use internal horizontal or vertical lines. Give each column a short or abbreviated heading. Authors should place explanatory matter in footnotes, not in the heading. Explain in footnotes all nonstandard abbreviations. For footnotes use the following symbols, in sequence:

***,†,‡,§,||,¶,**,††,‡‡**

Identify statistical measures of variations, such as standard deviation and standard error of the mean.

Be sure that each table is cited in the text.

If you use data from another published or unpublished source, obtain permission and acknowledge them fully.

Additional tables containing backup data too extensive to publish in print may be appropriate for publication in the electronic version of the journal. In that event an appropriate statement will be added to the text. Submit such tables for consideration with the paper so that they will be available to the peer reviewers.

IV.A.11. Illustrations (Figures)

Figures should be either professionally drawn and photographed, or submitted as photographic quality digital prints. In addition to requiring a version of the figures suitable for printing, this Journal asks authors for electronic files of figures in a format (e.g., JPEG or GIF) that will produce high quality images in the web version of the journal; authors should review the images of such files on a computer screen before submitting them, to be sure they meet their own quality standard.

For x-ray films, scans, and other diagnostic images, as well as pictures of pathology specimens

or photomicrographs, send sharp, glossy, black-and-white or color photographic prints, usually 127 x 173 mm (5 x 7 inches). Letters, numbers, and symbols on Figures should be clear and even throughout, and of sufficient size that when reduced for publication each item will still be legible. Figures should be made as self-explanatory as possible. Titles and detailed explanations belong in the legends, however, not on the illustrations themselves.

Photomicrographs should have internal scale markers. Symbols, arrows, or letters used in photomicrographs should contrast with the background.

If photographs of people are used, either the subjects must not be identifiable or their pictures must be accompanied by written permission to use the photograph. Whenever possible permission for publication should be obtained.

Figures should be numbered consecutively according to the order in which they have been first cited in the text. If a figure has been published, acknowledge the original source and submit written permission from the copyright holder to reproduce the material. Permission is required irrespective of authorship or publisher except for documents in the public domain.

IV.A.12. Legends for Illustrations (Figures)

Type or print out legends for illustrations using double spacing, starting on a separate page, with Arabic numerals corresponding to the illustrations. When symbols, arrows, numbers, or letters are used to identify parts of the illustrations, identify and explain each one clearly in the legend. Explain the internal scale and identify the method of staining in photomicrographs.

IV.A.13. Units of Measurement

Use only standard Units of Measurements. If some new measurements or scoring patterns are used they should be explained in detail in the text.

IV.A.14. Abbreviations and Symbols

Use only standard abbreviations; the use of non-standard abbreviations can be extremely confusing to readers. Avoid abbreviations in the title. The full term for which an abbreviation stands should precede its first use in the text unless it is a standard unit of measurement.

IV.B Sending the Manuscript to the Journal

This Journal accepts electronic submission of manuscripts, whether on disk or attachments to electronic mail. Electronic submission saves time as well as postage costs, and allows the manuscript to be handled in electronic form throughout the editorial process (for example, when it is sent out for review). When submitting a manuscript electronically, authors should consult with the instructions for authors of the journal they have chosen for their manuscript.

If a paper version of the manuscript is submitted, send the required number of 6 copies of the manuscript and figures; they are all needed for peer review and editing, and editorial office staff cannot be expected to make the required copies.

Manuscripts must be accompanied by a cover letter, which should include the following information.

- A full statement to the editor about all submissions and previous reports that might be regarded as redundant publication of the same or very similar work. Any such work should be referred to specifically, and referenced in the new paper. Copies of such material should be included with the submitted paper, to help the editor decide how to handle the matter.
- A statement of financial or other relationships that might lead to a conflict of interest, if that information is not included in the manuscript itself or in an authors' form
- A statement that the manuscript has been read and approved by all the authors, that the requirements for authorship as stated earlier in this document have been met, and that each author believes that the manuscript represents honest work, if that information is not provided in another form; and
- The name, address, and telephone number of the corresponding author, who is responsible for communicating with the other authors about revisions and final approval of the proofs, if that

information is not included on the manuscript itself.

The letter should give any additional information that may be helpful to the editor, such as the type or format of article in the particular journal that the manuscript represents. If the manuscript has been submitted previously to another journal, it is helpful to include the previous editor's and reviewers' comments with the submitted manuscript, along with the authors' responses to those comments. Editors encourage authors to submit these previous communications and doing so may expedite the review process.

