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Academic integrity and curbing Plagiarism

Publication or presentation of one's work on public platforms is the need of the day. Good research or conceptual work should be published for the benefit of the society in general and for the science in particular. Publication of the work also adds credits to one's bio-data which may be beneficial for his personal career growth. Due to this reason the inflow of new research journals and publications of articles in those journals is increasing day by day. This definitely has indented the academic honesty to more or less extent. Researchers or academicians at so many times are crossing the lines of sanctity and are publishing or presenting other's work as a whole or part of that as their own works without acknowledging the original workers or contributors. This mounts to be an academic dishonesty and plagiarism.

Academic integrity as defined in UGC regulations, 2018 is the "Intellectual honesty in proposing, performing and reporting any activity, which leads to creation of intellectual property". "Plagiarism" means the practice of taking someone else's work or idea and passing them as one's own (UGC regulations, 2018, Promotion of Academic Integrity and Prevention of Plagiarism in Higher Educational Institutions). In the same regulations UGC also recommends that "And whereas, assessment of academic and research work done leading to the partial fulfilment for the award of degrees at Masters and Research level, by a student or a faculty or a researcher or a staff, in the form of thesis, dissertation and publication of research papers, chapters in books, full-fledged books and any other similar work, reflects the extent to which elements of academic integrity and originality are observed in various relevant processes adopted by Higher Educational Institutions (HEIs)". Here it is pertinent to mention that in Ayurvedic institutions also the real picture is not so good and the issue of plagiarism is there. So many times students and faculty use others work full or part and present as their own knowingly or unknowingly.

It is of utmost importance that academic honesty or integrity must be maintained in the educational institutions. Every effort should be made to curb the menace of plagiarism. Although the UGC has notified the regulations in the Gazette of India on 23rd of July, 2018 yet every institute should adopt the policy to maintain the academic integrity and check the plagiarism. In National Institute of Ayurveda we have notified the policy under the heading "Plagiarism Policy of National Institute of Ayurveda". It is expected from every researcher, student and faculty that this policy should be applied while presenting or proposing their work in the form of synopsis, research proposals/projects, thesis, dissertations, research articles, case reports, and review articles, chapters in the books or full books.

Prof. Sanjeev Sharma
Director

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ORIGINAL ARTICLE

Efficacy of *Kampavatari Rasa* In *Kampavata* W.S.R. To Parkinson's Disease

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ABSTRACT

Kampavata (Parkinson's disease) is a slow progressive disorder of late adult life It is a burning problem among society in all countries around the world. The average age of onset is about 60 years, and fewer than 5% of patients present under the age of 40.

25 Patients of *Kampavata* were randomly selected and assessed on the basis of Webster scale as subjective criteria. Handgrip power, picking of pins with hands, walking time, butting time and chest expansion were used as Objective parameters.

Kampavatari Rasa was given in dose of 125 mg twice daily with lukewarm water for 30 days. After duration of treatment we compared base line data with data after treatment statistically. We have found Significant result in Bradykinesia, Tremor, Upper extremity swing, Gait, Self-care and Walking time.

Key Words: *Kampavata,* Parkinson's disease, *Kampa, Kampavatari Rasa*

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Introduction

Ayurveda is a monumental contribution of India to the world. As the name implies, it is an organized body having knowledge of healthy living. It represents a well codified human care system and speaks of the art and science of health and healing.

Ayurveda stands on three basic biological humours, named as *Vata, Pitta* and *Kapha*. Every humours has its aggravating and pacifying factors. *Vata* is most prominent and regulatory over others. Different Humours are prominent in different ages

like *Kapha* in childhood, *Pitta* in Young and *Vata* in old age.

Parkinson's disease has an annual incidence of about 18/100000 in the UK and a prevalence of about 180/100000. Age has a critical influence on incidence and prevalence, the latter rising to 300–500/100000 after 80 years of age. Average age of onset is about 60 years, and fewer than 5% of patients present under the age of 40.

The etiological factors of *Vata Vyadhi* in general have been explained in our classics, but separate *Nidana* for *Kampavata* are not explained. *Kampavata* is one of the *Vata Vyadhi* and it is also told that, *Na Kampo Vayuna Vina*[1] *i.e.* without *Vata*, there is no manifestation of *Kampa*.

Acharya Charaka mentioned*Vepathu* under *Nanatmaja* disorder of *Vata*[2]. Many other references regarding the *Kampa* are available in the name of *Vepathu, Vepana, Pravepana* etc. *Kampa* as one of the symptom of many other diseases like *Vataja Jwara*[3]*, Vataja Apasmara*[4]*, Anantavata*[5]*, Vishama Sannipataja Jwara*[6]*, Vatika Kustha*[7]*, Vatika Pandu*[8] and *Urustambha*[9] have been mentioned. *Acharya Sushruta* described that *Vata Vyadhi* kills the patient when accompanied with complications such as *Kampa*[10]. *Acharya Vagbhatt* mentioned *Kampa*as one of the symptom of *Vata Prakopa*. *Acharya Kashyapa* has listed *Vepathu* under the *Vata Nanatmaja* disorders[11].

A more detailed diagnostic approach for the first time was provided by *Basav Raj* explaining the symptoms of *Kampavata* viz. "*Karapada Tale Kampa*" (tremors in hands and legs), "*Dehabhramana*" (postural instability), "*Matiksheena*" (dementia), and "*Nidrabhanga*" (sleeplessness) and thus he definitely provided some new ideas in understanding of the disease.

The word *Kampa* is derived from the root "*Kapi Chalne*" and suffixed by "*Ghan*" which gives the meaning 'to move' or 'to shake'. "*Gatradi Chalanam*", that which produces shaking or movements in the body. The word *Kampa* conveys the meaning of shaking or tremor. The term *Vata* is derived from the root "*Vā*" and suffixed by "*Kth*". "*Va-Gatigandhanayoh*"[12] *Vata* is one of the three humours of the body. *Gati* and *Gandhana* are the two principal functions of *Vata* i.e., all the motor and sensory functions in the body are governed by *Vata*. *Kampavata* as one of *Vataja* disorder which has cardinal sign of *Kampa*.

Parkinson's disease is characterized by abnormalities of motor function. It interferes with activities of daily routine activities of life such as grooming, bathing, dressing, feeding etc. Taking all these into consideration this study was planned to evaluate the efficacy of *Kampvatari Rasa* in *Kampvata*.

Materials And Methods

- **Source of data:** Patients were selected from OPD of *Arogyashala* N.I.A. Jaipur and SSBH Jaipur. Patients were selected randomly irrespective of age, sex, religion, education, socio economic status & occupation.
- **Study design:** Open random type
- **Sample size:** 25 clinically diagnosed patients of *Kampavata*.
- **Drug:** *Kampvatari Ras* was prepared in the Pharmacy of National Institute of *Ayurveda*, Jaipur and packed in form of capsule to enhance its palatability for easy administration.
- **Dose-** 125 mg twice daily with luke warm water.
- **Time period of Clinical trial-** Internal administration of *Kampvatari Rasa* for 30 days.
- **Follow up-** Duration of follow up was 15 days.

Ethical Clearance- Clinical study was approved by Institutional Ethics Committee, by Order No-F10(5)/EC/2014/7223 on Date 07/11/2014.

Inclusion Criteria

1. Patients with clinical signs & symptoms of *Kampvata* in comparison with Parkinson's disease were selected.
2. Patients of either sex were selected.
3. Patients above 30 years of age.

4. Those who were ready to sign the consent form and follow the instructions as advised.

Exclusion Criteria

Patients with other systemic disorder which interfere with the treatment were excluded such as-

1. Alzheimer's disease
2. Drug induced
3. Trauma
4. Epilepsy
5. Ataxia
6. Hyperthyroidism
7. Wilson's disease etc.

Withdrawal Criteria

1. Patients developing any threatening complication during this trial. If any adverse effects will be found then it will be withdrawn from the study and informed to near by Pharmacovigilance cell.
2. Patient not willing to continue treatment.
3. Any other acute illness.

Criterias For Assessment

(1) Subjective Criteria

Most of the signs and symptoms of *Kampavata* are subjective in nature, to give the results and for statistical analysis "webster scale"[13] for parkinson's disease have been adopted.

Table No- I Subjective Criteria With Grading

PARAMETERS	FINDING	POINTS
Bradykinesia of	No involvement	0
Hands	Detectable slowing of the supination-pronation rate; beginning difficulty in handling tools buttoning clothes and with handwriting	1
	Moderate slowing of the supination-pronation rate in one or both sides; moderate impairment of hand function; handwriting is greatly impaired micrographia present	2
	Severe slowing of the supination-pronation rate; unable to write or button clothes; marked difficulty in handling utensils	3
Rigidity	Non-detectable	0
	Detectable rigidity in neck and shoulders; activation phenomenon is present; one or both arms show mild negative resting rigidity	1
	Moderate rigidity in neck and shoulders; resting rigidity is present if patient is not on medications	2
	Severe rigidity in neck and shoulders; resting rigidity cannot be reversed by medication	3
Posture	Normal posture; head flexed forward less than 4 inches	0
	Beginning poker spine; head flexed forward more than 5 inches	1
	Beginning arm flexion; head flexed forward up to 6 inches; one or both arms raised but still below waist	2
	Onset of simian posture; head flexed forward more than 6 inches; one or both hands elevated above the waist; sharp flexion of hands beginning inter-phalangeal extension; beginning flexion of knees	3

Upper	Swings both arms well	0
Extremity	One arm definitely decreased in amount of swing	1
Swing	One arm fails to swing	2
	Both arms fail to swing	3
Gait	Steps out well with 18-30 inch stride; turns about effortlessly	0
	Gait shortened to 12-18 inch stride; beginning to strike one heel; turnaround time slowing; requires several steps	1
	Stride moderately shortened to 6-12 inches; both heels beginning to strike floor forcefully	2
	Onset of shuffling gait; steps less than 3 inches; occasional stuttering-type or blocking gait; walks on toes; turns around very slowly	3
Tremor	No detectable tremor found	0
	Less than 1 inch of peak-to-peak tremor movement observed in limbs or head at rest or in either hand while walking or during the finger-to-nose testing.	1
	Maximum tremor envelope fails to exceed 4 inches; tremor is severe but not constant and patient retains some control of hands	2
	Tremor envelope exceeds 4 inches; tremor is constant and severe; patient cannot get free of tremor while awake unless it is a pure cerebellar type; writing and feeding self are impossible	3
Facies	Normal; full animation; no stare	0
	Detectable immobility; mouth remains closed; beginning features of anxiety or depression	1
	Moderate immobility; emotion breaks through at markedly increased threshold; lips parted some of the time; moderate appearance of anxiety or depression; drooling may be present	2
	Frozen facies; mouth opens >= 0.25 inches; drooling may be severe	3
Seborrhea	None	0
	Increased perspiration secretions remain thin	1
	Obvious oiliness present and secretion much thicker	2
	Marked seborrhea; entire face and head covered by thick secretion	3
Speech	Clear loud resonant easily understood	0
	Beginning of hoarseness with loss of inflection and resonance; good	1
	volume and still easily understood	
	Moderate hoarseness and weakness; constant monotone unvaried pitch; beginning of dysarthria hesitance stuttering difficult to understand.	2

	Marked harshness and weakness; very difficult to hear and to understand	3
Self-Care	No impairment	0
	Still provides full self-care but rate of dressing definitely impeded; able to live alone and may be employable	1
	Requires help in certain critical areas; very slow in performing most activities but manages by taking much time	2
	Continuously disabled; unable to dress feed self or walk alone	3

Interpretation:

- Minimum score: 0
- Maximum score: 30
- The higher the score the greater the disease severity and disability.

Table No- II Interpretation

Scale	Disability
1 – 10	early illness
11 - 20	moderate
21 – 30	severe or advanced

(2) Objective Criteria

1. Hand grip power: -

For this purpose the cuff of B.P apparatus folded, tied and inflated to such an extent so that the manometer recorded 20 mm of Hg constantly. The patient was asked to press the cuff with maximum power gripping the cuff in his hand. The record of the maximum grip was noted down. To avoid the errors 3 consecutive readings were taken giving a sufficient rest to the arm and the mean value of it was considered.

2. Chest expansion:

The degree of expansion of chest was measured by placing the measuring tape. Just below the nipples with its zero mark at the middle of sternum. Patients were instructed to take the deep breath in and out. The difference of expansions between inspiration and expiration was noted.

3. Picking of pins with hands:

The patients were asked to pick up the head of 20 pins one by one and keep away until all the 20 pins get collected. The time taken by the patient for this job was noted.

4. Walking time:

The walking time was measured by asking the patient to walk a distance of 20 feet in straight line. The patients were told to walk with maximum possible speed and the time was noted down in second with the help of a stopwatch.

5. Buttoning time:

Patient was requested to fix five buttons. Average time taken for buttoning was noted in seconds.

Observations And Results

After completion of the therapy of *Kampavatari Rasa* for one month, its effect on the clinical features was observed as presented in table. Various observations made and results obtained were computed statistically using Graph Pad Instat. Software Version 3.10 to find out the significance of the values obtained and various conclusions were drawn accordingly. For nonparametric data **Wilcoxon matched-pairs signed ranks test** was used. While for Parametric data **Paired 't' Test** was used and results were Calculated.

Table No- III Effect Of *Kampavatari Rasa* On Subjective Parameters

Symptoms	N	Mean		Diff.	% Of Change	SD	SE	W	P	Result
		BT	AT							
Bradykinesia	25	1.72	1.28	0.44	25.58%	0.82	0.16	99	0.0304	S
Rigidity	25	1.96	1.64	0.32	16.32%	0.90	0.18	76	0.1336	NS
Posture	25	1.64	1.40	0.24	14.63%	1.09	0.21	35	0.3303	NS
Upper extremity swing	25	2.00	1.52	0.48	24%	0.87	0.17	103	0.0237	S
Gait	25	2.32	1.76	0.56	24.13%	1.08	0.21	110	0.0258	S
Tremor	25	2.16	1.64	0.52	24.07%	1.12	0.22	88	0.0348	S
Facies	25	1.80	1.60	0.20	11.11%	0.86	0.17	40	0.3225	NS
Seborrhea	25	1.80	1.52	0.28	15.55%	0.84	0.16	43	0.1465	NS
Speech	25	1.72	1.40	0.32	18.60%	1.03	0.20	71	0.1564	NS
Self-Care	25	2.08	1.52	0.56	26.92%	0.96	0.19	108	0.0159	S

Table No- IV Effect Of *Kampavatari Rasa* On Objective Parameters

Criteria	N	Mean		Diff.	% Of Change	SD	SE	t	P	Result
		BT	AT							
Hand grip power	25	30.28	31.20	-0.92	-3%	2.97	0.59	1.54	0.1346	NS
Chest expansion	25	0.54	0.60	-0.05	-12%	0.14	0.02	1.93	0.0646	NS
Picking of pins with hands	25	60.08	59.64	0.44	0.73%	3.11	0.62	0.70	0.4862	NS
Walking time	25	68.72	67.48	1.2	1.74%	2.63	0.52	2.35	0.0271	S
Buttoning time	25	68.4	67.36	1.04	1.52%	2.80	0.56	1.85	0.0762	NS

Discussion

Indication of *Kampavatari rasa* is said for *Kampavata* in *Rasa Raj Sundar*. *Kampavatari Rasa* has mainly 3 ingredients, *Parada, Tamra Bhasma* and *Kutaki Swarasa Bawana*. *Parada* is having *Shadarasa, Snigdha Guna, Ushna Virya, Madhura Vipaka* and *Tridoshahara* properties. *Parada* is also *Sarvrogahara and* having *Yogavahi Guna*. *Parada* may helped in normalizing the *Vata Dosha* properties mainly *Chala Guna,* which are disturbed in *Kampavata*. *Tamra Bhasma* having *Madhura, Amla, Tikta, Kashaya Rasa* and *Madhura Vipaka*. *Katuka* having *Tikta Rasa, Sheeta Virya* and *Katu Vipaka*. Since we know that *Madhura, Amla, Lavana* helps in Decreasing *Vata Dosha properties and Katu, Tikta* and *Kashaya* helps in increasing the *Vata Dosha* properties. Some *Dravya* works with its *Rasa*, some with *Virya*, some with *Guna*, some with *Vipaka* and some with their *Prabhava*. So along with *Yogavahi* property of *Parada* and *Prabhava* may helped in modifying the *Kampavata* parameters.

However, it was the success of the therapy that improvement was noticed in the patients.

Parkinson's disease is a chronic, progressive, incurable type of *Vataja* disorder. *Kampavatari Rasa* was found good enough for treatment for *Kampavata*.

Conclusion

- There are so many etioligical factors like *Ahara, Vihara, Prakriti*, inheritance etc. for *Kampavata*, but the key point is that any factor, which vitiates *Vata*, can lead to *Kampavata*.
- Trial drug (*Kampavatari Rasa*) has significant result in Brady kinesia, Tremor, Upper extremity swing, Gait and Self care. It has insignificant result in Rigidity, Posture, Facies, Seborrhea and Speech.
- Trial drug (*Kampavatari Rasa*) has significant result in Walking time. It has insignificant result in Hand grip power, Chest expansion, Picking of pins with hands and Buttoning time.

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सारांश

कम्पवात वृद्धावस्था में धीमी गति से बढने वाली बीमारी है। विश्व के लगभग सभी देशों में यह एक ज्वलंत समस्या है। इस बीमारी के उत्पत्ति की औसत आयु 60 वर्ष है। जबकि मात्र 5 प्रतिशत रोगी ही 40 वर्ष के नीचे के पाए गए हैं। हमने कम्पवात के 25 रोगी यादृच्छिक तरीके से चयनित किये। उनका आंकलन करने के लिए हमने (वेब्स्टर स्केल) को व्यक्तिपरक मानदंड के तौर पर लिया एवम् हाथ के पकड़ने की शक्ति, हाथ से पिन उठाना, चलने में लगा समय, बटन बंद करने में लगा समय, सीने में विस्तार को लक्ष्यपरक मानदंड के तौर पर लिया। कम्पवातारि रस 125 मिग्रा. मात्रा में दिन में दो बार समशीतोष्ण जल से 30 दिन तक दिया। चिकित्सा अवधि के बाद हमने चिकित्सा से पहले एवम् बाद के डेटा का सांख्यिकीय रुप से तुलना किया। हमें सन्तोषजनक परिणाम प्राप्त हुए।

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ORIGINAL ARTICLE

A Comparative Study on The Effect of *Avasadahara Yoga* (*Kalpit*) and Psychotherapy in The Management of Depression

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ABSTRACT

Regarding mental illness, psychological temperament and emotions, *Ayurveda* has been written in detail. If the medical knowledge of the mental diseases described in *Ayurveda* is found in the context of depression, two main medical methods are revealed - non-materialistic treatment and medicinal therapy.

The physio-pathological studies of *Mansa Dosha* and the clinical study of 60 patients of depression, has been presented in the research paper.

The patients were divided into three groups in present study. Patients of group 'A' were given the hypothetical combination of drugs in the form of an *Arishta* (traditional fermented formulation) and group of 'B' patients were given psychotherapy. Meditation, chanting, praying and interviewing were used in psychotherapy. Both methods were used in the group 'C'. The results of the use of both methods were found to be more effective.

Key Words: *Avsad*, Depression, *Manas Doshas*, *Avasadahara Yoga*, Psychotherapy, Meditation, Counseling.

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Introduction

Mental disorder and psychological temperament are broadly described in *Ayurveda* texts. In today's materialistic society, human life has become speedy, mechanized, less affections and more centered, which contribute to more production of *Kama* (Desire), *Krodha* (anger), *Lobha* (greed), *Bhaya* (fear), *Shoka* (Grief), *Chinta* (Worry) and *Irshya* (envy) etc. like *Manasa Vikaras*. In this way, accurate knowledge of *Manasa* is necessary to

understand about nature of life and health[1].

Raja and *Tama* are the *Doshas* pertaining to the mind and the types of morbidity caused by them, are *Kama, Krodha, Moha, Lobha*, *Mada, Bhaya* etc. *Acharya Charaka* has advised to suppress these factors, because they tend to elevate *Raja* and *Tama Gunas*, which cause *Mano-dushti*. These obnoxious states of *Mana* produce *Mano-vikara* with involvement of *Sangyavaha* or *Manovaha Srotasa*[2].

That means depression is a state in which retardation of body and mind functions[3] seen i.e. psychomotor retardation.

Chakrapani has explained the term depression as incapability of mind as well as the body to work [4] i.e. cannot think or guess properly or inability to respond properly by mind body and speech.

According to Commentary of *Dalhan,* patient not doing any work due to fear of failure is called *Vishad*[5].

This study was design for evaluate the important of psychotherapy and *Ayrvedic* medicine.

Aims and Objectives

This study has been carried out clinical evaluation of *Avasadahara Yoga* and Psychotherapy in the management of depression on various scientific parameters

Materials & Methods:

Selection of Cases -

The patients of Depression fulfilling criteria for selection were registered from O.P.D., N.I.A., Jaipur.

[A] Inclusion Criteria -

The diagnosis of patients of depression was confirmed on the basis of detailed history, thorough clinical examination and scoring the Beck Depression Inventory II.

[B] Exclusion Criteria -

i) Patients superimposed with major psychiatric illness like Mania, Alzheimer's disease, Senile dementia, Schizophrenia, Obsessive compulsive disorders were not selected.

ii) Patients having fully diagnosed chronic disease like Malignancies, Hypothyroidism, Asthma, chronic renal Failure, cirrhosis of liver and other similar disorders were not selected.

iii) Patients with acute illnesses like myocardial infarction (M.I.), Cerebral-vascular Accident (C.V.A.), Congestive Heart Failure (C.H.F.), Chronic obstructive pulmonary disease (C.O.P.D.), meningitis.

iv) Patient suffering from drug induced Depressive illness.

[C] Discontinuation Criteria -

Patients were discontinued from the clinical trial; if they did not report for regular follow-up during clinical trial due to any reason. During trial period, if any other acute disease overlapped with classical manifestation of depression then also those patients were discontinued.

Drug content

Bramhi, Satavari, Vidharika, Ushir, Abhaya, Adrakh (Sunthi), Misi, honey, Sugar, Dhatki, Renuka, Trivrat, Pippali, Lawanga, Kusth, Aswagandha, Vibhitak, Guduchi, Aila, Vidang, Tvak and *Vacha*.