Copies of any permission to reproduce published material, to use illustrations or report information about identifiable people, or to name people for their contributions must accompany the manuscript.

V. References

A. References Cited in this Document

1. Davidoff F for the CSE Task Force on Authorship. Who's the Author? Problems with Biomedical Authorship, and Some Possible Solutions. Science Editor. July-August 2000: Volume 23 - Number 4: 111-119.
2. Yank V, Rennie D. Disclosure of researcher contributions: a study of original research articles in The Lancet. Ann Intern Med. 1999 Apr 20;130(8):661-70.
3. Flanagin A, Fontanarosa PB, DeAngelis CD. Authorship for research groups. JAMA. 2002;288:3166-68.
4. Peer Review in Health Sciences. F Godlee, T Jefferson. London: BMJ Books, 1999.
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6. Pitkin RM, Branagan MA, Burmeister LF. Accuracy of data in abstracts of published research articles. JAMA. 1999 Mar 24-31;281(12):1110-1.
7. Patrias K. National Library of Medicine recommended formats for bibliographic citation. Bethesda (MD): The Library; 1991.

B. Other Sources of Information Related to Biomedical Journals

World Association of Medical Editors (WAME) www.WAME.org <http://www.WAME.org>

Council of Science Editors (CSE) www.councilscienceeditors.org <http://www.councilscienceeditors.org>

European Association of Science Editors (EASE) www.ease.org.uk <http://www.ease.org.uk>

Cochrane Collaboration www.cochrane.org <http://www.cochrane.org>

The Mulford Library, Medical College of Ohio www.mco.edu/lib/instr/libinsta.html <http://www.mco.edu/lib/instr/libinsta.html>

Annexure I

Manuscript no. JOA/NIA/20 /

Authorship Criteria and Responsibility
Financial Disclosure, Acknowledgment and Copyright Transfer Form

Manuscript Title :

I/We certify that the manuscript represents valid work and that neither this manuscript nor one with substantially similar content under my/our authorship has been published or is being considered for publication elsewhere. For papers with more than 1 author, We agree to allow the corresponding author to serve as the primary correspondent with the editorial office, to review the edited typescript and proof.

I/We have seen and approved the submitted manuscript. All of us have participated sufficiently in the work to take public responsibility for the contents. All the authors have made substantial contributions to the intellectual content of the paper and fulfil at least 1 condition for each of the 3 categories of contributions: i.e., Category 1 (conception and design, acquisition of data, analysis and interpretation of data), Category 2 (drafting of the manuscript, critical revision of the manuscript for important intellectual content) and Category 3 (final approval of the version to be published).

I/We also certify that all my/our affiliations with or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript are completely disclosed on the title page of the manuscript. My/our right to examine, analyze, and publish the data is not infringed upon by any contractual agreement. I/We certify that all persons who have made substantial contributions to the work reported in this manuscript (e.g., data collection, writing or editing assistance) but who do not fulfil the authorship criteria are named along with their specific contributions in an acknowledgment section in the manuscript. If an acknowledgment section is not included, no other persons have made substantial contributions to this manuscript. I/We also certify that all persons named in the acknowledgment section have provided written permission to be named.

The author(s) undersigned hereby transfer(s), assign(s), or otherwise convey(s) all copyright ownership, including any and all rights incidental thereto, exclusively to the Journal of Ayurveda, in the event that such work is published in Journal of Ayurveda.

Authors' name(s) in order of appearance in the manuscript.

1. Name	Signatures	(date)
2. Name	Signatures	(date)
3. Name	Signatures	(date)
4. Name	Signatures	(date)
5. Name	Signatures	(date)
6. Name	Signatures	(date)

Annexure II

Manuscript Submission Checklist

Submitted by: E-mail ☐ Post ☐ Both ☐

Covering letter and submission :

1. Covering letter (in original) ☐
2. Copyright transfer form (in original) ☐
3. Illustrations (in original) ☐
4. Manuscript (E-mail/original) ☐
5. Category for which submitted ☐

Presentation and Format :

1. Printed on A4 paper with 1" margins on all sides in double space. ☐
2. Abstract, text, acknowledgement, references, legends, tables starting on a new page. ☐
3. Title page contains the following:
   - Full title of the paper ☐
   - Initials, surname and highest degree of authors, affiliation ☐
   - Name of Departments/Institution ☐
   - Details of Corresponding Authors including e-mail ☐
   - Numbers in Arabic numerals. ☐
4. Abstract (Hindi and English) and Key words provided. ☐
5. “What this study adds” Box (only for research papers and short communications). ☐
6. References. ☐
7. Pages numbered consecutively. ☐

Language and Grammar :

1. Uniform American English. ☐
2. Abbreviations spelt out in full for first time. ☐
3. Text arranged as per IMRAD format. ☐
4. Follows style of writing in Journal of Ayurveda. ☐
5. Conventional units used throughout manuscript. ☐

Tables and Figures :

1. No repetition of data in Table/graphs and in text. ☐
2. Figures are black and white (except Images), good quality; with labels on back. ☐
3. Table numbers in roman numerals and Figure numbers in Arabic numerals. ☐
4. Correct symbols used for footnotes to tables. ☐
5. Figure legends provided. ☐
6. Patient privacy maintained ☐

Short Communication

AYURVEDA NEWS AND VIEWS

Dr. Rizwana Parveen

National & Internal Seminars

1 Workshop on Yoga For Stress Management, organized by Morarji Desai National Institute of Yoga, New Delhi. Date : 10th to 28th July, 2017

2. National Seminar on Dravyaguna "Anuktadravya Vivechana-2017", organized by Gujarat Ayurved University, Jamnagar.

   Date : 20th and 21st July, 2017.

3. National Seminar on 'Charak Manthan', organized by Charak Vaidya Samuha, Nashik. Date : 21st to 23rd July, 2017.

4. International Conference on 'Environment Health and Policy Nexus', organized by Jagadguru Sri Shivarathreeswara University, Mysore.

   Date : 27th and 28th July, 2017.

5. Skill-cum-Technology Upgradation Programme on Improved Production Technologies of Medicinal and Aromatic Plants, organized at CSIR-CIMAP Research Centre, Bengaluru.

   Date : 27th to 29th July, 2017.

6. 22nd International Conference Ayurveda & Home Remedies, organized at The Hindu Temple Of Atlanta, USA.

   Date : 4th to 6th August, 2017.

7. Amrita Samyogam 2017: International Conference on Integrative Ayurveda and Modern Medicine, organized by Amrita School of Ayurveda, Kerala.

   Date : 6th and 7th August, 2017.

8. 'Arogya Bharati' National Seminar on Diabetes mellitus, organized at Dr. D. Y. Patil Auditorium, Navi Mumbai.

   Date : 16th & 17th August, 2017.

9. State Level Seminar on "Geriatric care through Ayurveda", organized at Mahatma Gandhi Ayurved College, Hospital & Research Centre, Wardha.

   Date : 4th August, 2017.

10. 3rd International Conference on Dravyaguna and Rasasastra-Bhaisajya Kalpana, organized by J S Ayurved Mahavidyalay and P D Patel Ayurveda Hospital, Nadiad.

    Date : 2nd and 3rd September, 2017.

11. National Conclave on "Medico-Surgical Perspective of Ayurveda Shaarir", organized by Ayurved Anusandhan Sansthan, Lucknow. Date : 2nd and 3rd September, 2017.

12. MAHOSHADHA - 2017: National Seminar on Evidence Based Cancer Management, organized by Muniyal Institute of Ayurveda Medical Sciences, Manipal.

    Date : 8th September, 2017.

13. CME Programme for Teachers of Dravyaguna, organized by Dr. B.R.K.R. Govt. Ayurvedic College, Hyderabad.

    Date : 11th to 16th September, 2017.

14. 1st Rashtriya Ayurveda Yuva Mahotsav 2017, organized by National Institute of Ayurveda, Jaipur.

    Date : 14th to 16th September, 2017.

15. HOSPREC 2017: Health & Medical records National Conference, organized by KLE's Shri.B.M.K Ayurvedic Medical College, Belagavi.

    Date : 15th and 16th September, 2017.

*Sr. Research Fellow-Journal of Ayurveda, NIA, Jaipur

16. Nutricon - 2017, organized by Shalom Institute of Health & Allied Sciences, Allahabad.

    Date : 14th and 15th September, 2017.