Psychotherapy:

Psychological counseling between the physician and the patient is undertaken (*Prashna*)[6]. Prashna have important role to start the counseling of a patient and questionnaires are also type of *Prashna Pariksha*.

Acharya Shushrut has mentioned treatment of mental diseases (*Manasa Roga*) by counseling of patients (*Shukhavaha Shabda*)[7].

Acharya charak mentioned *Adrvayabhoot Chikitsa* in form of *Upayo*[8].

Acharya Charak has mentioned about *Sadvrat Palan*[9] and *Chikitsa Sthan* cheptor 1 (part 4) about *Achar Rasayan*[10] . These are the techniques of privation of mental disease. So it may also include in psychotherapy.

The term *Satwavajaya*[11] implies the therapeutics for mental (emotional stresses) disturbances. As like the meaning of this word-victory of Mind, it is secured best by restraining the mind from desire for unwholesome objects and the cultivation of *Gyana* (knowledge), *Vigyana* (understanding), *Dharya* (courage), *Smriti* (recalling memory power) and *Samadhi* (concentration). The techniques of *Satwavajaya Chikitsa* include all technique of modern psychotherapy.

Acharya Vagbhatta mentioned in *Sutra Sthan* that the treatment of *Mano dosha* (*Raja and Tama*) use of *Dhee, Dharya* and *Atmadi Vigyana*[12].

So in addition to the above, *Ayurveda* envisages other method of treatment viz. – Meditation, *Shirodhara, Shirobasti, Abhyanga, Yoga*, Counselling etc.

In counseling, counselor hears any type of problem of patient and suggests solution as much as possible. Many patients feel loneliness, so counselors suggest for use of pleasure techniques.

3. Grouping & Administration of Drug:

Selected patients of depression were divided into three groups on random basis for the drug administration as follows -

Group A (*Avasadahara Yoga* Group):

Drug : Patients of this group were given *Avasadahara Yoga*

Dose : 15 ml twice in a day

Duration : 30 Days

Anupana : With equal amount of water (lukewarm)

Time : After meal

Group B (Psychotherapy Group) :

Drug : Psychotherapy including counselling, *Mantra Jap*, prayer and Meditation.

Duration : 30 Days

Time : Meditation with Mantra Jap done for 15-30 min. daily and given counselling 4 times in the period of 30 days.

Group C (Combined Group)

Both therapy given in group A & group B as mentioned above (Psychotherapy and *Avasadahara Yoga*).

Criteria of Assessment

During the trial and follow-up study the patients were assessed on the following parameters-

a) Subjective improvement.

b) Clinical improvement.

a) Subjective Improvement -

All the patients registered for the trial were specifically asked for any changes in their clinical manifestations and growing feeling of well being produced by the drug under trial.

b) Clinical Improvement -

For the assessment of clinical improvement, the incidence of presenting features was worked out and the severity of symptoms was rated in each case. For this purpose the following "Beck Depression Inventory (BDI)" was used.

The numerical system was used to rate or to report value on some measured dimension, for example, a scale ranging from 0 to 3, with 0 meaning strongly disagree and 3 strongly agree. In the scale various symptoms are graded into different grade as shown below -

Absent	0
Mild	1
Moderate	2
Severe	3

- Total BDI score can range from 0 to 63

  0-9 - Normal Non-depressed state

  10-18 - Mild Depression

  19-29 - Moderate Depression

  30-63 - Severe Depression

Duration of Clinical Trial And Followup Studies -

All the patients of three groups were regularly followed up 2 times i.e. on 15th day and 30th day to evaluate the therapeutic effect of treatment given. The patients were asked to fill up the Beck Depression Inventory for diagnosis before and after the treatment.

Observations

The data of the present study depicts that the maximum number of patients i.e. 65 % were male and 80% of the patients were Hindus.

The study reveals that majority of the patients i.e. 45% were reported in the age group of 21 – 30 years and maximum 30% of the patients were having higher secondary education level and maximum numbers of patients i.e. 48.33% were from middle class and maximum 33.33% of the patients were in service.

The data of the present study depicts that the majority of the patients i.e. 55% were married and most of the patients (78.33%) were belonging to urban habitat and 40.00% patients were having family history.

The present study mentions that dietary habit of most of the patients' i.e.55% was *Niramisha* (vegetarian), majorities i.e. 33.33% of the patients were having *Mandagni* and 55.00% were having *Madhyama Koshtha*.

In the present study, the available data depicts that maximum number of patients i.e. 53.33% were taking tea/coffee, however 18.33% of the patients were having addiction of sleeping pills, while 15.00% were having habit of chewing pan/tobacco and 06.67% each were smoking and use alcohol. No patients were addicted of snuffing or drugs.

The data of clinical study represents, 60.00% patients were having disturbed sleep and 25.00% patients were having irregular *Mala Pravritti*, whereas 26.67% patients had constipation.

The present study shows that maximum numbers of the patients i.e. 40.00% were having *Vata-kapha Sharirika Prakriti* and 51.67% were having *Tamasika Manasika prakriti*.

The present study shows that maximum numbers of the patients 58.33% were having *Madhyama Sara*, 71.67% were having *Madhyama Samhanana*, 68.33% were having *Madhyama Pramana*, 46.67% were having *Madhyama Satmya* and 68.33% were having *Avara Satva*.

The present study reveals that maximum numbers of patients i.e. 41.67% were having *Madhyama Abhyavaharana Shakti*, 40.00% were having Avara Jarana *Shakti,* 60.71% were having *Avara Vyayama Shakti*, 90.00% were from *Madhyama Vaya* and 66.67% belonged to *Jangala Desha*.

Results:

Effect Of *Avasadahara Yoga* (Group A) :

The present study denotes that statistically highly significant result was found in Pessimism (70.97%), in Sadness (66.67%), in Loss of pleasure (64.52%), in Irritability (55.88%) and in Tiredness or Fatigue (54.70%),

Statistically significant result was found in Agitation (49.26%), Changes in sleeping patterns (48.78%), Loss of energy (48.65%), Indecisiveness (47.50%), and Self Dislike (43.97%)

Statistically not significant result was found in Crying (40.30%), Suicidal Thoughts or wishes (35.00%), Self criticalness (34.21%), Changes in Appetite (32.24%), Punishment feelings (27.50%), Guilty feelings (25.00%), Past failure (21.88%), in worthlessness (19.12%) and Loss of Interest in Sex (16.07%)

The initial mean score were 29.85, 15.75 reduction with 42.24% decrease of BDI Score was noted, which was statistically highly significant ($P<0.01$).

Effect of Psychotherapy (Group B) :

The present study denotes that statistically highly significant result was found in Sadness (65.38%), in Self Dislike (64.29%), in Self criticalness (61.54%), in Loss of pleasure (56.25%), in Suicidal Thoughts or wishes (56.25%), in Pessimism (51.85%),

Guilty feelings (50.00%), in Agitation (50.00%), in Past failure (46.43%).

Statistically significant result was found in Indecisiveness (45.77%), Changes in sleeping patterns (45.71%), in Irritability (45.45%), in Crying (42.86%), in Punishment feelings (42.42%), in Tiredness or Fatigue (40.30%), Loss of Interest in Sex (38.86%), Loss of energy (37.84%).

Statistically not significant result was found in Changes in Appetite (30.85%) and in Worthlessness (27.83%).

47.86% decrease of BDI Score were observed which was highly significant (P<0.001).

Effect Of combine therapy (Group C) :

Statistically highly significant results were found in Guilty feelings (87.50%) and in Self Dislike 79.41%, whereas statistically significant result was observed in Self criticalness 76.67%, Changes in sleeping patterns (75.61%), punishment feelings (72.73%), Sadness (70.14%), followed by significant result in Pessimism(63.16%), Suicidal Thoughts or wishes (61.54%), Indecisiveness (60.71%), Loss of interest (59.38%), Agitation (58.62%), Loss of pleasure (58.54%), Loss of energy (56.76%), Irritability(55.88%), Past failure (55.56%), Concentration difficulty (51.61%), Loss of Interest in Sex (47.37%), in changes in appetite (47.06%), in Worthlessness (45.00%) and in Crying (44.44%).

The initial mean score was 32.6 which was reduced to 12.0 with 63.19% decrease of BDI Score, which was statistically highly significant (P<0.001).

Discussion:

In this study we choose the two distinct therapies (*Adravyabhut* & *Dravyabhut*) and evaluated its efficacy on the current disease Depression.

A very minor mistake of the physician may drop the patient into dark and become life threatening for him.

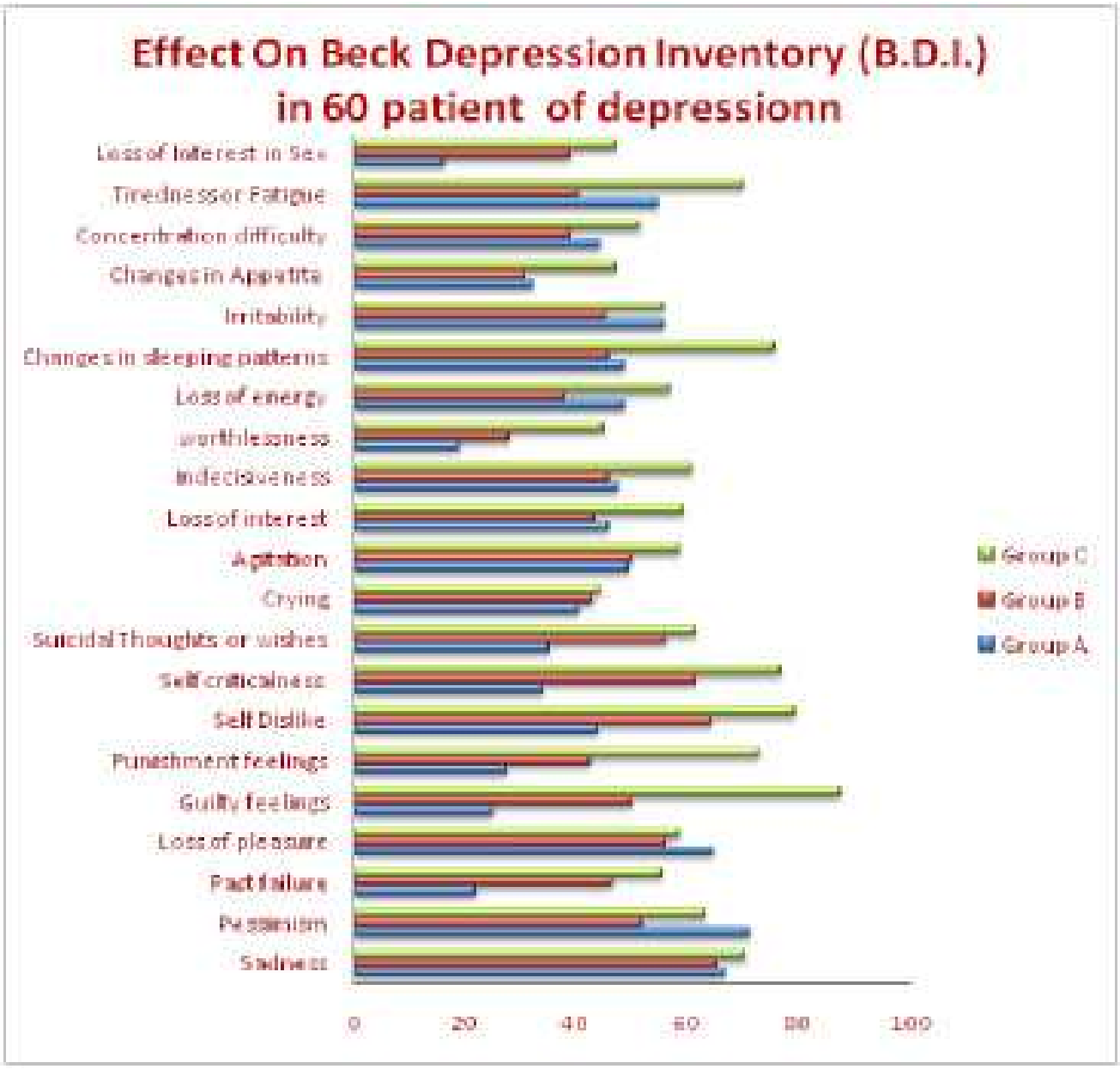
So we start our therapy in the both of dimension i.e. *Satva* to *Sharir* and *Sharir* to *Satva*

It is observed from our clinical study that the drugs having an aphrodisiacal effect, show a great role in mitigating the mental diseases specially those are depressive in nature.

Comparison of effect of Therapies:

Symptom	*Avasadahara Yoga* (Group A)	Psychotherapy (Group B)	Combine Therapy (Group C)
Sadness	66.67 %	65.38 %	70.45 %
Pessimism	70.97 %	51.85 %	63.16 %
Past failure	21.88 %	46.43 %	55.56 %
Loss of pleasure	64.52 %	56.25 %	58.54 %
Guilty feelings	25.00 %	50.00 %	87.50 %
punishment feelings	27.50 %	42.42 %	72.73 %
Self Dislike	43.97 %	64.29 %	79.41 %
Self criticalness	34.21 %	61.54 %	76.67 %
Suicidal Thoughts or wishes	35.00 %	56.25 %	61.54 %
Crying	40.30 %	42.86 %	44.44 %
Agitation	49.26 %	50.00 %	58.62 %
Loss of interest	45.77 %	43.33 %	59.38 %

Indecisiveness	47.50 %	45.77 %	60.71 %
Worthlessness	19.12 %	27.83 %	45.00 %
Loss of energy	48.65 %	37.84 %	56.76 %
Changes in sleeping patterns	48.78 %	45.71 %	75.61 %
Irritability	55.88 %	45.45 %	55.88 %
Changes in Appetite	32.24 %	30.85 %	47.06 %
Concentration difficulty	44.52 %	39.13 %	51.61 %
Tiredness or Fatigue	54.70 %	40.30 %	70.00 %
Loss of Interest in Sex	16.07 %	38.86 %	47.37 %



Effect On Total BDI Score

Combined therapy (Group C) 63.19% provided better relief in BDI score followed by Psychotherapy (Group B) 47.86% and *Avasadahara Yoga* (Group A) 42.24 %.

Overall Effect Of Therapies

Complete remission was seen in *Avasadahara Yoga* (Group A) in 05.00% patients and in combined therapy (Group C) in 15.00% patients.

75.00% patients got markedly improvement by combined therapy and 55.00% by Psychotherapy and followed by 50.00% by *Avasadahara Yoga*.

Moderately improved patients were noted 45.00% each in *Avasadahara Yoga* (Group A) and Psychotherapy (Group B) and 10.00% in combined therapy.

Comparison Of The Effects

On the basis of the comparison of the effects of all three groups on individual symptoms, total B.D.I. Score and overall effect discussed earlier, it was found that combined therapy provided better relief in the most of symptom which were having significant relief than other two therapies.

So it can be concluded that combined therapy proved better than Psychotherapy or Avasadahara Yoga administered therapy alone.

Probable Mode of Action of Psychotherapy:

Though clinically efficacy of Psychotherapy is proved, the nature of its action is very complex. Therefore, to understand the mode of action of Psychotherapy is a difficult task. Meditation processes enhance & the *Sattva* quality and Counseling itself seems to produce a relaxation response.

Probable Mode of Action of *Avasadahara Yoga:*

After considering the above description, it seems that all the drugs of *Avasadahara Yoga* having some action at psycho-neurological level and the combination of these drugs might be able to break the pathogenesis of depression at different levels.

All the drugs of *Avasadahara yoga* have *Rasayana* property, which replenishes the vital fluids in the body. That nourishes the body, sense, mind & intellect successively. But apart from *Rasayana* property some of the drugs have *Vrishya* & *Medhya Guna* also.

As a result it acts over the target organ instantly. It is a big question that there any relation between hypogonadism and Depression. It is seen that impotent, frigid or infertile (male & female) person are depressive. That is seems to be due to their fruitless work.

Conclusion:

Physical and psychological ailments affect each other. *Mana* plays an important role to controlling normal physiology and *Manas Doshas* (*Raja and Tama*) strongly afflict in every process and every step of life. It is seen that *Kaphaja Unmad* may be correlated with disease depression to some extent.

Though mental diseases are chronic in nature but it may be fatal. Short therapy is not sufficient to break down this complex phenomenon and so long term therapy is very essential.

The counseling is the life saving tool for depressive patients. Not only to the patient but it is applicable to the close relatives of patients too. Behavior of counselor should be like a friend for open conversation and lighting to problems specific.

Combined therapy proved better than individual psychotherapy as well as *Avasadahara Yoga* administered therapy.

Need large clinical study for explain the mood of action as modern parameters Further study should plan with some modern parameter.

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सारांश

मानस प्रकृति, मानस भावों एवं मानसिक रोग के संबन्ध मे आयुर्वेद में विस्तार से लिखा गया है। आयुर्वेद में वर्णित मानसिक रोगों के चिकित्सा संबन्धी ज्ञान को अवसाद रोग के परिपेक्ष में देखा जाये तो दो मुख्य चिकित्सा विधियाँ सामने आती है – अद्रव्यभूत चिकित्सा एवं द्रव्यभूत चिकित्सा। शोध पत्र में मानस दोषों के शरीर क्रियात्मक अध्ययन एवं मानस दोषों के विक्षोभ से उत्पन्न रोग अवसाद से ग्रस्त 60 रोगियों का चिकित्सीय अध्ययन को प्रस्तुत किया गया है। इस शोधकार्य हेतु रोगीयो को तीन समुहों में विभाजित किया गया। समुह 'ए' के रोगियों को द्रव्यभूत चिकित्सा औषध के रूप में कल्पित अवसादहर योग दिया गया एवं समुह 'बी' के रोगियों को अद्रव्यभूत चिकित्सा (साइकोथेरेपी) दिया गया। अद्रव्यभूत चिकित्सा (साइकोथेरेपी) में ध्यान, जप, प्रार्थना और साक्षात्कार को प्रयोग में लिया गया। समुह 'सी' मे दोनो चिकित्सा विधियों को संयुक्त रूप से प्रयुक्त किया गया। परिणाम में संयुक्त चिकित्सा विधि का प्रयोग अधिक प्रभावी पाया गया।

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ORIGINAL ARTICLE

Efficacy of an Ayurveda Compound in the Management of Iron Deficiency Anaemia: A Randomized Controlled Trial

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ABSTRACT

Background and objectives: Iron deficiency is the most common cause of nutritional anaemia in the world. Adolescent girls are at high risk of iron deficiency anaemia due to accelerated increase in requirements for iron. All allopathic oral iron preparations are gastric irritant and common side effects. Therefore present study was done to evaluate the safety and efficacy of an Ayurveda compound *Vajra Vatak Mandoor in* iron deficiency anaemia. **Design:** randomized control trial **Participants:** adolescent girls (12-15 years) **Methods:** 100 patients were selected from OPD and IPD of National Institute of Ayurveda, Jaipur and local school in Jaipur. That were satisfied the inclusion and exclusion criteria. They were randomly divided in two groups. In Group A administered *Vajra Vatak Mandoor* and in group B Iron and Folic Acid tablets for three month of duration with follow up at every forth night. **Results:** Non significant improvement in intergroup comparison, extremely significant improvement in most of clinical feature of and in laboratory parameters. **Conclusion:**The trial drug "*Vajra Vatak Mandoor*" is effective , safe and palatable in reduce incidence of the symptoms of *Pandu*.

Key Words: -*Pandu,* Iron deficiency anaemia, *Vajra Vatak Mandoor*

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Introduction

Globally, anaemia affects 1.62 billion people (95% CI: 1.50-1.75 billion) ,the population group with the greatest number of individuals affected is non-pregnant women. (468.4 million, 95% CI: 446.2-490.6)[1] Approximately one third of the world population is suffering from it. Iron deficiency is the most common cause of nutritional anaemia in the world. Nutritional iron deficiency is the commonest cause of anaemia in India.[2] 56% adolescent girls and

30% adolescent boys in India are affected by Anaemia according to the third National Family Health Survey. Adolescents (age 10-19 years), especially girls, are at high risk of iron deficiency and anaemia due to accelerated increase in requirements for iron, poor dietary intake of iron, malaria and worm infestation.

According to the Ayurveda classics the nearest correlation of iron deficiency anaemia can be made with *Pandu Roga*, because predominance of *Panduta* or pallor in the whole body is termed as *Pandu Roga*. *Pandu Roga* is *Pitta Pradhana Tridoshaja Vyadhi*. The decreased level of *rasa* and *rakta* which have the prime functions of nourishment and providing support to the vital function give rise to the symptoms.Pandu is divided into five types; *vatika, paittika, kaphaja, tridoshaja, mrid-bhakshanajanya pandu*. The *chikitsa* comprises of *Pittashamaka*, *Deepana-Pachana*, *Rasayana*, *Strotoshodhaka*, *Rakta Vardhak and Agni Vardhaka* medications. All allopathic oral iron preparations are gastric irritant and common side effects of oral iron include nausea, abdominal pain and either constipation or diarrhoea. Ferrous sulphate usually causes severe gastrointestinal side effects like gastritis, constipation/diarrhoea. Parenteral iron therapy may be required if iron cannot be absorbed from intestine and patient experiences intolerable gut symptoms.[3]

The present clinical study entitled "Study of Prevalence of Iron Deficiency Anaemia in Adolescent Girls and Efficacy of *Vajra Vatak Mandoor* in Its Management" has been carried out successfully and has been presented with the broad headings of Introduction, Literature Review, Review of Trial Drug, Demographic study, Clinical study (Materials and Methods, Observations and results) and Discussion.

Trial Drug - *Vajra Vatak Mandoor*. The compound has been rationally modified to make it in tablet form for easy administration.

Table no. I- Showing ingredients of *Vajra Vatak Mandoor*[4]

S.No.	Drugs	Botanical Name	Part used
1.	*Pippali*	*Piper longum*	fruit
2.	*Pippali mool*	*Piper longum*	root
3.	*Chavya*	*Piper chaba*	fruit
4.	*Chitrak mool*	*Plumbago zeylanicum*	root
5.	*Shunthi*	*Zingiber officinale*	rhizome
6.	*Maricha*	*Piper nigrum*	fruit
7.	*Devdaru*	*Cedrus deodara*	Heartwood
8.	*Haritaki*	*Terminalia chebula*	fruit
9.	*Vibhitak*	*Terminalia bellarica*	fruit
10.	*Aamalki*	*Emblica officinalis*	fruit
11.	*Vidanga*	*Embelia ribes*	fruit
12.	*Mustaka*	*Cyperus rotundus*	rhizome
13.	*Mandoor*	Fe_2O_3	

Aims And Objectives

1) To study its co-relation with the socio-economic status of the family.
2) To evaluate the safety and efficacy of an Ayurveda compound *Vajra Vatak Mandoor* in iron deficiency anaemia.