17. Workshop On Medical Humanities, organized by Jagadguru Sri Shivarathreeshwara University, Karnataka.

    Date : 14th and 15th September, 2017.

18. National Conference on Recent Advances in Ayurvedic Herbal Medicine, organized by Uttarakhand Ayurved University, Dehradun. Date : 15th and 16th September, 2017.

19. National Conference on Advances in Research on Aging and Neurological Disorders, organized by Banaras Hindu University, Varanasi.

    Date : 20th to 22nd September, 2017.

20. Workshop on Academia Research with Special Reference to PG Level Thesis Courses, organized at National Ayurveda Summit 2017, Gujarat.

    Date : 30th September, 2017.

Ayurvedic treatment found beneficial for kidney disease

According to latest news, Ayurvedic line of treatment can be beneficial for patients suffering from chronic kidney disease.

The latest news is that ayurvedic drug made of 'Punarnava' plant and other well-known kidney protective herbs in ayurvedic formulations have shown positive results in preventing and reducing high levels of serum creatinine, the kidney function parameters.

The Global Burden of Disease (GBD) study 2015 had revealed chronic kidney disease as the eight leading cause of death.

As per research paper published in The Indo American Journal of Pharmaceutical Research, the Neeri KFT, which is a blend of punarnava plant, lotus leaves, patharchur and other major herbs has proved to be life-saving drug for those kidney patients who are under regular dialysis. The drug has helped in maintaining histological parameter of kidneys, apart from reducing high levels of uric acid and electrolytes.

As we known, out body is made of two-thirds water, and it is the job of kidneys to maintain hydration level, flush out toxins by filtering blood, and in producing three hormones. These help in keeping blood pressure in check, stimulates red blood cells and helps in maintaining strong bones. A combination of diet, herbs and good lifestyle habits like Yoga can help in keeping your kidneys healthy.

Follow these health tips from Ayurveda, and keep your kidneys healthy:

• Keep yourself - hydrated

Drink at least ten glasses of water a day, so that your urine does not become concentrated, which can harm your kidneys. The kidneys detoxify the body by filtering the blood and secreting wastes through urine.

• Diet regimen

Although kidneys do their job of excreting wastes, they cannot always eliminate all toxins. So it is essential that you supplement your diet with calcium-rich ragi, eat plenty of fruits and include lemon in your diet. This is because protein-rich diet is acidic. So to maintain the pH balance of your body, the kidneys use calcium from your bones. Go for a low-protein diet and take care of your blood sugar and insulin levels. Do not take anything that leads to high blood pressure. For instance, a diet rich in sodium is not advisable, if you want to keep your kidneys healthy.

Drinking fresh lime juice early in the morning on empty stomach is considered good. Apple, Orange, Sweetlime, carrot, grape, beetroot, wheatgrass and parsley are considered healthy options. Parsley, being a natural diuretic is effective when taken in the form of tea.

Kidney beans, garlic, turmeric, watermelon, pomegranates and papaya are other good options. Cranberries are a popular remedy for kidney problems.

Ensure that you avoid coffee, tea, alcohol, and tobacco, as they are flushed out by the kidneys

exposing them to high level of acid.

• Herbs

Gokshura, an ayurvedic herbal preparation is prescribed for frequent kidney infections and problems caused by kidney stones. 'Chandraprabhavati' is also prescribed for those with recurrent kidney problems.

'Horsetail', the weed, has powerful diuretic properties, which can increase urine output and help flush the urinary tract and kidneys. It also has strong antioxidants that offer numerous benefits to kidneys and renal system. This herb can be taken as a capsule supplement or as tea. It is good to include it in your daily diet.

'Dandelion' can be consumed in the form of tea. It is very effective in keeping kidneys and the liver healthy. Being a diuretic, dandelion is an excellent kidney detox. The herb is also a rich source of nutrients as it contains iron, zinc, potassium, B complex vitamins and more. The roots are also effective in dissolving kidney stones.

• Lifestyle changes

Ayurveda suggests that one should not suppress nature's call. One should not control their urge to urinate as this can lead to urinary calculi, and other bladder and urinary infections later.

Minimize use of pain killers and nonsteroidal anti-inflammatory drugs, as they can damage your kidneys in the long run, with regular use. 'Turmeric' is considered to be a natural, effective pain reliever.