Methods

Study type: The clinical study was conducted in the form of an interventional, randomized control trial, open label, grouped (group A & group B).

End point: Safety and Efficacy

Number of patients to be completed in the clinical trial (sample size): 100

Timelines

Total trial period: 8 weeks

Washout/Preparatory Period: 4 weeks (if required)

Follow up period: 4 weeks

Statistical Analysis: 8 weeks

Selection of Cases

Subjects attended the O.P.D. and I.P.D. of *Kaumarbhritya* Department of National Institute of *Ayurveda*, Jaipur.

Age Group: Girls of 12-15 years of age were selected for the study.

Number of Cases: 100 cases (50 in each group)

Table no.II- Showing grouping of cases.

	Group A (n=50) **Trial drug (*Vajra Vatak Mandoor*)**	**Group B (n=50)** **Control drug (Iron Folic Acid tablets)**
Dose	500mg in two divided doses	100 mg elemental iron and 500 mcg folic acid
Dosage form	tablet	tablet
Route	Oral (After meals)	Oral (After meals)
Anupan	Butter milk	Water
Duration	8 weeks	8 weeks

Criteria For Selection Of Patients

Inclusion Criteria

1) Adolescent girls aged between 12-15 years.
2) Adolescent girls with iron deficiency anaemia (Hb 8 gm-12 gm %).
3) Adolescent whose parents were willing to give consent for clinical trial.

Exclusion criteria

1) Adolescent girls suffering from major systemic illness necessitating long term treatment.
2) Adolescent girls with evidence of malignancy.
3) Adolescent girls with concurrent serious hepatic dysfunction (defined as Aspartate amino-transferase and/or alanine aminotransferase >3 times of the upper normal limit) or renal dysfunction (defined as S. creatinine > 1.2mg/dl) uncontrolled pulmonary dysfunction (asthmatic and Chronic obstructive pulmonary disease patients)
4) Co-morbidity like Tuberculosis, Urinary tract infection and bleeding disorders etc.
5) H/o hypersensitivity to any of the trial drug or their ingredients.
6) Adolescent girls who have completed participation in any other clinical trial during the past six months.

Withdrawal Criteria

The participant may be withdrawn from the trial if there is:

1. Any major ailment necessitating the institution of new modalities of treatment.

   OR

2. Non-compliance of the treatment regimen (minimum 80% compliance is essential to continue in the study).

Assessment Criteria

For assessment of the efficacy of the trial therapy, following parameters were adopted-

Subjective: Based on clinical features of anaemia according to both modern and Ayurvedic parameters on the basis of presenting features on four point scale.

Objective: Laboratory findings were assessed before and after treatment. Hb%, Complete Blood Count, Peripheral Blood Smear, Stool routine and microscopic.

Adverse effects: To rule out the possible adverse effects of the trial drug record of information maintained on every follow-up i.e. gastric irritation, gastric upset, constipation diarrhoea, teeth discoloration, other untoward effect if any.

National Institute of Ayurveda, Jaipur. Institutional Ethics committee's approval was taken to conduct the clinical trial. Study was approved by IEC order no.-F10 (5)/EC/2014/7220. A voluntary signed, witnessed informed consent was obtained from the participant/ parents/ guardians prior to the start of clinical trial.

Observations And Results

Table no. III-Showing common observations of clinical study

S. No.	Factor	Classification	Group A (n=50)		Group B (n=50)		Total	
			No.	%	No.	%	No.	%
1	**Severity of Anaemia**	Mild (Hb<12-10%)	36	72	38	76	74	74
		Moderate (Hb <10-8%)	09	18	08	16	17	17
		Severe (Hb<8%)	05	10	04	08	09	09
2	**Age Group (in years)**	12 to <13	13	26	15	30	28	28
		13 to <14	18	36	17	34	35	35
		14 to <15	19	38	18	36	37	37
3	**Menarche**	Achieved	32	64	28	56	60	60
		Not achieved	18	36	22	44	40	40
4	**Relegion**	Hindu	22	44	30	60	52	52
		Muslim	28	56	20	40	48	48
		Others	00	00	00	00	00	00
5	**Economic status**	Higher	00	00	01	01	01	01
		Upper Middle	10	20	07	14	17	17
		Lower Middle	26	52	31	62	57	57
		Lower	14	28	11	22	25	25

6	**Habitat**	Urban Area	44	88	48	96	92	92
		Rural Area	06	12	02	04	08	08
7	**Immunization Status**	No immunization	11	22	14	28	25	25
		Incomplete	08	16	06	12	14	14
		Complete	10	20	07	14	17	17
		Unknown	21	42	23	46	44	44
8	**Diet**	Vegetarian	20	40	22	44	42	42
		Mixed	30	60	28	56	58	58
9	**Weight**	Average	32	64	30	60	62	62
		Under weight	18	36	19	38	37	37
		Over weight	00	00	01	02	01	01
10	**Hygienic Condition**	Good	14	28	09	18	23	23
		Moderate	30	60	27	54	57	57
		Poor	06	12	14	28	20	20
11	**Sleep**	Sound	32	64	26	52	58	58
		Disturbed	22	44	20	40	42	42
12	**Agni**	*Mandagni*	30	60	31	62	61	61
		Visamagni	13	26	09	18	22	22
		Tikshnagni	00	00	01	02	01	01
		Samagni	07	14	09	18	16	16
13	**Koshtha**	*Krura*	08	16	10	20	18	18
		Mridu	02	04	00	00	02	02
		Madhyam	40	80	40	80	80	80
14	**Appetite**	Poor	35	70	42	84	77	77
		Good	15	30	06	12	21	21
		Excessive	00	00	02	04	02	02
15	**Prakriti**	*Vata-Paittaja*	04	08	05	10	09	09
		Vata-Kaphaja	25	50	23	46	48	48
		Pitta-Kaphaja	21	42	22	44	43	43

Table No.VI – Showing Incidence of Causative Factors (*Nidana*) in the Patients of *Pandu Roga* at the Time of Registration (n=100)

Sr No.	Specific *Nidana*	No. of patients			%
		Group A (n=50)	Group B (n=50)	Total	
1	Food insufficient in quality	23	25	48	48
2	Food insufficient in quantity	16	13	29	29
3	Excess intake of *Amla, Lavana, Katu*	20	18	38	38
4	Excess intake of *Ushna, Tikshna, Ruksha*	16	20	36	36
5	Faulty diet habit	32	39	71	71
6	Excess intake of *Viruddhahar*	18	19	37	37
7	*Diwaswapna* (Day Sleep)	29	34	63	63
8	*Ratri Jagarana*	07	11	18	18
9	Exercise during digestion	02	03	05	05
10	*Nidanarthkararogas- Grahani*	10	12	22	22
11	*Nidanarthkararogas- Krimi*	20	22	42	42
12	*Nidanarthkararogas- Pratishyaya*	15	21	36	36

Table no. V- Showing Clinical Recovery in Cases of IDA Treated with *Vajra Vatak Mandoor* in Group A and Iron Folic Acid Tablets in Group B (Wilcoxon Matched pairs test)

Sr No.	Features	Group	Mean			% gain	SD	SE	P Value	Ipt
			BT	AT	Diff.					
1	Palpitation	A	1.980	1.200	0.7800	39.39	0.6788	0.0960	<0.0001	ES
		B	1.640	1.020	0.6200	37.80	0.6966	0.0985	<0.0001	ES
2	Dyspnoea	A	1.918	1.240	0.6531	34.05	0.8552	0.1222	<0.0001	ES
		B	1.860	1.260	0.6000	32.25	0.7284	0.1030	<0.0001	ES
3	Fatigue	A	1.840	1.180	0.6600	35.86	0.7453	0.1054	<0.0001	ES
		B	1.900	1.220	0.6800	35.78	0.7126	0.1008	<0.0001	ES
4	Vertigo	A	1.860	1.320	0.5400	29.03	0.7060	0.0998	<0.0001	ES
		B	1.840	1.260	0.5800	31.52	0.6728	0.0951	<0.0001	ES
5	Weakness	A	1.760	1.160	0.7000	39.77	0.7825	0.1107	<0.0001	ES
		B	1.820	1.120	0.7000	38.4	0.7354	0.1040	<0.0001	ES
6	Pallor	A	1.940	1.180	0.7600	39.17	0.6565	0.0928	<0.0001	ES
		B	1.900	1.200	0.7000	36.84	0.7071	0.1000	<0.0001	ES

7	Brittle Nails	A	0.160	0.100	0.0600	37.50	0.2399	0.0339	0.2500	NS
		B	0.220	0.180	0.0400	18.18	0.1979	0.0279	0.500	NS
8	Ankle	A	0.180	0.060	0.1200	66.66	0.3283	0.0464	0.0313	NS
	Oedema	B	0.140	0.060	0.0800	57.14	0.2740	0.0387	0.1250	NS
9	Smooth	A	0.320	0.300	0.0200	06.25	0.1414	0.0200	>0.9999	NS
	Tongue	B	0.420	0.220	0.2000	47.61	0.4041	0.0571	0.0020	VS
10	Loss of	A	2.100	1.300	0.8000	38.09	0.6061	0.0857	<0.0001	ES
	Appetite	B	1.840	1.160	0.6800	36.95	0.7407	0.1047	<0.0001	ES
11	Irritability	A	1.440	1.460	0.0200	1.38	3.087	0.4366	0.0019	VS
			1.360	1.020	0.3400	25	0.5194	0.0734	0.0002	ES

Both the trial and control showed extremely significant result over subjective parameters. Trial drug *Vajra Vatak Mandoor* on group A was found more effective over the subjective parameters -weakness, palpitation, pallor and loss of appetite with % gain of 39.77%, 39.39%, 39.17%, 38.09% respectively

Table no. VI -Showing pattern of Hematological Changes in Cases of Iron Deficiency Anaemia in Group A and in Group B (Paired 't' test)

Sr No.	Features	Group	Mean			% gain	SD	SE	P Value	Ipt
			BT	AT	Diff.					
1	Hemoglobin	A	11.04	12.14	1.094	9.90	0.6520	0.9220	<0.0001	ES
		B	10.11	11.25	1.114	11.31	0.5159	0.0729	<0.0001	ES
2	RBC	A	4.277	4.657	0.379	8.87	1.158	0.1638	0.0248	S
		B	4.033	4.517	0.484	12.01	0.2953	0.0417	<0.0001	ES
3	PCV	A	27.50	37.28	9.788	35.59	2.013	0.2847	<0.0001	ES
		B	27.83	36.88	9.050	32.51	2.951	0.4174	<0.0001	ES
4	MCV	A	68.57	78.09	9.516	13.87	3.337	0.4719	<0.0001	ES
		B	66.38	75.95	9.564	14.40	3.538	0.5003	<0.0001	ES
5	MCH	A	25.53	28.23	2.700	10.57	1.243	0.1758	<0.0001	ES
		B	24.61	27.60	2.988	12.13	1.278	0.1807	<0.0001	ES
6	MCHC	A	32.56	34.87	2.308	7.08	1.983	0.2804	<0.0001	ES
		B	32.59	34.15	1.552	04.76	1.368	0.1934	<0.0001	ES

In present study, *Aruchi* (Loss of appetite), *Avipaka* (Improper digestion), *Pandutva* (Paleness) were commonly observed premonitory symptoms, while *Shirnaloma* (Falling of hairs), *Pada Sada* (Weakness in feet), *Nirutsaha/ Shaithilendriya* (Apathetic) were most commonly observed symptoms. While in demographic study fatigue was most prevalent symptom which was observed during the survey.

Statistical calculation between before and after treatment findings of objective parameters all results were found extremely significant (P<0.0001) in both groups except RBC count in group A which was significant with P value 0.0248.

On intergroup comparison on subjective parameters, all results were found non-significant except smooth tongue which was very significant with P value 0.0043.

Probable Mode Of Action

***Doshahara* effect-** '*Vajravataka Mandoor*' has contents of *Triphala* having *Tridoshahara* properties. *Lauha Bhasm* is having *Kaphapitta Shamak* property and *Pandu* is *Pitta Pradhan Tridoshaja Vyadhi* so, due to these properties it is helpful in treating *Pandu*.

***Rasayana* effect-** *It* contains well known *Rasayana* drugs like *Amalaki,*[5] *Pippali*[6] *,Mandoor Bhasm*. *Mandoor Bhasma* is mentioned as a best drug for *Pandu Roga*. *Amalak*i is a proved drug for *Pandu,* moreover the presence of vitamin-C and ascorbic acid helps in absorption of iron.

***Agnivardhak* and *Dhatuposhan* effect-** When we analyze the formulations mentioned in the context of *Pandu*, it is evident that they contain herbal ingredients like *Panchkola, Maricha* etc. that are known correctors of the metabolism and enhancers of bioavailability of nutrients. 102 formulations are mentioned in the treatment of *Pandu* in *Ayurvedic* formulary of India among which 72 does not contain metallic iron. All these indicate that more emphasis was given in the text books of *Ayurveda* for factors affecting metabolism. *Trikatu* is present in *Vajravataka Mandoor*, so the drug increases the *Jatharagni* and *Dhathavagni* up to normal level and *Dhatunirman* process gets toned up which results ultimately to *Dhatupushti* and *Dhatu Prasadana* so due to these properties it is helpful in *Pandu Roga*.

***Srotoshodhak* effect**- Maximum number of drugs possess *Laghu, Ruksha Guna* and *Tikta Rasa*. So the drug also possess *Srotosodhak* property and help in clearing the *Srotas*.

***Krimihara* effect**- *Mustaka*[7] and *vidanga*[8] are having anti helminthic properties. Krimi is also most prevalent cause of anaemia in children because of poor sanitation and outside foods.

Pandu includes various types of anaemias, *kapha* dominant variety of *Pandu* has more resemblance with iron deficiency anaemia.In Ayurveda, more emphasis has been given for the correction of metabolism as well as supplementation of iron in treatment of *Pandu*.

As the study was planned aiming adolescent girls; tablet form was preferred due to its higher acceptance, palatability and easy dose fixation.Trial drug *Vajravataka Mandoo*r showed almost equal and extremely significant improvement as compared to control drug IFA tablets. However *Vajravataka Mandoor* showed better results on all cardinal features except vertigo and irritability. Trial drug *Vajra vatak Mandoor* was found more effective over the subjective parameters-weakness, palpitation, pallor and loss of appetite, which were the most common complaints of girls with anaemia.

All results were found extremely significant in both groups, however group A showed significant gain in Red Blood Cells count. After treatment maximum % gain was observed in Packed Cell Volume among all objective parameters in both groups A and B. In intergroup comparison all subjective and objective parameters showed non-significant result.

Study reveals that all the drugs used in *Vajravataka Mandoor* are effective in all the conditions described in the pathogenesis of *Pandu Roga*. Thus it can be considered as a useful drug.

Conclusion

Nutritional anaemia is a major public health problem in India and is primarily due to iron deficiency especially in girls where they are exposed to risk of onset of menarche. Trial drug *Vajra vatak Mandoo*r showed almost equal and extremely significant improvement as compared to control drug Iron Folic Acid tablets. However *Vajra vatak Mandoor* showed better results on all cardinal features except vertigo and irritability. All results were found extremely significant in both groups; however group A showed significant gain in Red Blood Cells count. In intergroup comparison all subjective and objective parameters showed non-significant result. No adverse effects were reported during entire period of study by any of the patients in trial group created with *Vajra vatak Mandoor*.

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सांराशः-

लौह तत्व की कमी जनित रक्ताल्पता एक प्रमुख स्वास्थ्य विषयक समस्या है। किशोरियो मे लौह तत्व की कमी जनित रक्ताल्पता अधिक पायी जाती है। आयरन की गोलियों का आमाशय क्षोभक व प्रतिकूल प्रभाव है। अतः वज्र वटक मन्डूर के प्रभाव का डबल ब्लाइन्ड प्लेसिबो नियन्त्रित अध्ययन किया गया हैं। इस चिकित्सकीय शोधकार्य 12–15 वर्ष तक की 100 किशोरियो का क्रम रहित तरीके से राष्ट्रीय आयुर्वेद संस्थान के बहिरंग एवं अन्तरंग इकाई बालरोग और स्थानीय विद्यालय से चयन कर दो समूह में बांट दिया। एक समूह–अ को वज्र वटक मन्डूर और समूह–ब में आयरन की गोलियो को 2 माह तक लगातार सेवन करवाया गया। Inter group मे non-significant परिणाम मिले, पर improvement समूह–अ में अधिक मिला। इसी प्रकार समूह–अ के रोगियों में पाण्डु के लगभग सभी लक्षणो में भी extremely significant परिणाम मिले। अतः किशोरियो मे लौह तत्व की कमी जनित रक्ताल्पता में वज्र वटक मन्डूर एक बहुत अच्छा विकल्प हैं, पूरे शोधकार्य के दौरान कोई हानिकारक प्रभाव सामने नहीं आया।

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ORIGINAL ARTICLE

Clinical Evaluation of Efficacy of *Madhura Aushadha Siddhataila Matravasti* And *Yonipichu* In *Sukhaprasava*

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ABSTRACT

Despite of advanced health care in the field of Obstetrics, a high number of women continue to die during childbirth, due to any cause, related to or aggravated by the pregnancy or during management of labour. Woman's health has been neglected since many decades due to gender inequality, poverty, illiteracy; working for the survival of mother is human rights imperative. Keeping in view the above facts and direct emergency of saving the mother, women's health is incorporated in the Millennium Development Goals. There have been substantial achievements from 1990 (baseline year for the MDGs) to date; but globally maternal deaths are 50% only decreased. But the situation is not very much normal, even now every year 289 000 maternal deaths are occurring worldwide, most are from preventable causes. To achieve these unmet goals of MDG 5, now there is consensus on evidence-based, cost-effective investments and interventions.

At this juncture, the pro-poor and cost effective interventions of *Ayurveda* are the best suitable methods for antenatal, intranatal as well as post natal care. A comprehensive antenatal care starting from conception to delivery is described under the heading *Garbhini paricharya* in *Ayurveda*. This antenatal care also incorporates the regimen to facilitate Eutocia (*Sukhaprasava*); *Vasti* is the procedure advocated for the same purpose.

The present clinical study is taken up to evaluate the efficacy of *Madhura aushadha siddha taila* in the form of *Vasti* (Biopurificatory enema) and *Yonipichu* (Vaginal tampon) in the management of labour.

Key words: Pregnancy, Labour, *Yonipichu*, *Sukha prasava, Madhura Aushada siddha taila Matra vasti*

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Introduction

Pregnancy is one of the most important events in the life of every woman. Child bearing and delivery are such physiological entities which are always ready to convert into pathological entities, if uncared. So, here *Prakriti Sthapanam* is essential to prevent the pathology, and is the main motto of antenatal care.

To prevent the pathological changes that occur during labour proper antenatal care is essential. The life of an unborn child is dependent on the mother. According to *Acharya Charaka*, the woman is root of offspring.[1]

The present study is taken up to evaluate the clinical efficacy of ninth month regimen of *Garbhini* mentioned by *Charaka* on *Prasava* (labour), that is use of *Madhura Aushadha Siddha taila Matravasti and Yonipichu* for the purpose of *Sukha* and *Nirupadrava Prasava*.

The *Prasava'*[2] is defined as *Prakruta* if it fulfills the following criteria- *Swabhava* -spontaneous in onset, *Upasthita kala* – onsets at term, *Avakshira*-cephalic presentation, *Swabhawika kala*-without undue prolongation.

At the onset of labour the foetus gets turned and comes forward due to action of *Prasooti Maruta* and then expelled out through *Apatyapatha* this is termed as normal labour. Pregnancy especially during course of labour is the most critical stage. As *Acharya Kashyapa* has described labour as a critical phase of women's life[3] Facilitating Prasava to culminate into *Sukhaprasava* is one of the aims of *Masanumasika Garbhiniparicharya*. It is the unique stage where maternal adaptation occurs easily to provide a favorable outcome for both mother and foetus.

As per *Ayurveda* the *'Apana Vayu'* plays an important role in the foetal expulsion.[4] *Vayu* is essential for contraction and retraction of mayometrium and to expel the foetus. To keep this *Vayu* in balanced state, *Acharya* have advised the administration of *Anuvasana Vasti* and *Yonipichu*. *Vayu* is most likely to be vitiated during pregnancy, and it is described that there is no other remedy more beneficial than administration of "*Matravasti* and *Pichu* particularly in affliction of *Vayu* .[5]

Rationality of selection of trial drugs:

Madhuraushadha Sidda Taila: *Madhura aushadha siddha taila Matravasti* described to use during ninth month of pregnancy. Eight drugs *Ashwagandha, Shatavari, Vidarikanda, Yastimadhu, Mudgaparni, Mashaparni, Jivanti* and *Bala* were selected from *Madhura skandha* described in Charaka Vimanasthana-8[6]; these drugs were selected due to their availability and expected high degree of clinical effects. *Murchana* of *Tila taila* done according to the reference of *Bhaishajyaratnavali-Jwararogadhikar Adhyaya*.[7] After *murchana*, *Madhura aushadha siddha Taila* was prepared as per the *Tailapaka vidhi* by adding eight drugs to *murchita Tilataila*. The oil was prepared in Pharmacy of National Institute of Ayurveda, Jaipur.

Aims & Objectives

1. To evaluate the efficacy of *Madhura aushadha siddha taila Matravasti* along with *Yonipichu* after completion of 32 weeks of pregnancy on process of labour.
2. To study ninth month *Garbhini Paricharya* of *Acharya Charaka*
3. To reduce the complications of intra-natal period, especially third stage complications.
4. To evaluate the effect of procedure on early puerperium.

Materials And Methods

Selection of patients:

All Primi pregnant women were recruited from OPD/IPD of PG Department of *Prasutitantra* and *Striroga*, National Institute of *Ayurveda*, Jaipur. All subjects were thoroughly examined and selected strictly as per the criteria of inclusion. The patients were randomly allocated into two different groups and trial drug were given after taking written informed consent of the patients. Total 35 patients were registered for the present study, 17 patients under Group-A (*Matravasti* and *Yonipichu),* among them 02 patients were dropped out. Under Group-B total 18 patients were registered, among them 03 patients were dropped out.

This work is approved by Institutional Ethical Committee vide letter No. F1O(5)EC/2014 dated 07/11/2014

Trial Groups: Two

Group-A

Madhura aushadha siddha taila Matravasti - The trial drug were administered after completion of 32 weeks of gestational age, once in a week up to 36 weeks of gestational age; after completion of 36 weeks of gestation, twice in a week till delivery.

***Matra vasti* dose**- 60 ml

Madhura aushadha siddha taila Yonipichu - given once in a week after completion of 32 to 36 weeks then continued daily till delivery.

Group-B

Under this group patients were registered as control, no drug was administered.

1. **Study type:** Interventional
2. **Study design:** Randomized controlled trial
3. **Allocation:** Randomized

   Randomization method: Randomization is done through simple random method
4. **Masking:** Open label
5. **Purpose:** Treatment
6. **Sample size:** 30 (15 in each group)
7. **End point:** Efficacy

Criteria of Inclusion:

- Pregnant woman between the ages of 20-30 years.
- Primipara with single intrauterine fetus after completed 32 weeks of gestational age.
- Normal fetal position at term.

Criteria of Exclusion:

- Age less than 20 years and more than 30 years
- Multipara, multiple pregnancy
- Pregnancy associated with any systemic diseases
- Pregnancy associated with malignancy of genital tract
- History of Bad obstetric history
- Polyhydraminos
- Pre-eclamsia/Eclamsia
- Intra Uterine Growth Retardation
- Mal -presentation
- History of Ante-Partum Haemorrhage
- Contracted pelvis
- Vaginal obstruction (adhesion & stenosis)
- Pregnancy associated with placental abnormalities
- Pregnancy associated with reproductive tract abnormalities/pathology.

Criteria for Withdrawal:

1. On development of any complications patient will be withdrawn from trial
2. 100% non-compliance of trial

Laboratory investigations:

- Blood – Complete Blood picture, ABO Rh, Bleeding Time, Clotting time, HIV, HBsAg, VDRL, Fasting Blood sugar, LFT, RFT
- Urine-Routine & microscopic
- TSH
- Ultrasonography for Fetal well being
- Other investigations like ECG, Serum Blood Urea, Serum Creatinine, will be advised in suspected cases to rule out the other specific diseases

Criteria of Assessment

Clinical result were assessed on the basis of duration and events of stages of labor and nature of delivery and accordingly grades were given to the patients:

Grade-o

Onset of labor - Spontaneous

Partogram - Before alert line

Uterine contractions - Normal pattern

Type of delivery - Spontaneous vaginal delivery without episiotomy.

Grade-I

Onset of Labour - Spontaneous

Partogram - Before alert line/ between alert line & action line

Uterine contractions - Normal pattern

Type of delivery - Spontaneous vaginal delivery with episiotomy.

Grade-II

Onset of Labour - Induced

Partogram - Before alert line/ between alert line & action line

Uterine contractions - Normal /Irregular pattern

Type of delivery - Spontaneous vaginal delivery with or without episiotomy.

Grade-III

Onset of labour - Spontaneous/Induced

Partogram - After alert line

Uterine contractions - Irregular pattern

Type of delivery - Caesarian section

Statistical Analysis:

The data collected on the basis of observations were analyzed using appropriate statistical test (Paired 't' test was used for parametric data and Wilcoxan rank sign test for non-parametric data and ANOVA for comparative analysis) to evaluate the significances at different levels i.e. at 0.05, 0.01 and 0.001 levels.

The obtained results were interpreted as follows-

- Insignificant or Not significant (NS or NQS) - $p>0.05$
- Significant (S) - $p<0.05$
- More or very Significant - $p<0.01$
- Highly or Extremely Significant - $p<0.001$

Observations:

Table -I Incidence of Age

S. No.	Age	Number of Patients		Total	Percentage
		Group -A	Group –B		
1..	20-23	6	9	15	50.00
2	24 -27	7	4	11	36.67
3.	28 -30	2	2	4	13.33
	Total	**15**	**15**	**30**	**100.0**

Table -II - Incidence of occupation

S. No.	Occupation	Number of patients		Total	Percentage
		Group - A	Group – B		
1.	Labour	00	00	00	0.00
2.	Housewife	11	13	24	80.00
3.	Service	4	2	6	20.00
4	Business	00	00	00	0.00
	Total	**15**	**15**	**30**	**100.0**

Table -III Incidence of Height

S.No.	Height	Number of patients		Total	Percentage
		Group - A	Group –B		
1.	4'10" - 4'11"	01	03	04	13.33
2.	5.0"- 5'2"	09	11	20	66.67
3.	5'3" –5'5"	05	01	06	20.00
4	>5'5"	00	00	00	0.00
Total	15	15	30	100.0	

Table -IV Incidence of Gravidity

S. No.	Gravidity	Number of patients		Total patients	Percentage
		Group - A	Group – B		
1.	Primi Gravida	15	11	26	86.67
2.	Second Gravida	00	04	04	13.33
3.	Multi Gravida	00	00	00	0.00
Total	15	15	30	100.0	

Table - V Incidence of vasti pratyagamana kala

S. No.	*Vasti pratyagamana kala*	Group A	Total patients	Percentage
1.	1-3 hrs	00	00	0.00
2.	4-6 hrs	5	5	33.33
3.	>6hrs	10	10	66.67
	Total	**15**	**15**	**100.0**

This table indicates that maximum number of patients i.e. 66.67% had *Vasti pratyagamana* in > 6 hrs and 33.33% patients had 4-6 hrs (Table -V).

RESULTS

Table - VI Incidence of Prasava kala

S. No.	Gestational period in week	Patients				Total patients	%
		Group A		Group B			
		No	%	No	%		
1.	<37 wks	1	6.66	1	6.66	2	6.66
2.	38-39 wks	10	66.66	8	53.33	18	60.00
3.	40-41 wks	4	26.66	6	40	10	33.33
	Total	**15**	**100**	**15**	**100**	**30**	**100.0**

Table -VII Effect of Therapy on Contractions

S.No.	Contractions	Group-A		Group-B		Total	%
		No	%	No	%		
1.	Good	9	60	5	33.33	14	46.67
2.	Fair	5	33.33	7	46.66	12	40.00
3.	Poor	1	6.66	3	20	4	13.33
	Total	**15**	**100**	**15**	**100**	**30**	**100.0**

Table - VIII Incidence of Rupture of Membrane

S. No.	Rupture of Membranes	Number of Patients				Total	%
		Group A		Group B			
		No	%	No	%		
1.	Pre labour	03	20.00	07	46.66	10	33.33
2.	At labour Early	06	40.00	06	40.00	12	40.00
3.	At labour Late	06	40.00	02	13.33	08	26.67
	Total	**15**	**100**	**15**	**100**	**30**	**100.00**

Table - IX Grade of labor wise distribution

S. No.	Grade of labor	Number of Patients				Total	%
		Group A		Group B			
		No	%	No	%		
1.	0	00	00.00	01	06.66	01	03.33
2.	1	12	80.00	06	40.00	18	60.00
3.	2	02	13.33	05	33.33	07	23.33
4.	3	01	06.66	03	20.00	04	13.33
	Total	**15**	**100**	**15**	**100**	**30**	**100.00**

Table -X Showing effect of therapy on different symptoms in Group -A (Wilcoxon Signed Rank Test)

Group-A	B.T.	Mean A.T.	Dif.	Mean %	No.	S.D.	S.E.	+ve rank	-ve rank	Sum of all rank	P	Signi-ficance
Vibandha	1.40	0.33	1.07	76.19%	13	1.28	0.33	79.5	11.5	68	0.035	S.
Udarashoola	1.20	0.27	0.93	77.78%	12	0.59	0.15	78	0	78	0.01	S.
Katishoola	1.60	0.67	0.93	58.33%	13	0.46	0.12	91	0	91	0.007	S.
Daurbalyata	2.13	0.80	1.33	62.50%	15	0.49	0.13	120	0	120	0.004	H.S.
Kshudha-vaishmya	1.53	0.73	0.80	52.17%	10	0.68	0.17	55	0	55	0.02	S.
Nidravaishmya	1.33	0.67	0.67	50.00%	9	0.62	0.16	45	0	45	0.028	S.
Swetasrava	1.40	0.60	0.80	57.14%	9	0.77	0.20	45	0	45	0.028	S.
Yonikandu	0.93	0.20	0.73	78.57%	10	0.59	0.15	55	0	55	0.02	S.

Table -XI Effect of therapy on different symptoms in Group-B

Group-B	B.T.	Mean A.T.	Dif.	Mean %	No.	S.D.	S.E.	+ve rank	-ve rank	Sum of all rank	P	Signi-ficance
Vibandha	1.47	1.47	0.00	0.00%	0	0.00	0.00	0	0	0	N.D.	N.D.
Udarashoola	1.40	1.40	0.00	0.00%	0	0.00	0.00	0	0	0	N.D.	N.D.
Katishoola	1.60	1.60	0.00	0.00%	0	0.00	0.00	0	0	0	N.D.	N.D.
Daurbalyata	2.00	2.00	0.00	0.00%	0	0.00	0.00	0	0	0	N.D.	N.D.
Kshudha-vaishmya	1.53	1.47	0.07	4.35%	1	0.26	0.07	1	0	1	N.D.	N.D.
Nidravaishmya	1.00	0.93	0.07	6.67%	0	0.26	0.07	0	0	0	N.D.	N.D.
Swetasrava	1.33	1.33	0.00	0.00%	0	0.00	0.00	0	0	0	N.D.	N.D.
Yonikandu	1.00	1.00	0.00	0.00%	0	0.00	0.00	0	0	0	N.D.	N.D.

N.D.= Not define

Table -XII Inter Group Comparison of effect of therapy on different symptoms (Comparison between the groups by Mann-Whitney Test)

Symptoms	U1	U2	U'	Z	P Value	Significance
Vibandha	45	180	45	2.799	0.005	H.S.
Udarashoola	22.5	202.5	22.5	3.73	0.0001	H.S.
Katishoola	15	210.0	15	4.04	0.00005	H.S.
Daurbalyata	0	225	0	4.666	0.00001	H.S.
Kshudhavaishma	44	181	44	2.84	0.0049	H.S.
Nidravaishma	52	173	52	2.5	0.012	S.
Swetasrava	45	180	45	2.799	0.005	H.S.
Yonikandu	37.5	187.5	37.5	3.11	0.001	H.S.

Table -XIII Showing effect of therapy on the duration of stages of labour in Group-A (Paired t-test).

Stages	Mean B.T.	Mean A.T.	Mean Dif.	Mean %	No.	S.D.	S.E.	t	P	Signi-ficance
1st stage	12	7.07	4.93	41.11%	15	1.98	0.51	9.65	<0.001	H.S
2nd stage	120	32.00	88.00	73.33%	15	13.73	3.55	24.82	< 0.001	H.S.
3rd stage	30	6.67	23.33	77.78%	15	3.09	0.80	29.28	< 0.001	H.S.

Table -XIV Showing effect of therapy on the duration of stages of labour in Group-B (Paired t-test)

Stages	Mean B.T.	Mean A.T.	Mean Dif.	Mean %	No.	S.D.	S.E.	t	P	Signi-ficance
1st stage	12	09.93	02.07	17.22%	15	1.44	0.37	5.57	< 0.001	H.S
2nd stage-	120	43.20	76.80	64.00%	15	27.95	7.22	10.64	< 0.001	H.S.
3rd stage-	30	11.00	19.00	63.33%	15	6.32	1.63	11.64	< 0.001	H.S.

Table no XVI - Incidence of Effect of therapy on early purperium

S.No.	Symptoms	Patients				Total	%
		Group A		Group B			
		number	%	number	%		
1.	PPH	1	6.66	1	6.66	2	10.00
2.	*Jwara*	1	6.66	4	26.67	5	16.66
3.	*Kampa*	0	0	0	0	0	00
4.	*Pipasa*	0	0	0	0	0	00

5.	*Atisara*	0	0	0	0	0	00
6.	*Yonibhedan*	0	0	0	0	0	00

Discussion

Acharya Charaka mentioned use of *Anuvasana vasti* and *Yonipichu* in ninth month of *Garbhini paricharya* for the purpose of facilitating normal labour, get healthy offspring as well as to reduce the post partum complications.[8] The present study is carried out to evaluate the same therapy clinically in *Garbhini* women. Study carried out under two groups, Group-A (trial group) and Group-B (control group). Trial group subjects were given *Madhuraushadha siddha taila Matravasti* and *Yonipichu* with the same oil on 30 patients, i.e. 15 under each group.

Discussion on observation of Clinical Study:

Most of the patients i.e. 50.00% in the study were found in the age group of 20-23, followed by 36.67% patients in the age group of 24-27 yrs (Table-I). On observation of occupation it is found that maximum number of patients i.e. 80.00% patients were housewives and 20.00% patients were in service (Table-II). Observation of height reveals that maximum number of patients i.e. 66.67% were between 5'to 5'2" in height followed by 5'3"-5'55" i.e. 20% (Table-III). Maximum patients were Primi gravida i.e. 86.67% and 13.33% were second gravida (Table-IV). As per as *Vasti Pratyagamana Kala* is concerned, 66.67 % patients had *Vasti Pratyagamana Kala* more than 6 hrs, 33.33% patients had 4-6 hrs. As the *Jirna Kala* of *Matravasti* is 6 hours and maximum number of patients retained the drug up to the specific time period.

Results

Above table depicts that maximum number of patients of group A i.e. 66.66% had delivered at 38-39wks of gestational period, followed by 26.66% patients had onset of labor at 40-41wks.

Group B 53.33 % of patients delivered at 38-39wks of gestational period, followed by 40% patients had onset of labor at 40-41wks (Table VI)

This table indicates that maximum number of patients in group A i.e. 60% had good contractions, in 33.33% patients had fair contractions and 6.66% had poor contractions. Group B 46.66% had fair contractions in 33.33% patients had good contractions and 20% had poor contractions (Table VII).

Group A above table reveals 40 % patients had rupture of membrane at early labour and 40% patients had late labor, while 20% had ROM at pre labor.

Group B reveals 46.66% patients had rupture of membrane at pre labour and 40% patients had early labor, while 13.33% patient had ROM at late labor (Table VIII). The above table deciphers that in Group A 80% patient achieved grade 1, 13.33% achieved grade 2, 6.66% patient undergone LSCS. i.e. Grade 3. In Group B 40% achieved Grade 1, 33.33% patient achieved Grade 2 and 20% patient undergone LSCS. (Table IX)

Above table shows that in group A 76.19 % relief was observed in *Vibandh*, 77.78% in *Udarashoola*, 58.33% in *Katishoola*, 62.50% in *Daurabalya*, 52.17% in *Kshudhavaishamya,* 50% in *Nidravaishamya*, 57.14% in *Shwetasrava*, and 78.57% relief observed in *Yonikandu*. There is H.S. result in *Daurabalya* and S. result in other symptoms (Table X) In group B Not Define result in any symptoms (Table -XI).

This table deciphers that in *Vibandh* in group A 76.19 %, in group B 0% relief was observed.

In group A77.78% relief was observed in *Udarashoola* and in group B 0% relief was observed.

In group A 58.33% relief was observed in *Katishoola* and in group B 0% relief was observed.

In group A 62.50% relief was observed in *Daurabalya* and in group B 0% relief was observed.

In group A 52.17% relief was observed in *Kshudhavaishamya* and in group B 4.35%% relief was observed.

In group A 50% relief was observed in *Nidravaishamya* and in group B 6.67% relief was observed. In group A 57.14% relief was observed in *Shwetasrava* and in group B 0% relief was observed. In group A 78.57% relief was observed in *Yonikandu* and in group B 0% relief was observed (Table XII).

Above table reveals that the mean duration of Ist stage of labour was 12 hrs and actual time taken was 7.07 hrs showing highly significant effect. The mean duration second stage was 120 min and actual time taken was 32 min, which shows highly significant effect.

The mean duration third stage was 30 min and actual time taken was 6.67 min which shows highly significant effect. Above table reveals that the mean duration of first stage of labour was 12 hrs and actual time taken was 9.93 hrs showing highly significant effect.

The mean duration second stage was 120 min and actual time taken was 43.20 min, which shows highly significant effect. The mean duration third stage was 30 min and actual time taken was 11 min which shows highly significant effect (Table XIV).

On first Stage- In Group A and Group B shows statistically highly significant difference i.e. Group A was better than Group B.

On second Stage- Group A and Group B shows significant difference i.e. Group A was better than Group B. **On third Stage**- Group A and Group B shows significant difference i.e. Group A was better than Group B.

Above table reveals that 10% patient had PPH and *Jwara* occurred in 16.66% of patients *Kamp, Pipasa, Atisaar* and *Yonibhedan* was not observed in any patient.

Group A 6.66 % patients had observed PPH and 6.66% patients had observed *Jwara*. Group B 6.66 % patients had observed PPH, 26.67% patients had observed *Jwara* (Table XVI)

Discussion on Effect of Therapy:

Prasavakala: Maximum number of patients i.e. 60% was delivered between 38 - 39 weeks of gestation. This is the natural period of gestational age for parturition and in the present study also maximum number of patients was delivered in this time period. This shows that if *Apana Vayu* and *Vyana Vayu* are stayed in *Samavastha*, they will initiate the labour at proper time with regular uterine contractions. Administration of *Matravasti* keeps these *Vayu* in *Samavastha*.

Contractions: This table indicates that maximum number of patients i.e. 46.67% had good contractions, 40.00% had fair contractions and 13.33% patients had poor contractions. *Vasti* maintains *Apanavayu* in *samavastha* and causes regular uterine contractions in coordinated manner. The present study shows that power required for normal labour was sufficient in maximum patients.

Rupture of membranes (ROM): Maximum number of patient's i.e. 40.00% had rupture of membranes during early stage of labour, while 33.33% had rupture at pre-labour and 26.67% had during later time of labour. Rupture of membranes itself can initiate and enhance the labour pains and shorten the duration of labour. ROM is caused by infections sometimes, but in the present study none of the cases had history of premature rupture of membranes. The *krimighna* property of *Madhura Aushadha Siddha Taila* prevented the premature ROM, while on the other hand proper uterine contractions caused ROM during labour.

Mode of delivery: In Group-A *Matravasti* and *Yonipichu* were given. *Vasti* regulates and maintains *Apana Vayu* in *samavastha* and also helps in increasing the laxity of birth canal. Maximum patients of this group were delivered normal vaginally with episiotomy. One patient had history of leaking before the onset of labor, so that patient had undergone Caesarean section. In Group B, 3 patients were undergone Caesarean section due to non-progress of labour and fetal distress.

Grade of labour: In Group-A, 80% patients achieved Grade 1, 13.33% achieved Grade 2, 6.66% patients undergone Caesarean section i.e. Grade 3. In Group-B 40% achieved Grade 1, 33.33% patients achieved Grade 2 and 20% patient undergone Caesarean section. Grading was done on the basis of pre-planned history sheet that depend on the

partogram, as in Group A *Matra Vasti* and *Pichu* might have helped in softening and relaxing the ligaments and fibrous tissues. So, time taken for labour was less, and hence patients were delivered under Grade 1. One Patient undergone LSCS, due to non-progress of labour and premature rupture of membranes.

Effects of therapy on different *Lakshanas*:

In Group A 76.19% relief was observed in *Vibandh*, 77.78% in *Udarashoola*, 58.33% in *Katishoola*, 62.50% in *Daurbalyata*, 52.17% in *Kshudhavaishamya*, 50% in *Nidravaishmya*, 57.14%% relief was observed in *Shwetasrava* and 78.57% relief in *Yonikandu*.

In Group B, 4.35% relief was observed in *Kshudhavaishamya,* 6.67% relief was observed in *Nidravaishamya* and not defined any relief in other symptoms like *Vibandha, Udarashoola, Katishoola, Daurbalyata, Shwetasrava* and *Yonikandu*.

Effect of therapy on the duration of stages of labour:

In general the mean duration of first stage of labour is 12 hours, whereas in the present trial, in Group A, actual time taken was 7.07 hours, this shows the highly significant effect of trial drugs. The mean duration of second stage is 120 minutes, and actual time taken was 32 min, which shows statistically highly significant effect. The mean duration of third stage is 30 minutes and an actual time taken was 6.67 min which shows highly significant effect.

In Group B the mean duration of first stage of labour is 12 hours and actual time taken was 9.93 hours showing highly significant effect. The mean duration of second stage is 120 minutes and actual time taken was 43 minutes, which shows statistically highly significant effect. The mean duration of third stage is 32 minutes and actual time taken was 11 minutes which shows highly significant effect.

In Group A, *Vasti* by its nature caused *Vatanulomana* and promoted *Prasootimaruta* to expel the foetus in time without undue prolongation, as the birth canal also become soft and smooth due to *Vasti and Pichu* helped in easily and timely expulsion of foetus.

Probable Mode of Action of *Madhura Aushadha Siddha Taila:*

From a number of drugs, only eight drugs were selected from *Madhura Skandha* for present study. These drugs were selected due to their easy availability and expected high degree of clinical effects. In this trial drugs were selected for the preparation of *Madhura Aushadha Sidhha Taila*.

The contents of *Madhura Aushadha Siddha Taila* are-

- As, the ingredients of *Taila are Balya, Brimhaneeya, Snehana, Garbhaposhaka,* and *Rasayana* properties provides strength to the *Manspeshi* of *Garbhasaya* and *Yoni*.
- Being *Shoolhara* and *Vedanasthapana* property of *Satavari*[9] and *Ashwagandha*[10] plays important role in relieving backache and lower abdominal pain.
- *Tila oil* as a main ingredient maintains normal vaginal flora physiology. It relieves in painful conditions of vagina. It controls the vaginal yeast infection.
- As the *Moorcchita Tila Taila* also has the properties of *Moorcchana Dravyas-Manjistha, Amalaki, Haritaki, Bibhitaka, Haridra, Lodhra, Twaka, Ketaka, Vata, Mustaka*, so *Madhura Aushdha Siddha Taila* has the properties of *Vedanasthapana, Deepana, Mutrala, Rasayana, Anulomana, Krimighna, Shothahara*.
- Hence when *Madhura Aushadha Siddha Taila* (a combination of all mentioned drugs) is used on patient in the form of *Anuvasana Vasti* and *Pichu* then that results in the combined effect of all these together.
- The administration of *Madhura Aushadha Siddha Taila Matra Vasti* improves *Snigdha* property in the mother's body parts like abdomen, flanks, and sacrum and genital organs. It also promotes the natural functioning of *Vyana-Vayu* and *prasutimarut* and helps in *Sukhaprasava*.