Certain yogic postures like 'janu shirshasana', can help in keeping your kidneys healthy, as the squeezing and soaking action will wring out the kidneys, getting rid of all stale, toxic blood, and a fresh supply of oxygenated blood fills the area. 'Kapalabhati' breathing which involves forces exhales and passive inhales is also highly recommended.

Finally, keep your blood sugar, blood pressure and cholesterol levels within normal range. Quit smoking, and ensure that you maintain a healthy weight, as being overweight can make your kidneys work harder.

Glowing health, courage, enthusiasm, self-esteem and vitality are all hallmarks of strong kidneys and a balanced navel chakra.

12 tips to beat pre-menstrual blues with Ayurveda

Pre-menstrual Syndrome or (PMS) is a group of symptoms that women suffer a week prior to the onset of their menstrual cycle. For many women, PMS is not of serious concern, and they do not experience any significant change in their body. But, some go through a really rough phase, which brings about various changes, which could be physical, emotional or behavioural. The changes present themselves a week or two before the commencement of menstrual cycle, and will phase out once you hit your period.

Some of the often associated symptoms include bloating, tender breasts, abdominal pain, cramps, anxiety, irritability, depression, vomiting and diarrhea, among others. In case you experience any such symptoms a week before your periods, these Ayurvedic tips and guidelines can help you relieve it to a great extent.

Ayurveda believes that the three fundamental doshas – Vata, Pitta and Kapha should be in a state of balance to remain in good health. According to Ayurveda, PMS is not a disease, but, a symptom of doshic imbalance, and it will vary from one woman to another. PMS can be classified based on the imbalance of these doshas:

Vata types: The vata type PMS, which is associated with low back ache, low abdominal pain, mood swings, anxiety, headache and sleep disorders, may also appear as irregular menstrual flow and irregularity in bowels.

Pitta type: An imbalance of pitta can cause symptoms like irritability, mood swings, lower abdominal cramp, burning sensation when passing urine, and sometimes hives. Cool and sweet foods like pears, sweet melons etc., can help counter the effects of imbalance.

Kapha type: Symptoms associated with kapha imbalance may include bloating, weight gain, water retention, drowsiness and sluggishness.

Tips:

1. **'**Dashamoola Tea' (half-teaspoon of dashamoola,

steeped in a cup of hot water for 10 minutes), with a little honey added for taste, can be taken twice a day every week prior to your periods.

2. Try having 10 cherries daily on empty stomach a week before onset of menstruation.

3. Take half a teaspoon of the herbal mixture made with 2 parts shatavari, 1 part brahmi, and 1 part musta, twice a day with warm water.

4. Add a pinch of cumin powder to aloe vera gel, and consume, which can help ease symptoms to a great extent. Else, take one tbsp of aloe vera gel with a pinch of black pepper, thrice a day.

5. Mix a tablespoon of aloevera gel with half a teaspoon of Trikatu (an ancient ayurvedic concoction made by using equal parts of black pepper, and ginger), which can help immensely.

6. Shatavari is a soothing traditional Ayurvedic herb, helpful to relieve irritability and excessive heat. It also improves health of female reproductive tissue. About 500 to 1000mg of the herb can be taken twice daily.

7. Keep your meals light while you experience symptoms. Avoid foods that make you feel heavy. Primary focus should be vegetables and fruits. Eat food which is warm, or atleast at room temperature.

8. Warm oil (choose the one that suit your body type) massages with coconut oil / sesame seed oil /rose / sandalwood oil a week prior to onset of menstruation, can help.

9. Hot oil packs to the lower abdomen can help relieve symptoms of severe cramps and discomfort.

10. Aim for atleast 30 minutes of exercise daily, as it helps in balancing hormone levels and improving mood swings. However, during your menstrual period, you may rest if needed.

11. Breathing exercises and relaxing yoga poses like Shavasana and half-spinal twists are beneficial. Vajrasana and sun-salutations are also beneficial.

12. Drink enough water, and have lots of fibre foods to keep your digestion healthy. Ayurveda believes that digestion is the cornerstone of health. If your body stores toxins, the PMS symptoms that you experience may be more severe.

PMS is a natural phenomenon, and not a disease, but, when it begins to disrupt your daily life, it can be a cause of concern. In such a case, discuss with your doctor about more effective ways of tackling it.

Sources of information

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