Probable Mode of Action of drug according to modern science:

Uterine muscles are involuntary muscles. The act of contraction and relaxation of uterus occurs in particular period only. In pregnant uterus, these actions can be seen at the time of labour.

- Colonic irrigation reduces the chance of infections and allows labour in time without premature rupture of membranes as infection is main cause of PROM.
- *Pichu* with *Madhura Aushadha Siddha Taila* maintains the natural vaginal flora prevents from infections the use of *Pichu* also helps in cervical ripening by altering the cervical matrix releasing prostaglandins which facilitates normal labour.
- The wholesome effect of *Vasti* act on nervous system which helps to release natural oxytocin from posterior pituitary as well as help in increasing the oxytocin receptors.

Prostaglandins are local hormone. Prostaglandin helps in the process of parturition also effect on inflammation and immunity. Thus helps in easy labour, as prostaglandins facilitates labour here this drug increases the permeability of membranes makes cervix soft. All the components of drug also improves the neurological functions which may help to release oxytocin from pituitary so overall contributes in *Sukhaprasava*. During and after the trial no adverse event or side effects were occurred.

Conclusion

- This clinical trial shortened the first and second stages of labour by having good effect on ripening of cervix and stretching and relaxing of vaginal canal and perineum in Group-A.
- In Group A one patient undergone Caesarian section while in group B 3 patients were undergone Caesarian.

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सारांश

गर्भावस्था के दौरान (प्रसूतितंत्र के क्षेत्र में) उत्तम स्वास्थ्य एवं परिचर्या के उपरान्त भी, प्रसव के दौरान या गर्भावस्था अथवा प्रसव की जटिल कारणों से स्त्रियों की मृत्यु हो जाती है। स्वास्थ्य के दृष्टिकोण से कई दशकों से महिलाएं, समाज में अत्यन्त उपेक्षित हैं, जिसका कारण, लिङ्ग असमानता, गरीबी, अशिक्षा इत्यादि है। मातृत्व के अस्तित्व की रक्षा करना मानवाधिकार का ध्येय है। उपरोक्त तथ्यों को ध्यान में रखते हुए मिलेनियम डेवलपमेंट गोल्स के अन्तर्गत, आपातकालीन स्थिति में मातृत्व की रक्षा तथा महिलाओं के स्वास्थ्य संवर्धन को शामिल किया गया है। सन 1990 (एमडीजी के आधारभूत वर्ष) से आज तक पर्याप्त उपलब्धियां हैं; लेकिन विश्व स्तर पर मातृ मृत्यु दर केवल 50 प्रतिशत घटी है। परन्तु स्थिति बहुत सराहनीय नहीं है, आज की तिथि में भी विश्व स्तर पर प्रत्येक वर्ष 289000 मातृ मृत्यु हो रही है। अधिकांश मृत्यु के कारण परिहार योग्य हैं। एमडीजी 5 के लक्ष्यों को प्राप्त करने के लिए, वर्तमान परिवेश में साक्ष्य-आधारित, न्यूनतम मूल्य के निवेश सर्वसम्मत प्रबन्धन उपलब्ध है।

आधुनिक युग में आयुर्वेद के माध्यम से निर्धन व्यक्तियों के लिए भी गर्भावस्था में/प्रसवपूर्व, प्रसवकालिन के साथ हीं साथ प्रसवोत्तर परिचर्या हेतु सर्वाधिक उपयुक्त एवं प्रभावी चिकित्सा प्रबन्ध न्यूनतम राशि के व्यय पर उपलब्ध हैं। गर्भिणी परिचर्या के अन्तर्गत, गर्भाधान से प्रारम्भ होकर प्रसव तक सञ्चालित किए जाने वाली व्यापक परिचर्या आयुर्वेद में वर्णित है। यह परिचर्या आहार एवं विहार के व्यवस्था को सम्मिलित कर सुखप्रसव (यूटोसिया) को सम्पन्न कराती है। इस उद्देश्य को प्राप्त करने में बस्ति एक महत्वपूर्ण एवं निर्दिष्ट प्रक्रिया है।

वर्तमान अध्ययन के अन्तर्गत मात्राबस्ति तथा योनिपिचु के प्रयोग से प्रसव के प्रबन्धन में प्रभाव का आंकलन करना है।

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ORIGINAL ARTICLE

Clinical Study on The Effect of *Shatahvadi Dhumapana* with or without *Pippali Rasayana* in *Peenasa* With Special Reference to Chronic Simple Rhinitis

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ABSTRACT

Chronic simple rhinitis, though not life threatening, is much troublesome and irritating disease reducing the quality of life of an individual in day to day activity. Management of chronic simple rhinitis in Allopathy is through antibiotics, nasal decongestants and nasal irrigations with alkaline solutions, which provides symptomatic relief. *Peenasa,* mostly said to be synonymous to *Pratishyaya,* is more aptly the chronic stage of *Dushtapeenasa* and can be correlated to chronic simple rhinitis. Ayurveda provides better management of this disease.

In present study, 30 patients of *Peenasa, (*chronic simple rhinitis) were studied into two groups. In group-I, patients were advised S*hatahvadi Dhumapana* and in group-II, patients were advised *Shatahvadi Dhumapana and Pippali Rasaayana* orally. Better relief was observed in group II which received combined treatment than group I which received only *Shatahvadi Dhumapana* therapy.

Key Words - ***Peenasa*, chronic simple rhinitis,, *Shatahvadi Dhumapana*, *Pippali Rasaayana*.**

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Introduction

Peenasa is a *Nasagataroga*, i.e. a nasal disorder explained by almost all *Acharyas* in *Ayurveda*. Though the term is more commonly taken to be synonymous to *Pratishyaya*,[1] it is more specifically used to mean the advanced stage of *Pratishyaya*. This differentiation is clear from the explanation by *Acharya Sushruta*[2] and also from the etymological meaning of the word *(Peenam Sthoolam Api naram syati nashayati iti*). The main symptoms of *Peenasa* are *Nasarodha* (nasal

obstruction), *Nasashopha* (swollen turbinates), *Nasasrava* (nasal discharge), *Shirahshoola* (headache) and *Kaphotklesha* (Post-nasal discharge)[3,4] These correlate with the symptoms of chronic simple rhinitis.[5]

Though this condition is not fatal, it is a much disturbing and debilitating disease and it affects the quality of life to a great extent. Management of chronic simple rhinitis in Allopathy is through antibiotics, nasal decongestants and nasal irrigations with alkaline solutions, which provides symptomatic relief. The symptoms generally reappear on the withdrawal of the drugs. Moreover, antibiotics are not recommended for prolonged usage which causes undesirable side effects. Nasal decongestants should not be taken for more than five days and in case of continuous usage, may cause a condition called rhinitis medicamentosa, Therefore an alternative solution in *Ayurveda* is sought for, which provides relief from all the symptoms of the disease and also improve immunity thereby reducing the recurrent attacks.

Dhumapana is a simple but much efficacious treatment for *Peenasa*. *Shatahvadi Dhuma* is an important and effective formulation mentioned in *Ashtanga Hridaya* for the management of *Peenasa*.[6] So also, *Rasayana* is an important line of treatment of *Peenasa* and the line of treatment of *Dushta Peenasa* is mentioned to be on the line of treatment of *Rajayakshma*.[7] *Pippali Rasayana* is an important *Rasayana* prescribed for *Kapha* predominant diseases in general and *Peenasa* in particular.[8] Therefore the effect of *Shatahvadi Dhumapana* alone and the combined effect of *Shatahvadi Dhumapana* and *Pippali Rasayana* are studied and compared in this trial.

In ancient times, Ayurveda was practised in consonance with other occult sciences like *Jyotisha* and *Mantravada*. Textual references of astrological integration is also found in many diseases. A book named *Veerasimhavaloka*, which describes the planetary correlation with occurrence of diseases and their astrological management, is available in print. Planetary coincidence for the occurrence of *peenasa* is also described therein.[9] An attempt was also be made to find out whether any such coincidence can be found out from the planetary positions of the patients presenting with the complaints of *peenasa*. Any coincidence, if proved, would help to advice the patients that are liable for the disease to take precautionary measures to avoid serious affliction of the same.

Aims And Objectives:

- To clinically evaluate the efficacy of *Shatahvadi Dhumapana* in *peenasa* with special reference to Chronic Simple Rhinitis.
- To clinically evaluate the efficacy of combined effect of *Shatahvadi Dhumapana* and *Pippali Rasayana* in *peenasa* with special reference to Chronic Simple Rhinitis.
- To compare the results to suggest whether *Shatahvadi Dhumapana* alone will be more effective in the control of chronic simple rhinitis or the combination of *Shatahvadi Dhumapana* and *Pippali Rasayana* is more effective in the above case.
- To find out if any planetary or astrological correlation to the occurrence of *peenasa* as described in *Veerasimhavaloka* can practically be found and to suggest any preventive step based on the result.

Material And Methods:

In the present study, 33 patients who were attending the OPD and IPD of NIA, Jaipur with clinical signs and symptoms of *Peenasa* with special reference to chronic simple rhinitis were selected for the study. This study was cleared by institutional ethics committee with letter no.F10(5)/EC/2014/7224 dated 7-11-2014.

Inclusion criteria:

Patients suffering from three or more of the following symptoms for more than three months were selected for study.

1. Nasal obstruction
2. Nasal discharge
3. Headache
4. Swollen turbinate
5. Post-nasal discharge

The exact date, time and place of birth of the patients are also obtained if reliable data can be presented by the patient.

Exclusion criteria

1. Patients below 12 years and above 80 years
2. Pregnant women.
3. Patients with history of congenital disorders of nose.
4. Patients suffering from gross deviation of nasal septum and associated with other nasal pathology like nasal polyps, etc.
5. Patients with uncontrolled systemic diseases like diabetes mellitus and hypertension.
6. Rhinitis associated with hyperthyroidism, exanthemas, adenoidal hyperplasia, choanal atresia and nasal tumors.
7. For the purpose of astrological assessment, the patients who have no reliable data on the exact date, time and place of birth were excluded.

Withdrawal criteria:

The patients developed any side effect or could not follow the instructions given, were withdrawn from the trial.

Grouping of patients:

i) Group-I: 16 patients of *Peenasa* (Chronic Simple Rhinitis) were advised *Shatahvadi Dhumapana* alone. 15 patients completed the course of treatment and one patient left against medical advice.

ii) Group 2: 17 patients of *Peenasa* (Chronic Simple Rhinitis) were advised *Shatahvadi Dhumapana* once a day and *Pippali Rasayana* (orally). 15 patients completed the course of treatment and 2 patients left against medical advice.

Drugs and posology:

i) Shatahvadi Dhumapana: Three puffs each in each nostril, three times continuously with two sittings of 7 days with interval of 7 days

ii) Pippali Rasayana:: 5gms. Three times a day after meal with honey for 30 days

Follow up study

Patients were asked to attend the O.P.D for one month for the follow up study

Criteria Of Assessment:

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

Subjective criteria include –

1) Headache
2) Post-Nasal Drip
3) Swollen Turbinates
4) Nasal Obstruction
5) Nasal Discharge

Radiological and laboratory criteria include

1) TLC, DLC, ESR, TEC
2) X-Ray PNS Water's view

Statistical Analysis

The information regarding demographic data was given in percentage. The scoring of criteria of assessment was analyzed statistically in terms of mean values of B.T. (Before Treatment), A.T. (After treatment), S.D. (Standard Deviation) and S.E. (Standard Error). The results obtained were considered Significant for p value <0.01 and insignificant for p value>0.05.

In individual I and II group – Wilcoxon matched pairs signed ranks test were performed for nonparametric data.

In intergroup comparison between I and II group - Mann Whitney test for nonparametric data.

Observation And Results:

Total 33 patients were registered in clinical study; amongst them 30 patients completed the treatment and 3 patients discontinued the treatment. So some important observation of 33 patients and results of 30 patients are given below-

Observation:

- Maximum number of patients were in the of age

group of 32-41 years (27.27%), females (54.55%), married (69.7%), Hindu (69.7%), educated up to secondary (39.4%) belonged to middle class (69.7%), vegetarians (78.79%), housewives (39.4%) and urban (90.91%) Majority of patients had *Vata-Kaphaja* (33.3%), and *Rajasa Prakriti* (63.64%).

- Majority of patients had *Vishama* Dietetic habits (66.67%), addictions like smoking and alcohol (78.79%), medium appetite (54.55%) and sound sleep (65.90%).
- Maximum number of patients showed *Madhyama Vikrti, Sara, Samhanana, Pramana, Sattva, Satmya* i.e. respectively 60.61%, 72.73%, 63.64%, 72.73%, 72.73%% and 75.76% respectively.
- Majority of patients had perenniel of disease (42.43%)
- DNS was present in 36.36% patients, tenderness of sinuses in 97.97% patients ,and haziness over maxillary sinus area in X-Ray of PNS in 90.91%,
- All had haziness over any part of the sinuses in varying orders, 93.94% had nasal discharge, 75.76% had nasal obstruction, 69.7% had headache and 36.36% each had nasal obstruction and swollen turbinates.
- Regarding astrological data, only 4 patients had their exact date and time of birth readily available with them. Therefore further studies on the same could not be carried out with such a meager data.

Results:

Table No. I: Showing effect of therapy in subjective parameters in Group-I (Wilcoxon matched paired single ranked test)

Sl. No	Symptoms	Mean		Dif.	% of Change	SD	SEM	W	p value	Results
		B.T.	A.T.							
1.	Headache	1.330	0.600	0.73	54.89	0.704	0.182	45	0.0039	S
2.	Post-Nasal Drip	0.733	0.267	0.467	63.71	0.516	0.133	28	0.0156	S
3.	Swollen Turbinates	0.667	0.400	0.267	40.02	0.458	0.118	10	0.1250	NS
4.	Nasal Obstruction	1.333	0.333	1.000	75.18	0.756	0.195	66	0.001	S
5.	Nasal Discharge	1.533	0.333	1.200	78.28	0.676	0.174	91	0.0002	S

SD: Standard deviation, SEM: Standard error of mean, W: Wilcoxan Sign, S: Significance, NS: Non Significance

Table No. II Effect of Therapy In radiological and Laboratory Parameters in Group-I (Student's Paired 't' test)

Sl. No.	Investigation Parameter	Mean		Dif.	% of Change	SD	SEM	t Value	p value	Res-ults
		B.T.	A.T.							
1.	Haziness in X-Ray	5.4	3.2	2.2	40.74	0.941	0.243	9.054	<0.0001	S
2.	ESR	21.667	12.533	9.134	42.16	10.12	2.613	3.495	0.0036	S
3.	TLC	7106.7	6820	286.7	4.02	1523.6	393.38	0.729	0.4782	NS
4.	Eosinophil %	3.6	3.267	0.333	9.25	3.374	0.137	0.3827	0.7077	NS
5.	TEC	264.8	218.67	46.13	17.42	0.51	0.114	0.7283	0.4784	NS

SD: Standard deviation, SEM: Standard error of mean, W: Wilcoxan Sign, S: Significance, NS: Non Significance

Table No. III: Effect of Therapy in Subjective Parameters in Group-II (Wilcoxon matched paired single ranked test)

Sl. No	Symptoms	Mean		Dif.	% of Change	SD	SEM	W	p value	Results
		B.T.	A.T.							
1.	Headache	1.533	0.467	1.066	69.6	0.704	0.182	78	0.0005	S
2.	Post-Nasal Drip	0.6	0.2	0.4	66.67	0.507	0.131	21	0.0313	S
3.	Swollen Turbinates	0.4	0.133	0.267	66.67	0.594	0.153	6	0.25	NS
4.	Nasal Obstruction	1.0	0.2	0.8	80.0	0.715	0.2	45	0.0039	S
5.	Nasal Discharge	1.733	0.133	1.6	92.33	0.507	0.131	120	<0.0001	S

SD: Standard deviation, SEM: Standard error of mean, W: Wilcoxan Sign, S: Significance, NS: Non Significance

Table No. IV: Effect of Therapy in Radiological and Laboratory Parameters in Group-II (Student Paired 't' test)

Sl. No.	Investigation Parameter	Mean		Dif.	% of Change	SD	SEM	t Value	p value	Results
		B.T.	A.T.							
1	Haziness in X-Ray	6.267	1.533	4.734	75.54	1.751	0.452	10.468	<0.0001	S
2	ESR	11.933	11.333	0.6	5.02	10.568	2.729	0.2199	0.8291	NS
3	TLC	6313.3	5753.3	560	8.87	743.35	191.93	2.918	0.0112	S
4	Eosinophils %	4.133	3.2	0.933	22.57	1.751	0.452	2.064	0.0580	NS
5	TEC	271.53	195.93	75.6	27.84	121.60	31.397	2.408	0.0304	S

SD: Standard deviation, SEM: Standard error of mean, W: Wilcoxan Sign, S: Significance, NS: Non Significance

Table No. V: Intergroup comparison of subjective parameter of *Peenasa* (Mann-whithey U test)

Sl. No	Symptoms	Mean of Grp.		SD of Grp.		SEM of Grp.		U	p value	Results
		A	B	A	B	A	B			
1	Headache	0.733	1.067	0.704	0.704	0.182	0.182	141	2.054	NS
2	Post-Nasal Drip	0.467	0.4	0.516	0.507	0.133	0.131	120	0.7353	NS
3	Swollen Turbinates	0.267	0.267	0.458	0.594	0.118	0.153	118	0.7782	NS
4	Nasal Obstruction	1.0	0.8	0.756	0.775	0.195	0.2	134.5	0.4768	NS
5	Nasal Discharge	1.2	1.6	0.676	0.507	0.175	0.131	148.5	0.0992	NS

SD: Standard deviation, SEM: Standard error of mean, S: Significance, NS: Non Significance

Table No. VI: Intergroup Comparison of X-Ray and Laboratory Parameters of *Peenasa*

S No	Parameter	Mean of Grp.		SD of Grp.		SEM of Grp.		t Value	p value	Results
		A	B	A	B	A	B			
1.	Haziness in X-Ray	2.2	4.733	0.941	1.751	0.243	0.452	4.935	< 0.0001	S
2.	ESR	9.133	0.6	10.12	10.568	2.613	2.729	2.259	0.0322	S
3.	TLC	286.67	560	1523.6	743.35	393.38	191.93	0.6245	0.5394	NS
4.	Eosinophils	0.333	0.933	3.374	1.751	0.871	0.452	0.6114	0.5475	NS
5	TEC	46.133	75.6	245.33	121.6	63.343	31.397	0.4168	0.6813	NS

SD: Standard deviation, SEM: Standard error of mean, S: Significance, NS: Non Significance

Table No. VII: % wise Improvement of Signs and Symptoms in Both Groups

S.N.	Cardinal Symptoms	Result In Percentage			
		Group-I		Group-Ii	
1	Headache	54.89	S	69.6	S
2	Post-Nasal Drip	63.71	S	66.67	S
3	Swollen Turbinates	40.02	NS	66.67	NS
4	Nasal Obstruction	75.18	S	80.0	S
5	Nasal Discharge	78.28	S	92.33	S

S: Significance, NS: Non Significance

Discussion:

Effect of Therapy on Assessment Criteria:

Statistically significant relief was found in nasal discharge in both groups. The relief in nasal obstruction was significant in Group-I and Group-II. Headache showed statistically significant relief in Group-I and Group-II. The relief in post-nasal drip was statistically significant in both the groups, but there was insignificant relief in swollen turbinates in both the groups.

Inter Group Comparison:

In comparative study over criteria of assessment, statistically insignificant difference was observed between two therapies in all assessment criteria.

Conclusion:

- The disease *Peenasa* which is described in *Ayurvedic* classics can be correlated to chronic simple rhinitis.
- Chronic stage of non-specific rhinitis is known as chronic simple rhinitis and if the condition is left untreated it may lead to several health hazards.
- The term *Peenasa* is mostly used in the context of advanced stage of *Dushta Pratishyaya*.
- *Dhumapana* is an important treatment modality indicated for all types of *Urdhvajatrugata Rogas*, especially in *Peenasa*.
- *Shatahvadi Dhumavarti* is an important and efficacious formulation for *Dhumapana*.
- *Rasayana* is an important treatment

recommended in all debilitating diseases. It is also highly beneficial in *Peenasa* as it gives not only rejuvenation to *Dhatus* but also cures many chronic diseases. *Traikalika Pippali Rasayana* is a type of *Vatatapika Rasayana* and is highly effective in *Peenasa*.

- Statistically significant relief was found in nasal discharge in both groups. The relief in nasal obstruction was extremely significant in Group-I and Group-II. Headache showed statistically significant relief in Group-I and Group-II. The relief in post-nasal drip was statistically significant in both the groups, but in swollen turbinates there was insignificant in both the groups.
- Hence it can be concluded that combined use of *Shatahvadi Dhumapana* and *Pippali Rasayana* is more effective in controlling the disease *Peenasa* than *Shatahvadi Dhumapana* alone.
- The symptoms like headache and nasal discharge had better improvement with the combined therapy.

Thus it can be concluded that this combined treatment is effective in management of *Peenasa* with special reference to chronic simple rhinitis

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सारांश

पीनस (क्रोनिक सिंपल रायनाइटिस) यद्यपि जानलेवा नहीं है, लेकिन परेशानी देनेवाला रोग है जो कि व्यक्ति की दिन प्रतिदिन की गतिविधियों में जीवन की गुणवत्ता को कम करता है। एलोपैथी में इस रोग की चिकित्सा एंटीबायोटिक दवाओं, Oral decongestants और क्षारीय द्रवों से नासा प्रक्षालन आदि हैं, जो लक्षणात्मक राहत देते हैं। पीनस ज्यादातर प्रतिश्याय के पर्याय रूप से प्रयोग होता है, परन्तु दुष्टपीनस की जीर्ण अवस्था अधिक समुचित संज्ञा है और क्रोनिक सिंपल रायनाइटिस से संबद्ध किया जा सकता है। आयुर्वेद इस रोग की बेहतर चिकित्सा प्रदान करता है। वर्तमान शोधकार्य में पीनस (क्रोनिक सिंपल रायनाइटिस)के 30 मरीजों का दो समूहों में अध्ययन किया गया। समूह-प्रथम के मरीजों को शताह्वादि धूमपान और समूह-द्वितीय के मरीजों को शताह्वादि धूमपान और पिप्पली रसायन मौखिक रूप से दिया गया। द्वितीय समूह में बेहतर परिणाम प्राप्त हुए जिसमें संयुक्त उपचार दिया गया था।

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ORIGINAL ARTICLE

A Comparative Study of two samples of *Kushmand Khand* in *Amlapitta*: A prospective randomized control trial

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ABSTRACT

From stone-age to space age food pattern of people has undergone numerous changes.These changes have been always for the better aspect of life. Most of the *vikara* are deeply rooted in underprivileged dietary habits like *Ajirne Bhojana*, *Akale Bhojana, Akale Anshana, Virudha Bhojana, Atimatrasy Amla, lavana, Katu Rasa Sevanam* etc; improper life style like *Vegvidharana, Divaswapa, Ratri Jagrana* etc; and *Mansik Bhavas* like *Chinta, shoka, bhaya, krodha* etc. and *amlapitta* is one of them. Keeping this in mind it was decided to carry out clinical trial on 30 patients presenting classical signs and symptoms of *Amlapitta*. The patients were selected irrespective of their age, sex, religion etc. Selected patients were divided into Group A and Group B respectively and treated by *Kushmanda Khanda* prepared using *ghrita* (KKG) and *Kushmanda Khanda* prepared without using *Ghrita* (KKW). In group A and B there were 15 patients in each. The results were analyzed on the basis of improvement in cardinal, associated signs and symptoms. Statistically analysis between Group A and Group B for the observation parameters *Avipaka, Aruchi, Utkelesh, Tikta-Amlodgara, Gaurava, Klama, Chhardi* and *Shirhshula* found no significant changes and it showed that the relief % of both Groups were closely similar. But in observation parameter of *Daha* the difference value of group A is higher than group B. It shows that group A has higher relief as compare to group B.

Keywords: *Khushmanda Khanda*, Acidity, *Avalehya, Bhaishajya kalpana*

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Introduction

In the present era stress has taken a toll on human life. *Amlapitta* is a common disease which has its root cause in hurry, worry and curry. It is one such worldwide disease born as a result of various ups and downs during human's life span.

Amlapitta is not considered as a separate disease in *Bruhatatrai* but is mentioned as a symptom

in number of places by *Acharya Charaka*. *Acharya Kashyapa* was the first to give a detailed description of the disease[1] and analyzed it on *Doshika* basis, whereas *Acharya Madhavakara* has described the disease in detail and classified it on the basis of *Gati*[2] *i.e. Urdhvaga Amlapitta* and *Adhoga amlapitta*. *Amlapitta* can be correlated with acid reflux syndrome which comprises of various types of gastro-oesophageal reflux diseases like gastritis, dyspepsia, heartburn, hyperacidity, hypoacidity etc. described in modern sciences.

Now a day's heart burn, reflexes of food taken, loss of appetite, abdominal pain sour belching, nausea etc. has become very common complain to visit hospital. By taking antacids the person neutralizes acid which is the first line of immunity and becomes more prone to various infections. While in *Ayurveda* we concentrate more on *Agni Vraddhi* and *Aam pachana* by various mean.

The drug selected under the study *Kushmanda Khanda* is described in *Bhavaprakash Uttarardh Madhyam Khanda Amlapitta Shleshmpitt Adhikara*[3] and *Raktapitt Adhikara*[4] with ingredients *Kushmanda Swarasa, Amalaki Churna,* Sugar, *Godugdha* and *Goghrita*. Clinical efficacy is the ultimate expectation from drug, hence present study was planned to evaluate the comparative efficacy of *Kushmanda Khanda* prepared by two different classical references.

Aims and objectives -

1. To assess the efficacy of *Kushmanda Khanda* in the management of *Amlapitta*.
2. To compare the relative efficacy of *Kushmanda Khanda* prepared with using *Ghrita* (sample KKG) and without using *Goghrita* (Sample KKW) in the management of *Amlapitta*.

Materials & Methods-

Selection of patients

Thirty patients irrespective of their sex, occupation, religion, socio economic status etc. were selected from the O.P.D. and I.P.D. of National Institute of *Ayurveda*, Jaipur (Rajasthan).

Design of study

- Study Type : Interventional
- No. of Group : Two
- No. of patient : 30
- Treatment period : 30 days
- Follow-up period : 15 day

Inclusion criteria

1. Patients between the age group of 16 to 60 years.
2. Patients having the classical signs and symptoms of *Amlapitta like Avipaka, Klama, Utklesha, Tikta amlodgara, Daha, Chardhi, Shirah shula, Gaurava, Aruchi* etc.

Exclusion criteria

1. Patients below 16 yrs. of age and above 60 yrs. of age.
2. Patients suffering from *Amlapitta* along with other diseases like diabetes, Tuberculosis, heart diseases etc.
3. Patients suffering from *Amlapitta* for more than 5 years.
4. Patients suffering from *Annadravashula* and *Parinama shula*.

Drug intervention

Dose	: 12gm.
Dosage form	: Granules
Route of Administration	: Oral
Time of Administration	: Twice daily
Anupana	: Luke warm water
Duration of therapy	: 30 Days

Division in groups

Group A-15 patients : Sample KKG

Group B -15 patients : Sample KKW

Note: Patients were guided regarding *Pathya/ Apathya* regimen by the Investigator.

Assessment Criteria-

During the Trial and Follow up, patients were assessed in accordance with the following parameters-

Subjective Parameters-

Improvement was observed according to the specially designed criteria's that were made related to *Amlapitta* like *Avipaka, Daha, Utklesha* etc.

Laboratory Investigations-

All feasible investigations namely R.B.S., C.B.C., E.S.R.; and Urine-routine and microscopic examination were done before the administration of the medicine to rule out other diseases.

Scoring pattern

Table No. I Grading for *Amlapitta*

S.No.	Features	Grading	Score
1	*Avipaka*	G_0-No A*vipaka*	0
		G_1- *Avipaka* for a small time and feeling proper hunger	1
		G_2-Avipaka for a small time but not feeling hunger	2
		G_3-Feeling of heaviness and indigestion throughout the day and symptoms occurring daily	3
2	*Aruchi*	G_0-Normal appetite	0
		G_1-Unwelling to take food but eat	1
		G_2-Intake of food decreases	2
		G_3-No interest to intake food	3
3	*Utklesh*	G_0-Absent	0
		G_1-Feeling nausea occasionally	1
		G_2- Feeling nausea regular after taking meal	2
		G_3- always present and come gastric content in mouth	3
4	*Tikta Amlodgara*	G_0- Absent	0
		G_1- occasionally present after lunch or dinner	1
		G_2- present most of the time after taking lunch or dinner and after digestion/*vaman shanty*	2
		G_3- always present	3
5	Daha	G_0- Absent	0
		G_1-Mild *daha* present	1
		G_2-*Madhyam daha* which mitigated by *vamana* or intake of milk	2
		G_3- .Severe *daha* which cannot mitigated by *vamana*	3

6	*Chhardi*	G_0-Absent	0
		G_1-.Feeling nausea	1
		G_2-Occasionally present	2
		G_3- Regular *vamana*	3
7	*Shirshshula*	G_0-Absent	0
		G_1- occasionally present	1
		G_2- present most of the time	2
		G_3-Always present	3
8	*Gaurava*	G_0-Absent	0
		G_1-Feeling heaviness but less than 6 hrs.	1
		G_2- Feeling heaviness for more than 6 hrs.	2
		G_3- Feeling always heaviness	3
9	*Klama*	G_0- Absent	0
		G_1-Without any hard work in day time feeling fatigue at evening time	1
		G_2- Without any hardwork in whole day and night feeling fatigue in morning	2
		G_3-Every time feeling fatigue and no any desire of work	3

Statistical Analysis

Analysis between Group A and Group B on objective parameter for inter group had been done by Student T Test (paired) and non parametric data by Mann-Whitney test with the help of Graph Pad Prism 6 software. For intra group comparisons, for the nonparametric variables wilcoxon paired test was used for statistical analysis.

Non-significant : P >0.05

Significant : P <0.05

Highly significant : P < 0.01

Observations and Results:

Main symptom wise distribution

In the present study, Tikta *amlodgara, Utklesh, Avipaka and Gaurava* was observed in all the patients. *Shira Shoola* was found in 60 % patients and *klama* and *Daha* was observed in 86.67 % patients.

Distribution based on *Aaharaja nidana*

Maximum number of patient's i.e.56.66% had *Virudhashana* followed by *Adhyasana* and *Guru Bhojana* i.e. 13.33% and 10%.

Distribution based on *Viharaja nidana*

Maximum number of patients i.e. 63.33% were had *Vega Dharana Viharaj Nidana* followed by *Buktwa Divasvapna* and*Upavasa* i.e.23.33% and 13.33% of total patients.

Distribution based on *Maanasik Bhava Janya Nidana*

Maximum number of patients i.e. 50% had *Chinta Manasik Nidan* followed by *Krodha* and *Shoka Manasik Nidan* i.e. 23.33% and 13.33% of total patients.

Results of therapies

Statistical Analysis of Group A

Table NoII: Showing statistical Analysis

Group A	BT	AT	Diff	Relief %	S.D	S.E.M	P Value	Sig.
Avipaka	2.13	1.13	1.00	46.94	0.9258	0.3651	0.0054	S(**)
Aruchi	1.80	1.00	0.80	44.44	0.6761	0.3073	0.0019	S(**)
Utklesh	1.87	0.87	1.00	53.47	0.7559	0.3333	0.0074	S(**)
Tikta Amlodgar	1.93	0.73	1.20	62.17	0.8619	0.2582	0.0015	S(**)
Daha	1.80	1.00	0.80	44.44	0.6761	0.2582	0.0037	S(**)
Chhardi	0.00	0.00	0.00	0.00	0.0000	0.0000	———	
Shirhshula	0.53	0.33	0.20	37.73	0.4140	0.2108	0.5361	N.S.
Gaurava	1.47	0.80	0.67	45.57	0.7237	0.2582	0.0306	S(*)
Klama	1.07	0.53	0.53	49.53	0.8338	0.3416	0.0234	S(*)

Significant **More Significant

This table depicts the effect of the research drug KKG had been observed on the patients of Group A. It shows that its effect was significant on *Avipak* (P value = 0.0054), *Aruchi* (P value = 0.0019), *Utklesh* (P value = 0.0074), *Tikta amlodgar* (P value =0.0015), *Daha* (P value = 0.0037), *Gaurava* (P value =0.0306), *Klama* (P value = 00234) and effect on *Chhardi, Shirhshula* were found not significant.

Statistical Analysis of Group B

Table No III Showing statistical analysis

Group B	BT	AT	Diff	Relief %	S.D	S.E.M	P Value	Sig.
Avipaka	2.20	1.13	1.07	48.48	0.7037	0.1817	0.0035	S(**)
Aruchi	2.07	1.13	0.93	45.16	0.8837	0.2282	0.0026	S(**)
Utklesh	1.87	0.93	0.93	50.00	0.8837	0.2282	0.0079	S(**)
Tikta Amlodgar	1.87	0.87	1.00	53.57	1.0000	0.2582	0.0046	S(**)
Daha	1.00	0.80	0.20	20.00	0.4140	0.1069	0.0039	S(**)
Chhardi	0.00	0.00	0.00	0.00	0.0000	0.0000	———	
Shirhshula	1.20	0.87	0.33	27.78	0.6172	0.1594	0.6076	N.S
Gaurava	1.73	0.87	0.87	50.00	0.9904	0.2557	0.0143	S(*)
Klama	1.33	0.73	0.60	45.00	0.8281	0.2138	0.0359	S(*)

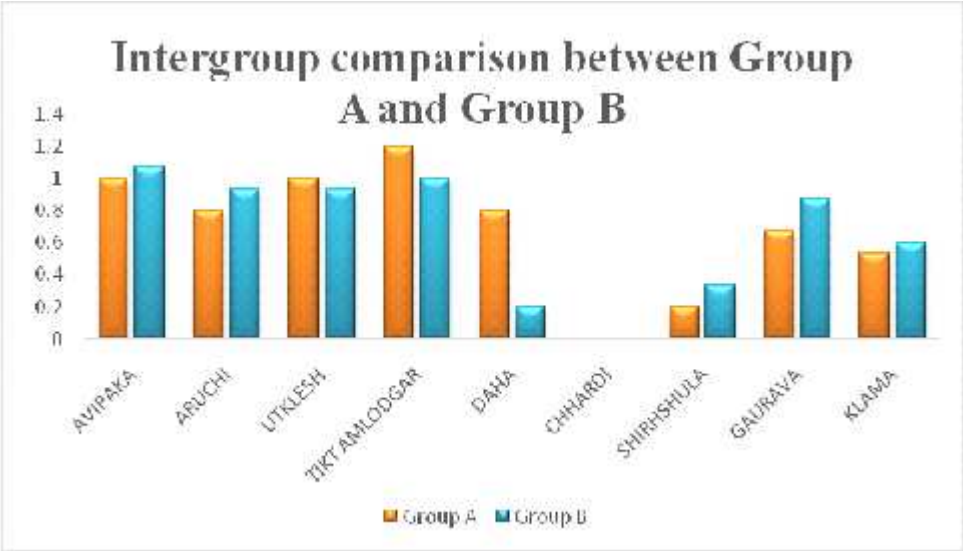
This table depicts the effect of the research drug (KKW) had been observed on the patients of Group B. It shows that its effect was significant on *Avipaka* (P value = 0.0035), *Aruchi* (P value= 0.0026), *Utklesh* (P=value 0.0079), *Tikta amlodgar* (P value=0.0046), *Daha* (P value= 0.0039), *Gaurav* (P value=0.0143), *Klama* (P value = 0.00359) and effect on *Shirhshula* was found non -significant.

Table No VI Inter group comparison between Group A and Group B

S. No.	Group A vs. Group B	Group A	Group B	P Value	Sig.
1	*Avipaka*	1.00	1.07	0.7449	N.S
2	*Aruchi*	0.80	0.93	0.8131	N.S
3	*Utklesh*	1.00	0.93	0.7727	N.S
4	*Tikta Amlodgar*	1.20	1.00	0.5087	N.S
5	*Daha*	0.80	0.20	0.0157	S
6	*Chhardi*	0.00	0.00	—-	—-
7	*Shirhshula*	0.20	0.33	0.4270	N.S
8	*Gaurava*	0.67	0.87	0.7606	N.S
9	*Klama*	0.53	0.60	0.3594	N.S

This table show the inter group comparison between Group A and Group B. Observation parameters *Avipaka*(p value=0.7449), *Aruchi*(p value=0.8131), *Utklesh*(p value=0.7727), *Tikta amlodgara*(p value=0.5087), *Shirhshula* (p value=0.4270), *Gaurava* (p value=0.7606), *Klama*(p value=0.3594) shows non-significant changes. No significant changes denote that both Groups have closely similar relief.

Daha observation parameter is statistically significant (p value=0.0157).It shows that Group A shows better relief in *Daha* than Group B.



Overall Effect of Therapy:

The grading percentage has been defined as the ratio of difference % of individual patient of before treatment to after treatment observations multiply by hundred. This grading confirms the overall effect of drug on patients compare to their before treatment observation parameters score.

Complete Relief	- 76-100%
Moderate Relief	- 51-75%
Mild Relief	- 26-50%
No Relief	- 0-25%

- In Group A 68% of patients had relief. Out of which 30% of patients had mild relief, 8% had moderate relief and 30% of patient had complete relief.
- In Group B 58.66 % of patients had relief. Out of which 18% of patients had mild relief, 14% had moderate relief and 26.66% of patients have complete relief.

Discussion

Formulation was in the form of *Avaleha* but we prepare granules with following reasons:

- To make more palatable.
- To enhance the self-life of drug.
- To make much attractive.
- To decide proper dose

Lukewarm water had been chosen for *Anupana* because lukewarm water enhances the dissolution and disintegrations of drug and *Acharya Charaka* indicates pacification of *Amlapitta* in *Dugdha gunas*[5]. It is believed that milk is capable of providing a soothing and protective layer in the stomach and esophagus, protecting sensitive tissue from the harmful acid reflux. But, the fatty part of the milk is capable of creating further acidity which is why non-fat milk is the preferred method when trying to combat the acidity of the stomach[6].

Statistically analysis between Group A and Group B for the observation parameters *Avipaka, Aruchi, Utkelesh, Tikta-Amlodgara, Gaurava, Klama, Chhardi* and *Shirhshula* were found not significant changes. It show that the relief % of both Groups were closely similar and in observation parameter *Daha* the difference value of group A is higher than group B. It show that group A have higher relief % on *Daha* as compare to group B. Difference in the relief percentage of group A and B may be due to variation in the ingredients of sample KKG and KKW mentioned in the *Bhava prakash Uttrardha Madhayam Khanda* in reference of treatment of *Amlapitta*.

Probable mode of action of *Kushmanda Khanda*

Some contents of *Kushmanda Khanda* are *laghu* and *Ruksha* in property. There is increase of *Drava Guna* in *Amlapitta*. *Kledaka Kapha* and *Pachaka Pitta* are *drava* in dominancy. So *laghu-Ruksha Guna* performs the function of *Dravansha - Shoshana*. Other functions of *laghu – Ruksha Guna* are *lekhana, Stambhana* and *Ropana*. *Kashaya Rasa* tones up the tissues and hastens healing of ulcers. *Amalaki* being of *Kashaya rasa* might be rapidly healing the ulcers and toning up the gastric and duodenal mucosa making them more resistant against the action of acid. This procedure might be responsible for normalization of the acid output and increase of mucin levels in the gastric juice. Besides giving relief from symptoms the drug had also imparted *Rasayana* effects. Whether this phenomenon is due to correction of the pathology or due to the claimed *Rasayana* effects of the drug as described in *Ayurvedic* texts is not certain, but the effect is there. Probably both the factors may be operating. *Amalaki* has been considered as one of the fore most *Rasayana* drugs imparting a long healthy life. Properties of *Kushmanda* i.e. *Sheeta Virya, Guru, Snigdha* and *Madhura Rasa* are opposite to *Gunas* of *Pitta* so act as *Pitta Shamaka*.

Conclusion

The pharmaceutical processing of *Kushmanda Khanda* is easy and economic. Sample KKG have good antacid capacity than sample KKW which was confirmed in clinical trial. In observational parameters i.e. *Avipaka, Aruchi, Tikta-Amlodgara, Utkelesh, Daha, Gaurava* and *Klama,* both samples had shown statistically significant changes at various stages of trial i.e. before treatment, at fifteen days follow up and after treatment. The results comprise that KKG formulation is better than KKW due to addition of *Ghrita* having Pitta *Shamaka* property. Above study concludes that *Kushmanda Khanda* can be easily utilized as an effective medicine for the treatment of *Amlapitta*.

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सारांश

पाषाण युग से अंतरिक्ष युग तक भोजन तरीकों में कई परिवर्तन हुये हैं। ये परिवर्तन जीवन के बेहतर पहलू के लिये किये गये है। समस्त विकारों की जड़ भोजन की आदतों में निहित है जैसे अजीर्ण, अकाल एवं विरूद्ध भोजन, लवण, कटु, रस सेवन आदि, अनियमित जीवन शैली जैसे रात्रि जागरण, वेग विधारण, दिवास्वप्न, मानसिक भाव जैसे क्रौध्र, चिंता, शोक। अम्लपित्त उनमें से एक विकार है जिसे ध्यान में रखते हुए यह अध्ययन तैयार किया गया। चिकित्सकीय शोध में 30 रोगियों को ग्रुप ए एवं ग्रुप बी में विभाजित किया गया। ग्रुप ए में कुष्माण्ड खंड घृत सहित (KKG) तथा ग्रुप बी में कुष्माण्ड खंड बिना घृत (KKW) के दिया गया। हर ग्रुप में अविपाक, अरूचि, उत्क्लेष, गौरव, क्लम, छर्दि आदि मापदंडों पर अवलोकन किया गया। सांख्यिकी विश्लेषण के आधार पर अन्य मापदंडों से दाह के लक्षणों में ग्रुप ए में बी के तुलना ज्यादा अंतर पाया गया। अतः कुष्माण्ड खंड घृत सहित निश्चित रूप से अम्लपित्त की चिकित्सा में अधिक लाभकारी है।

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ORIGINAL ARTICLE

Clinical Study on the Effect of An Ayurveda Formulation In The Management of *Medodushti* W.S.R. To Dyslipidaemia

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ABSTRACT

Purpose: The World Health Organization estimates that Dyslipidaemia is associated with more than half of global cases of ischemic heart disease and more than 4 million deaths per year. World Health Organization (WHO) in 2002 reported that high cholesterol level is one of the main non-communicable disease-related risk factors in India. As described in *Ayurveda*, *Medodushtijanya* sign & symptoms shows strikingly resemblance with Dyslipidaemia explained in modern text. While treating the *Medodushti,* selection of *Dravya* should have criteria that help in *Lekhana* of excessive *Meda-Kapha* without *Vayu-Prakopa* & normalising the *Agni* both at the level of *Jatharagni* & *Dhatwagni*. **Method:** In this clinical study, 50 clinically diagnosed patients were registered and divided into two groups with 25 patients in each group. In group A, patients were administered Ayurveda formulation in dose of 2 tab. (500 mg each) twice in a day (2gm/day) with lukewarm water for 60 days. In group B, 25 patients were administered Capsule *Shuddha Guggulu* (extract) in dose of 1 capsule twice in a day (500 mg/day) for 60 days with lukewarm water. **Result:** The results were highly significant (p value < 0.001) in both subjective parameters i.e. *Pipasadhikya, Daurbalya, Swedadhikya, Kshudrashwasa, Angasada*a as well as objective parameters i.e. body weight, B.M.I., Waist-hip Ratio, Waist-height Ratio & Lipid profile in both groups. On intergroup comparison statistically non-significant difference was found in all subjective & objective parameters of both groups, except Body weight where in Group A was quite significant than Group B (p value < 0.05). So, both the therapies have almost similar effect on all the parameters assessed. **Conclusion:** From the observation & result, it can be concluded that *Ayurveda* formulation can be used effectively in the management of Dyslipidaemia & its results are comparable and even better with that of *Shuddha Guggulu*.

Key Words: *Medodushti*, Dyslipidaemia, *Ayurvedic* formulation, *Shuddha Guggulu*.

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Introduction:

During last centuries, life style alteration has been characterised by increased calories, fat intake & reduction in physical activities along with a dramatic increase in non communicable diseases (NCDs). Cardiovascular diseases account for most NCD death of 17.5 million people annually. Raised Blood Pressure, increased Blood Glucose, elevated Blood Lipids and Obesity are 'intermediate risk factors' which can lead to Cardiovascular disease, a NCDs. The epidemiology and economics of Dyslipidaemia is extensive and it is closely linked to the pathophysiology of CVD and a key independent modifiable risk factor for Cardiovascular disease. Dyslipidaemia is a disorder of lipoprotein metabolism, which can include overproduction or deficiency of lipoproteins or both. The disorder can manifest as an elevation of plasma cholesterol, Triglycerides, or both, or alow high density lipoprotein level or all three together that contributes to the development of atherosclerosis. High-density-lipoprotein (HDL) cholesterol however confers protection. Generally the risk of CHD rises as the ratio of total cholesterol to HDL-cholesterol (TC:HDL-C) rises. Dyslipidaemia may be related to the other diseases (Secondary Dyslipidaemia) or to the interaction between genetic predisposition and environmental factors.

In India, there has been an alarming increase in the prevalence of CVD over the past two decades so much accounting for 24% of all deaths among adults aged 25–69 years.[1] The World Health Organization estimates that Dyslipidaemia is associated with more than half of global cases of ischemic heart disease and more than 4 million deaths per year.[2] World Health Organization (WHO) in 2002 reported that high cholesterol level is one of the main non-communicable disease-related risk factors in India.[3] Almost one third of the population of developed countries is detected to be having Dyslipidaemia; however, prevalence varies depending on ethnic group studied. There is a wide variation in the prevalence of Dyslipidaemia in India depending on habitat, socioeconomic stratum and lifestyle practices. South Asians are facing growing "epidemics" of Obesity and Dyslipidaemia. Diabetic Dyslipidaemia in India is one of the main causes for Coronary Artery Disease (CAD) mortality.The management of Dyslipidaemia is directed at the identification of those at high risk of cardiovascular disease and the primary prevention and secondary prevention of cardiovascular disease by the management of all risk factors, including smoking, hypertension, diabetes and obesity.

As described in *Ayurveda*, *Medodushtijanya* Sign & Symptoms shows strikingly resemblance with Dyslipidaemia explained in modern text. According to *Ayurveda, Nidana* for *Medo Dhatu Dushti* is excessive intake of *Shleshma Vardhak Ahara-Vihara* and reduced exercise causes *Agnidushti* resulting in excessive formation of *Sama Meda*. Thus it presents as *"Medovriddhi* and *Medodushti"*.

Medodushti involvement have been seen in pathogenesis of various disease for e.g. in *Prameha,* there is *'Bahu Abaddha Meda Dhatu'* and in obesity there is *Sthoola Rupa* of *Meda Dhatu Dushti/Vriddhi*. That can be considered as *Baddha* of *Medo Dhatu*. *Meda Dushti* mentioned in *Prameha & Sthaulya* in *Ayurveda*, can be considered as Dyslipidaemia. It should be treated on the lines of management of *Medoroga* and *Prameha*.

Materials & Methods

A) Aims & objectives:

The present clinical trial has been undertaken with the following three objectives:

- Conceptual & clinical studies on *Medodushti* & Dyslipidaemia.
- To evaluate clinical efficacy of *Ayurvedic* formulation made up of *Daruharidra*, *Devdaru*, *Musta*, *Amalaki*, *Haritaki*, *Vibihitaka* in the patients of Dyslipidaemia (*Medodushti*).
- To compare the efficacy of selected *Ayurvedic* formulation and Capsule *Shuddha Guggulu* in Dyslipidaemia (*Medodushti*).

B) Selection of cases:

The study was conducted on 50 clinically diagnosed & confirmed patients of *Medodushti*

(Dyslipidaemia) on the basis of subjective & objective parameters. Patients were randomly selected from OPD & IPD of Aarogyashala, P.G. Department of Kayachikitsa NIA Hospital, Jaipur. A regular record of assessment of all patients was maintained according to Performa prepared for the study.

C) Inclusion criteria:

i. Patients between the age group of 20-60 years in either sex.

ii. Diagnosed & confirmed cases of Dyslipidaemia (*Medodushti*) on the basis of criteria given by NCEP-ATPIII (Serum Cholesterol ? 200 mg/dl, Serum Triglycerides ? 150mg/dl, LDL Cholesterol ? 130mg/dl, HDL Cholesterol < 40mg/dl) and patients having alterations in any one or more component of the lipid profile as follows were included in present study.

iii. Patients willing to sign the consent form.

D) Exclusion criteria:

i. Patients having medical history of Unstable angina, Myocardial Infarction, Heart failure, stroke within 3 months of Study, Uncontrolled Hypertension (Diastolic Blood Pressure > 100 mmHg), Uncontrolled Diabetes Mellitus, Impaired Renal function(Creatinine ≥ 2 mg/dl), Hypothyroidism, Jaundice, Hepatitis, Chronic infections & other serious diseases.

ii. Pregnancy, Lactation and patients having Dyslipidaemia due to drugs e.g. Glucocorticoids, Diuretics etc.

E) Study Design:

Randomized, Control & Open level, Clinical study.

F) Grouping and Administration of Drug:

Registered 50 patients were randomly divided into 2 Groups of 25 patients in each as below:

Group A - 25 patients were administered Trial Drug 'Tablet *Medonorm*' in dose of 2 tab. (1 tab = 500mg) twice in a day (2gm/day) with lukewarm water for 60 days.

Table I: Contents of Ayurveda formulation

Name of drug	Latin name	Proportion	Part used
Daru haridra	*Berberis aristata*	1part	Stem
Devdaru	*Cedrus deodara*	1 part	Stem
Musta	*Cyperus rotandus*	1 part	Rhizome
Bibhitaka	*Terminalia belerica*	1 part	Fruit
Haritaki	*Terminalia chebula*	1 part	Fruit
Aamlaki	*Emblica officinalis*	1 part	Fruit

Group B - 25 patients were administered Capsule *Shuddha Guggulu* (Extract) in dose of 1 capsule twice in a day (500mg/day) for 60 days with lukewarm water.

Follow-Up Study:

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

F) Criteria For Assessment:

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

a.) Subjective Criteria

Ayurveda is a subjective science. To give

results, objectively and for statistical analysis, following signs and symptoms of *Medodushti* was adopted :

i. *Kshudra Shwasa* (Breathlessness on exertion)

ii. *Angasada* (sluggishness of body)

iii. *Kshudhadhikya* (excessive hunger)

iv. *Pipasadhikya* (excessive thirst)

v. *Swedadhikya* (excessive sweating)

vi. *Atinidra* (excessive sleep)

vii. *Daurbalya* (weakness)

viii. *Kricchavyavayata* (difficulty in sexual intercourse)

ix. *Krathana* (snoring)

Score was given according to the severity of symptoms. The details of the score adopted for the main signs and symptoms in present study were as follows:

0 = None (Symptom is not present at all)

1 = Mild (Symptom is present but not bothering)

2 = Moderate (Symptom is bothering but tolerable)

3 = Severe (Symptom is not tolerable and needs medication)

b) Objective Criteria:

It was assessed mainly on the basis of Biochemical investigations as Lipid Profile and along with Anthropometric assessment before starting the treatment and after completion of treatment in terms of percentage relief and statistical evaluations. For the better assessment of clinical significance of changes in lipid profile & Anthropometric assessment, a grading system was developed & used in present trial.

1) Anthropometric Assessment:

The following Anthropometric assessments were done before & after the treatment using weighing machine & measurement tape:

- Weight of the Patient (in Kg)
- B.M.I.

B.M.I. = Weight of the patient (in Kg) ÷ [Height of the patient (in metre)]^2

Classification of adults according to BMI[4] :-

BMI	CLASSIFICATION	GRADE
< 18.5	Underweight	0
18.5-24.99	Normal	1
25.0-29.99	Overweight	2
>30	Obese	3

- Waist - Height Ratio: Ratio between the waist circumference & height of the patient was calculated.

Waist- Height Ratio Classification[5]:-

Waist-Height Ratio	Health Risk	Grade
0.4	Ok	0
0.5	Consider Action	1
0.6	Take a action	2

- Waist - Hip Ratio:

Ratio between the waist & hip circumference of the patient was calculated.

Waist-Hip Ratio Classification[6] :-

Male		Female		Risk Category	Grade
< 60 yr.	>60 yr.	< 60 yr.	>60 yr.		
<0.90	<0.95	<0.80	<0.85	Low	0
0.90-0.95	0.95-1.03	0.80-0.86	0.85-0.90	Moderate	1
>0.95	>1.03	>0.86	>0.90	High	2

2) Biochemical Parameter Assessment:

Following Biochemical parameters were done before the commencement & after completion of the treatment

- **Routine Blood Investigation-:** Haemoglobin (Hb gm%) ,Total Leucocytes Count (TLC) ,Differential Leucocytes Count (DLC), ESR (mm/hr)
- **Lipid profile-:** Serum Total Cholesterol (Sr.TC), Serum Triglycerides (Sr.TG), Serum Low Density Lipoprotein (Sr.LDL), Serum Very Low Density Lipoprotein (Sr.VLDL), Serum High Density Lipoprotein (Sr. HDL)
- **Fasting Blood sugar (FBS)**
- **RFT (Renal Function Test)-:** Blood Urea, Serum Creatinine

ATP III Classification of LDL, Total and HDL Cholesterol and Triglycerides[7] :

Lipoprotein	Concentration (mg/dl)	Interpretation	Grade
TC	<200	Desirable	0
	200-239	Borderline high	1
	>240	High	2
LDL-c	<100	Optimal	0
	100-129	Near/above optimal	1
	130-159	Borderline high	2
	160-189	High	3
	>190	Very high	4
HDL-c	<40	Low	0
	>60	High	1
TGs	<150	Normal	0
	150-199	Borderline high	1
	200-499	High	2
	>500	Very high	3

Observations:

20 patients in age group 41-50 & 19 patients in age group 51-60 were found; it shows overall 78% patients belong to 4th to 6th decade of life. According to sex, i.e.60% was female & 40% were male. 66% patients belonged to Hindu community. 96 % patients were married. Maximum 40% patients were housewives followed by 38% service class. About 72% patients belonged to Middle class. Max. 60 % Patients had *Vata-Kaphaj Prakriti* & 28 % *Pitta Kaphaj Prakriti*, which is highly associated with the development of Dyslipidaemia. 50% patients were belonging to *Rajasik Manasa Prakriti*. 72% patients were of *Madhyama Sara*. 70% were having *Madhyama Samhanana*. But they were having complaint of Fatigueness, due to *Mamsashaithiya* & *Abaddha Meda* leading to lethargy. 72 % patients showed *Madhyama Satva* followed by 18% patients with *Avara Satva*. 84% patients showed *Madhyama Abhyavaharan Shakti*. While 82% patients showed *Madhyama Jarana Shakti* followed by 14% patients had *Avara Jarana Shakti*. 46 % patients each showed *Madhyam & Krura* nature of *Koshtha*. It is due to *Samana Vayu Prakopa* in there diseased individuals. 42% patient showed *Vishamagni,* followed by 40% patients of *Mandagni*. 62% were found to have *Madhura Rasa* dominant diet followed by 60% patients of *Lavana Rasa* dominant diet. 46% patients were dominantly having *Adhyashana* in their Dietary Habits, followed by 32% patients with *Vishmashana*. 36% patients showed Day time sleeping but maximum 70% patients showed about 8 hrs of sleeping. Daytime sleeping leading to *Doshaprakopa* especially formation of *Ama* which further causes *Apakva-Ama Rasa* & further impairs *Dhatuposhana*. 62% patients showed *Madhyama Vyayama Shakti*. Imparied *Anna Rasa* leading to impaired nutrition of further *Dhatu,* thus whatever the *Dhatu* are formed, they have *Shaithilya Guna*. 8 patients gave a history of being tensed for one or other cause, 2 patients showed depressed mood & 3 patients were having features of Anxiety. All these emotional conflict are important etiological factors for *Medodushti*. Higher incidence of various *Nidana* like 66% patients with *Guru Sevena,* 64% patients with *Madhura Sevena,* 66% had history of *Snigdha Sevena,* 70% patients with *Kshirad Sevena,* 14% *Swapnasukha,* 56 % with *Avyayama,* 34% with *Diwaswapna* etc. were found to be etiological factors in *Medodushti*. Max 56% patients showed no habit of exercise. About 08 % patients, in the study showed history of Diabetes mellitus, 14 % were having history of Hypertension & Osteoarthritis each. 54 % patients had shown BMI between 25- 29.99 and 20 % had BMI > 30. 64 % patients had Total serum cholesterol in Borderline high range i.e. 200-239 mg/dl & 13% had high range i.e. above 240 mg/dl. 46% patients had LDL cholesterol in near optimal range i.e. 100-129, while HDL cholesterol was found to be within normal range in nearly all the patients. In 58% patients Borderline high i.e. 150-199 mg/dl Triglycerides level was found and 28% of patients had high level i.e. 200-499 mg/dl of triglycerides.

Results:

Table No II -: Showing effect of Therapy in Subjective Parameters. (Wilcoxon matched-pairs signed ranks test)

Variable	Group	Mean		Mean	%	SD	SE±	P	S
		BT	AT	Diff.	Relief	±	±		
Kshudhadhikya	Gr. A	0.44	0.12	0.32	72.73%	0.56	0.11	<0.05	S
	Gr. B	0.36	0.12	0.24	66.66%	0.44	0.09	<0.05	S
Pipasadhikya	Gr. A	0.84	0.28	0.56	66.66%	0.58	0.12	<0.0001	HS
	Gr. B	0.68	0.16	0.52	76.47%	0.52	0.10	<0.0001	HS
Daurbalya	Gr. A	1.08	0.20	0.88	81.48%	0.60	0.12	<0.0001	HS
	Gr. B	0.96	0.08	0.88	91.66%	0.67	0.13	<0.0001	HS

Swedadhikya	Gr. A	0.96	0.44	0.52	54.16%	0.65	0.13	<0.001	HS
	Gr. B	0.60	0.20	0.40	66.66%	0.58	0.11	<0.01	HS
Atinidra	Gr. A	0.32	0.12	0.20	62.50%	0.41	0.08	>0.05	NS
	Gr. B	0.16	0.04	0.12	75.00%	0.33	0.66	>0.05	NS
Kshudrashwasa	Gr. A	0.88	0.36	0.52	59.09%	0.59	0.12	<0.001	HS
	Gr. B	0.64	0.28	0.36	56.25%	0.49	0.1	<0.01	HS
Angasada	Gr. A	0.68	0.08	0.60	88.23%	0.76	0.15	< 0.01	HS
	Gr. B	0.92	0.12	0.80	86.95%	0.87	0.17	<0.001	HS
Krucchvyavayata	Gr. A	0.13	0.1	0.03	25%	0.18	0.03	>0.05	NS
	Gr. B	1.66	0.10	0.06	40%	0.2537	0.04	>0.05	NS
Krathana	Gr. A	1.04	0.44	0.60	57.69%	0.65	0.12	<0.001	HS
	Gr. B	0.96	0.52	0.44	45.83%	0.51	0.10	< 0.001	HS

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

Table No III -:Showing effect of Therapy in Anthropometric Parameters (Paired't' Test & Wilcoxon matched-pairs signed ranks test)

Parameters		**Group**	**Mean**		**Mean**	**%**	**SD**	**SE±**	**t**	**P**	**S**
			BT	**AT**	**Diff.**	**Relief**	**±**	**±**			
Body Weight (kg)		A	68.76	66.12	2.64	04%	1.19	0.24	11.13	<0.0001	HS
		B	71.08	69.12	1.96	2.75	1.17	0.23	8.36	<0.0001	HS
B.M.I. (Kg/m²)	Value	A	28.04	27.00	1.03	3.70	0.68	0.13	7.632	<0.0001	HS
		B	27.11	26.38	0.72	2.67	0.38	0.77	9.415	<0.0001	HS
	Grade	A	1.92	1.68	0.24	12.5	0.43	0.09	-	<0.05*	S
		B	2	1.72	0.28	14	0.46	0.09	-	<0.05*	S
Waist-Height ratio	Value	A	0.61	0.57	0.04	6.5	0.05	0.009	3.674	<0.01	HS
		B	0.59	0.55	0.04	7.2	0.05	0.009	3.674	<0.01	HS
	Grade	A	1.84	1.64	0.20	10.87	0.41	0.08	-	>0.05*	NS
		B	1.64	1.44	0.20	12.19	0.41	0.08	-	>0.05*	NS
Waist-Hip Ratio	Value	A	0.95	0.93	0.022	2.10	0.03	0.005	4.43	<0.001	HS
		B	0.952	0.934	0.018	1.89	0.02	0.004	4.28	<0.001	HS
	Grade	A	1.92	1.76	0.16	8.33	0.37	0.075	-	>0.05*	NS
		B	1.84	1.56	0.28	15.21	0.46	0.092	-	<0.05*	S

(Note - * - Wilcoxon matched-pairs signed ranks test)

Table No IV -: Showing effect of Therapy on Lipid Profile (Paired't' Test & Wilcoxon matched-pairs signed ranks test)

Variable		Group	Mean		Mean	%	SD	SE±	t	P	S
			BT	AT	Diff.	Relief	±	±			
Sr.TC (mg/dl)	Value	Gr. A	225.24	195.68	29.56	13.12	14.74	2.95	10.02	<0.0001	HS
		Gr. B	220.04	186.56	33.48	15.21	20.03	4.01	8.36	<0.0001	HS
	Grade	Gr. A	1.240	0.44	0.80	64.51	0.50	0.10	-	<0.0001*	HS
		Gr. B	1.08	0.32	0.76	70.37	0.52	0.10	-	<0.0001*	HS
Sr.TG(mg/dl)	Value	Gr. A	181.48	148.80	32.68	18.00	19.81	3.96	8.25	<0.0001	HS
		Gr. B	177.84	152.28	25.56	14.37	46.02	9.20	2.78	<0.01	HS
	Grade	Gr. A	1.2	0.44	0.76	63.33	0.60	0.11	-	<0.01*	HS
		Gr. B	1.12	0.56	0.56	50	1.08	0.22	-	<0.05*	S
Sr.LDL(mg/dl)	Value	Gr. A	138.36	113.04	25.32	18.3	17.08	3.42	7.411	<0.0001	HS
		Gr. B	132.88	104.68	28.2	21.22	17.71	3.543	7.959	<0.0001	HS
	Grade	Gr. A	1.84	0.96	0.88	47.82	0.73	0.14	-	<0.0001*	HS
		Gr. B	1.64	0.72	0.92	56.09	0.64	0.12	-	<0.0001*	HS
Sr.VLDL (%)		Gr. A	36.36	29.72	6.64	18.26	3.97	0.79	8.368	<0.0001	HS
		Gr. B	35.56	30.04	5.52	15.52	9.435	1.887	2.925	<0.01	HS
Sr.HDL(mg/dl)		Gr. A	50.40	51.12	-0.72	1.43	3.13	0.62	1.15	>0.05	NS
		Gr. B	51.72	50.2	1.52	2.93	4.89	0.99	1.55	>0.05	NS
FBS (mg /dl)		Gr. A	88.44	86.28	2.16	2.44	8.68	1.73	1.24	>0.05	NS
		Gr. B	95.48	89.56	5.92	6.24	11.16	2.23	2.65	<0.05	S

(Note - Sr.TC-Serum Total Cholesterol; Sr.TG-Serum Triglycerides; Sr. LDL-Serum Low Density Lipoproteins; Sr. VLDL- Serum Very Low Density Lipoproteins; Sr. HDL-Serum High Density Lipoproteins; FBS-Fasting Blood Sugar; HS: Highly Significant; S: Significant; NS: Non Significant * - Wilcoxon matched-pairs signed ranks test)

On intergroup comparison in all subjective & objective parameters of both group, there were no statistically significant difference was found except Body weight where Group A was quite significant than Group B (p value <0.05). So, both the therapy have similar efficacy on all the parameters assessed.

Discussion-

Ayurveda formulation containing drugs- *Devdaru, Musta, Daruharidra, Aamlaki, Vibhitaki* and *Haritaki* is indicated as a *Kwatha* preparation in *Prameha Chikitsa*.[8] *Abaddha Meda Dushti* mentioned in *Prameha* in *Ayurveda*, can be considered as Dyslipidaemia so this formulation was selected to treat *Medodushti*. Trial drug in tablet form was a modified form of *Kwath* by *Ghansattva* method. It pacifies the vitiated *Kapha Dosha* which is dominant in the pathogenesis of Dyslipidaemia as well as depletes the excessively produced *Rasa*, *Mamsa*, *Meda*, *Vasa*, *Sweda* and *Kleda* which are all similar in attributes to *Kapha Dosha*. Drugs like *Musta*, *Triphala*, *Daruharidra* digest the *Ama Dosha* present at the *Jatharagni* level as well as the *Medodhatvagni* level. *Triphala*, is *Rasayana* in nature which lead to formation of optimal *Dhatu* and protect the body from injury due to vitiated *Dosha*. *Dipana* and *pachana* effects of *Katu* and *Tikta Rasa* would have acted upon *Dhatvagnimandya* and helped in normalising the body metabolism.

Shuddha Guggulu is mentioned by *Acharya Vagbhatta* for *Sthoulya Chikitsa*. There are so many researches available that prove that *Guggulu* can be used to treat Dyslipideamia. *Katu, Tikta Rasa , Katu Vipaka, Laghu, Ruksha, Tikshna Guna* and *Ushna Virya* of *Guggulu* helps in *Amapachana,* correct *Agnivyapara* all over the body, remove *Srotorodha* and correct the defects in *Dhatu parinama*. It has *medohara* and *Lekhaniya* properties so directly acts on *meda dhatu* and prevents *medodhatuvriddhi*.

So, both drugs possess almost all the qualities required for a drug to treat Dyslipidaemia. Thus the drugs appeared successful in breaking the *Dosha- Dushya Sammurchana*.

Conclusion:

- Dyslipidaemia is very much prevalent in today's society & the risk factors for cardiovascular disorders are mostly seen associated with Diabetes Mellitus & Hypertension.
- On the basis of their clinical manifestations the clinical entity Dyslipidaemia can be correlated with the term "*Medodushti*".
- It was observed that Dyslipidaemia is most common in patients of 4th to 6th decades of life, & is commonly found in individuals having sedentary lifestyle, faulty dietary habits.
- In this clinical study, the therapeutic results in patients of group A, treated with Ayurveda formulation (Tab. *Medonorm*) and in patients of group B, treated with *Shuddha Guggulu* (Extract) were almost equal in all subjective parameters.
- Thus, Ayurveda formulation (Tab. *Medonorm*) can be used effectively in the management of Dyslipidaemia & its result are comparable and even better with that of *Shuddha Guggulu*.

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सारांश–

उद्देश्यः विश्व स्वास्थ्य संगठन का अनुमान है कि डिस्लिपिडिमिया आधे से अधिक इस्कीमिक ह्रदय रोग और प्रति वर्ष लाख से अधिक मौतों की वैश्विक मामलों के साथ जुडा हुआ है विश्व स्वास्थ्य संगठन (डब्ल्यू.एच.ओ.) ने 2002 में उच्च कोलेस्ट्रोल के स्तर को भारत में मुख्य गैर संचारी रोग से सम्बंधित जोखिम वाले कारको में से एक माना है आयुर्वेद में वर्णित मेदोदुष्टि जन्य रूप और लक्षण आधुनिक विज्ञान में बताए गए डिस्लिपिडिमिया के साथ समानता रखते है मेदोदुष्टि का इलाज करते समय, द्रव्य का चयन के मापदंड इस प्रकार होने चाहिए कि वो जठराग्नि और धात्वाग्नि दोनों अग्नि के स्तर को सामान्य बनाने और वायु प्रकोप किये बिना अत्यधिक मेद–का लेखन करने में मदद करने वाली हो

विधि – इस नैदानिक अध्ययन में 50 नैदानिक रोगियों का चयन किया गया और 25–25 रोगियों के दो समूह में बाटा गया था। ग्रुप–ए में 25 रोगियों को आयुर्वेदिक फार्मूलेशन दो गोली की खुराक एक दिन में दो बार (2 ग्राम/दिन) गुनगुने पानी के साथ 60 दिनों के लिए में दी गई। ग्रुप बी में 25 रोगीयों को शुद्ध गुग्गुलु (extract) एक केप्सूल एक दिन में दो बार की खुराक (500 मिलीग्राम/दिन) में गुनगुने पानी के साथ 60 दिनों के लिए दी गई।

परिणाम – दोनों समूहों में व्यक्तिपरक मापदंडो जैसे कि पिपासाधिक्य, दौर्बल्य, स्वेदाधिक्य, क्षुद्रश्वास एवं उद्देश्यपरक मापदंडो जैसे की शरीर के वजन, बी.एम.आई., डब्लू.एच.आर, कमर ऊँचाई के अनुपात और लिपिड प्रोफाइल में परिणाम सांख्यिकीय रूप से बेहद महत्त्वपूर्ण (p value <0.001) थे। इंटर ग्रुप तुलना करने पर सभी व्यक्तिपरक और उद्देश्यपरक मापदंडो में शरीर के वजन को छोड़ कर दोनों समूहों में सांख्यिकी रूप से नॉन सिग्नीफिकेंट परिणाम मिले। ग्रुप A में शरीर के वजन में ग्रुप B की तुलना में सिग्नीफिकेंट परिणाम (p value <0.05) मिले। अतः दोनों ग्रुप का सभी मापदंडो पर लगभग समान प्रभाव है।

निष्कर्ष – अवलोकन एवं परिणाम से यह निष्कर्ष निकाला जा सकता है कि आयुर्वेद फोर्मुलेशन डिस्लिपिडिमिया के प्रबंधन में प्रभावी ढंग से इस्तेमाल किया जा सकता है और तुलना करने पर उसके परिणाम तुलनीय रूप से शुद्ध गुग्गुलु से और भी बहेतर है

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A Clinical Study On The Efficacy Of *Ardhanarishvara Rasa Nasya* and *Nimbadi Guggulu* In The Management Of *Kaphaja Shiroroga* W.S.R. To Sinusitis

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ABSTRACT

Kaphaja Shiroroga is one among the 11 types of *Shiroroga* mentioned by *Aacharya Sushruta*. In modern science, it can be correlated to sinusitis. Sinusitis is a major problem in the society due to its recurrent exacerbations and complications. Drugs selected for present study *Ardhanarishvara rasa* and *Nimbadi Guggulu* are having *Kaphavatahara, Lekhaniya, Srotoshodhana* and *Shothahara* properties which helps in break down of the pathogenesis of sinusitis. The chief procedure to remove *Doshas* from *Shiras* is *Shodhana Nasya*. Therefore *Nasya* with *Ardhanarishvara Rasa* due to its medicinal properties helps in removing the vitiated *Kapha* accumulated in *Shiras*. In present study 30 patients of *Kaphaja Shiroroga* (sinusitis) were selected and randomly divided into two groups of 15 patients each. Group A was treated with *Ardhanarishvara Rasa Nasya* and Group B was *Ardhanarishvara Rasa Nasya* and *Nimbadi Guggulu* orally. Their individual and comparative effects were revealed in the study. A significant relief was found in most of the symptoms and signs of *Kaphaja Shiroroga* (Sinusitis) after the trial.

Key words: *Kaphaja Shiroroga*, Sinusitis, *Nasya, Nimbadi Guggulu*

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Introduction

Acharaya Sushruta has mentioned 11 types of *Shiro-Roga*[1] in *Uttar Tantra* and *Kaphaja Shiroroga* is one of them. The clinical features of *Kaphaja Shiroroga* described by *Aacharya Sushruta* are - *Guru Pratistabdham* (Heaviness and fullness of head), *Himam* (Coldness in head), *Shuna Akshikoota Vadanam* (Swelling of face especially around the

eyes), *Shirobhitapa* (Headache), *Shirogalam Kaphopdigdham* (Feeling of having a coating of phlegm inside the head and throat)[2]. Sinusitis is defined as inflammation of paranasal sinuses. Signs and symptoms of sinusitis are headache, pain and swelling of affected sinus, heaviness in head, nasal discharge, nasal obstruction, post nasal drip, low grade fever, halitosis, anorexia, periorbital swelling, lassitude etc. On the basis of these clinical features, *Kaphaja Shiroroga* can be correlated to sinusitis in modern science.

Sinusitis is a major problem in the society due to its recurrent exacerbations and complications. Due to increased environment pollution and busy life style in present era, incidence of rhinitis is increasing which leads to sinusitis if not properly treated. It is the fifth most common diagnosis for which antibiotics are prescribed.[3] In India chronic sinusitis affects nearly 134 million people, making it the country with the second largest number of sufferers in the world.[4] Sinusitis itself is rarely life threatening, but if the infection extends into surrounding deep tissues it can lead to serious complications like: orbital cellulitis, subperiosteal abscess, orbital abscess, frontal and maxillary osteomyelitis, subdural abscess, meningitis, brain abscess.[5]

In modern science, only symptomatic relief is achieved with antibiotics, decongestants, analgesics etc., but the rate of recurrence is very high. In advanced cases, surgical procedures are advised which are expensive, and invite complications.

In *Kaphaja Shiroroga,* vitiated *Kapha Dosha* accumulates in *Shiras* causing obstruction in *Srotas* of head. *Aacharya Vagbhatta* has mentioned that the drugs used for the treatment of *Kaphaja Shiroroga* should have *Katu, Ruksha, Ushna* and *Teekshna* properties,[6] for removal of *Kapha* and *Shodhana* of *Srotas*. The contents of drugs *Ardhanarishvara Rasa*[7] and *Nimbadi Guggulu*[8] selected for present study have these properties along with analgesic, antibiotic and anti-inflammatory effect and thus help in breakdown of the pathogenesis of sinusitis.

In *Ayurveda, Nasya* is the chief procedure to remove *Doshas* (infectious material) from *Shiras* as it is quoted that *"Nasa hi Shiraso Dwaram"*.[9] In *Kaphaja Shiroroga* treatment *Shirovirechana* (*Shodhana*) *Nasya* is recommended. The term "*Shirovirechana"* itself denotes the process of cleansing of head. Hence *Avapeeda Nasya* (comes under *Shirovirechana* type) with *Ardhanarishvara Rasa* due to its medicinal properties helps in removing the vitiated *Kapha* there by clearing the *Srotas* (sinuses) situated in *Shiras* (skull and face).

Therefore the present study entitled "A Clinical Study on the Efficacy of *Ardhanarishvara Rasa Nasya* and *Nimbadi Guggulu* in the Management of *Kaphaja Shiroroga* w.s.r. to Sinusitis" had been designed to analyze and evaluate the complete concept and etiopathogenesis of sinusitis vis-à-vis *Kaphaja Shiroroga* based on clinical study, as a whole in light of *Ayurvedic* and modern concepts

Aims and Objectives

1. Aetiopathogenesis and clinical study of *Kaphaja Shiroroga* with special reference to sinusitis.
2. To evaluate the efficacy of *Nasya* with *Ardhanarishvara Rasa* in the management of *Kaphaja Shiroroga* (Sinusitis).
3. To evaluate the efficacy of *Nasya* with *Ardhanarishvara Rasa* and *Nimbadi Guggulu* orally in patients suffering from *Kaphaja Shirahshoola* (Sinusitis).
4. To compare the efficacy of trial drugs in *Kaphaja Shiroroga.*

Material and Methods

I. Study Design: The present study is an interventional, randomized, open label, and parallel group trial.

II. Selection of Patients

Source: Patients attending the O.P.D. and I.P.D. of *Shalakya* Tantra of National Institute of Ayurveda, Jaipur were screened for the present study. Freely given informed written consent was obtained from every subject prior to research participation. A research proforma was prepared to study all the conditions of patients.

Ethical clearance: Institutional Ethics Committee (IEC) approval was taken prior to initiation of research workvide letter number F10(5)/ EC/2014/7224 dated 7-11-2014.

Inclusion Criteria

1. Patients fulfilling the diagnostic criteria which were based on the signs and symptoms of *KaphajaShiroroga*explained in *Ayurvedic* classics and sinusitis as per modern science.
2. Patients between the age group of 8 to 80 years.

Exclusion criteria

1. Patients not willing for the trial were excluded.
2. Pregnant women.
3. Patients with chronic debilitating infectious diseases.
4. Patients suffering from pain and facial swelling due to alveolar abscess, cellulitis of cheek, furuncle, angioneuroticoedema, trigeminal neuralgia, temporal arteritis.
5. Patients with malignancies of sinuses.

III. Grouping of patients:

In the present study 34 clinically diagnosed patients of *Kaphaja Shiroroga* (Sinusitis) were selected and randomly divided into two groups. Randomization was done on the basis of random number table. Out of these 34 patients 30 patients completed the trial.

Group A: 15 patients of *Kaphaja Shiroroga* (Sinusitis) were given *Nasya* with *Ardhanarishvara Rasa*.

Group B: 15 patients of *Kaphaja Shiroroga* (Sinusitis) were given *Ardhanarishvara Rasa* for *Nasya* and *Nimbadi Guggulu* orally.

IV. Administration of Drugs:

i) Ardhanarishvara Rasa

- **Dose** : 4 drops per nostril
- **Duration:** Two sittings of 7 days with interval of 7 days

ii) Nimbadi Guggulu

- **Dose:** 2 tablets of 500 mg twice daily orally with luke warm water
- **Duration :** 1 month

V. Investigations: X-Ray PNS, Hb%, TLC, DLC, ESR, Absolute eosinophil count

VI. Follow up: A follow-up was done for one and half month after completion of the treatment at fortnight intervals to check status of the patients.

Assessment Criteria

For assessment of the efficacy of the trial therapy, following subjective and objective parameters were adopted:

Subjective criteria:

1) *Shiroabhitapa* (Headache)
2) *Shiroguruta* (Heaviness in head)
3) *Galam Kaphaupadigdham* (Post nasal drip)
4) *Shunakshikootavadanam* (Periorbital and facial oedema)
5) Nasal obstruction
6) Nasal discharge
7) Tenderness over sinuses

Objective criteria:

1) Haziness in sinuses in X-ray

Statistical Analysis

Various observations made and results obtained were computed statistically using Graph Pad Instat 3 software. Individual A and B group: Wilcoxon matched pairs signed ranks test for nonparametric data. Intergroup comparison between A and B group: Mann Whitney test for nonparametric data. The obtained results were interpreted as:

- Not significant $p > 0.05$
- Significant $p \leq 0.05$
- Very significant $p \leq 0.01$
- Extremely significant $p \leq 0.001$

Observation and Results

In the present trial total 34 patients were registered at the beginning but 4 patients discontinued the trial before its completion and therefore had to be excluded out of the trial. So observation and results of 30 patients are given below:

Observations:

In present study, maximum numbers of patients were in the age group of 21-30 years (33.33%), male and female were equal. Majority of patients had chronic type of sinusitis (80%) and 73.33% had seasonal attacks of the disease. Maximum patients had mild headache (70%), thick (muco-purulent) nasal discharge (40%), 46.66% patients had right and left frontal sinus tenderness on palpation and maximum patients 93.33% had left maxillary sinus opacity followed by 83.33% with right maxillary sinus opacity in X-Ray PNS.

Among 30 patients, headache was found in 93.33% patients, *Shiroguruta* in 90% patients, 50% patients had *Kaphaupadigdham Galam*(post nasal discharge), 23.33% patients were with complaint of Periorbital or Facial edema (*Shuna Akshikootavadanam)*, 86.66% patients had nasal obstruction and nasal discharge was found in 66.66% patients.

Results:

Table I. Effect of therapy on subjective parameters in Group A (Wilcoxon matched paired single ranked test)

S. No.	Symptoms	Mean		Dif.	% of Change	SD	SE	W	P	Results
		BT	AT							
1	*Shiroabhitapa* (Headache)	1.86	0.66	1.20	64.27	0.86	0.22	78	0.0005 p<0.001	ES
2	*Shiroguruta* (Heaviness in head)	1.33	0.33	1.00	75.01	0.65	0.16	78	0.0005 p<0.001	ES
3	*Kaphaupadigdham Galam* (Post nasal drip)	0.93	0.46	0.46	50.02	0.63	0.16	21	0.0313 p<0.05	S
4	*Shunakshikoot-avadanam* (Periorbital and Facial edema)	0.26	0.06	0.20	74.99	0.41	0.10	6	0.2500 p>0.05	NS
5	Nasal obstruction	1.86	0.86	1.00	53.56	0.65	0.16	91	0.0002 p<0.001	ES
6	Nasal discharge	1.20	0.46	0.73	61.10	0.70	0.18	45	0.0039 p<0.01	VS
7	Tenderness over sinuses	2.40	0.66	1.73	72.20	1.98	0.51	36	0.0078 p<0.01	VS

Table II. Effect of therapy on subjective parameters in Group B (Wilcoxon matched paired single ranked test)

S. No.	Symptoms	Mean		Dif.	% of Change	SD	SE	W	P	Results
		BT	AT							
1	*Shiroabhitapa* (Headache)	1.86	0.60	1.26	67.86	1.10	0.28	66	P=0.001	ES
2	*Shiroguruta* (Heaviness in head)	1.93	0.66	1.26	65.54	0.70	0.18	91	0.0002 p<0.001	ES
3	*Kaphaupadigdham Galam* (Post nasal drip)	1.13	0.46	0.66	58.84	0.61	0.15	45	0.0039 p<0.01	VS
4	*Shunakshikootava-danam* (Periorbital and Facial edema)	0.20	0.06	0.13	66.65	0.35	0.09	3	0.5000 p>0.05	NS
5	Nasal obstruction	1.40	0.53	0.86	61.90	0.63	0.16	66	P=0.001	ES
6	Nasal discharge	1.13	0.26	0.86	76.49	0.83	0.21	45	0.0039 p<0.01	VS
7	Tenderness over sinuses	3.40	0.86	2.53	74.50	3.33	0.86	36	0.0078 p<0.01	VS

Table III. Intergroup comparison of subjective parameters of *Kaphaja Shiroroga* (Mann Whitney test)

S. No.	Symptoms	Mean		SD		SE		U	P	Results
		G_A	G_B	G_A	G_B	G_A	G_B			
1	*Shiroabhitapa* (Headache)	1.20	1.26	0.86	1.10	0.22	0.28	113.50	>0.05	NS
2	*Shiroguruta*	1.00	1.26	0.65	0.70	0.16	0.18	136.50	>0.05	NS
3	*Kaphaupadigdam Galam* (Post nasal drip)	0.46	0.66	0.63	0.61	0.16	0.15	133.50	>0.05	NS
4	*Shunakshikoota-vadanam* (Periorbital and Facial edema)	0.20	0.13	0.41	0.35	0.10	0.09	120	>0.05	NS
5	Nasal obstruction	1.00	0.86	0.65	0.63	0.16	0.16	121	>0.05	NS
6	Nasal discharge	0.73	0.86	0.70	0.83	0.18	0.21	121.50	>0.05	NS
7	Tenderness over sinuses	1.73	2.53	1.98	3.33	0.51	0.86	122	>0.05	NS

Discussion

Statistically extremely significant results were found in Headache, Heaviness in head, Nasal obstruction and Haziness in sinuses and very significant results were found in nasal discharge and tenderness over sinuses in both group.The symptomatic improvement was considerable in all the subjective parameters. But the overall percentage change was less in haziness in sinuses in X ray PNS.

Intergroup comparison of efficacy of two therapies on subjective and objective parameters of *KaphajaShiroroga*/sinusitis shows that all the parameters have p value >0.05 which is statistically not significant**.** This shows that there is no statistical difference in efficacy of both treatments.

But on comparing symptomatic improvement in both groups it was found that average percentage of relief was higher in 'Group B' i.e. 63.27%, followed by 'Group A' i.e. 59.07%. It shows that effect of therapy was a little more in Group B in comparison to Group A.

It is clear from the above description that in both the group statistically extremely significant relief was observed in symptoms like headache, heaviness in head and nasal obstruction and very significant results in nasal discharge and tenderness over sinuses. It could be attributed to *Avapeeda Nasya* which is a *Shodhana Nasya*. Here *Purvakarma* i.e. *Abhyanga* helped in *Dosha Mardavkaran*, steam inhalation helped in *Kapha Vilayana* and *Nasya* being *Vyadhi Pratyanika* helped in relieving the symptoms. *NasyaDravyas* are quickly absorbed and produce rapid local and systemic effects. *Nasya Dravyas* in *Ardhanarishvara Ra* have proven anti-inflammatory, *Kaphavataghna* and *Teekshna* property which helped in mucociliary clearance. These drugs helped in relieving mucosal edema, clearing nasal obstruction. Mechanical obstruction in sinus ostia was removed, thereby causing free drainage of mucous from the sinuses.

Average percentage of relief was more in Group B treated with *Ardhanarishvara Rasa Nasya*and internal medication of *Nimbadi Guggulu. Nimbadi Guggulu,* mentioned in the classic for *Duhsaha* (unbearable) *Shiroruja* of *Vata-Kapha*origin, a combination of *Nimba*, *Triphala*, *Patola Vasa* and *Guggulu*, have proven *Shothahara* (anti-inflammatory), *Vednahara* (analgesic), antimicrobial and immune modulatory effects. Thus it helped in reduction of inflammation and infection and thereby sinuses get proper drainage and ventilation and hence relief in the symptoms of *Kaphaja Shiroroga*.

Conclusion

Shiras (head) is one of the most vital organs of body and forms the root of body where the entire special sense organs - eyes, ears, nose, and tongue are situated. Therefore paranasal sinuses which are air filled spaces in the bones of skull are one among the structures of *Shiras*. In management of *Kaphaja Shiroroga*, main concentration is given to the *Dosha Apkarshana* from *Urdhvajatru Pradesha* and the main treatment which can drain the retained discharge (vitiated *Kapha*) from the sinuses is *Shodhana Nasya*. In the present study, *Nasya* with *Ardhanarishvararasa* which is a *Teekshna Avapeeda Nasya* showed considerable relief in both groups. Combined use of *Nimbadi Guggulu* and *Ardhanarishwara Rasa Nasya*is more effective for controlling the disease *Kaphaja Shiroroga* (Sinusitis). Study should be carried out on large sample to ascertain the effect of drug.

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सारांश

कफज शिरोरोग आचार्य सुश्रुत द्वारा उल्लिखित 11 प्रकार के शिरोरोगों में से एक है। आधुनिक चिकित्सा विज्ञान में इसका सायनुसाइटिस से सहसम्बन्ध किया जा सकता है। पुनरार्वतक प्रकोप और उपद्रवों के कारण सायनुसाइटिस समाज में एक बडी समस्या है। वर्तमान अध्ययन के लिए चयनित औषधियां अर्धनारीश्वर रस एवं निम्बादि गुग्गुलु कफवातहर, लेखन, स्रोतोशोधन और शोथहरगुणयुक्त हैं जो कि सायनुसाइटिस की सम्प्राप्ति विघटन में सहायक हैं। शिरः प्रदेश के दोषों को निकालने के लिए शोधन नस्य मुख्य प्रक्रिया है। इसलिए अर्धनारीश्वर रस नस्य शिर में संचित विकृत कफ को निकालने में सहायक है। वर्तमान अध्ययन में कफज शिरोरोग के 30 रोगियों का चयनकर 15–15 रोगियों के 2 समूहों में विभाजित किया गया। ग्रुप ए को अर्धनारीश्वर रस नस्य एवं ग्रुप बी को अर्धनारीश्वर रस नस्य और निम्बादि गुग्गुलु मुख द्वारा रूप से दिया गया। दोनों समूहों के व्यक्तिगत और तुलनात्मक प्रभाव का अध्ययन किया गया। परीक्षण के बाद कफज शिरोरोग के अधिकांश लक्षणों में महत्त्वपूर्ण परिणाम प्राप्त हुए।

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ORIGINAL ARTICLE

A Study of *Vyanghara Karma* of *Laksha* obtained from different host plants

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ABSTRACT

Introduction - *Vyanga* is a common disorder generally affecting the face area and can be an embarrassing condition. *Vyanga* is considered as a *Kshudra roga*. *Laksha* is described as *Vyanganashan dravyas* in *Ayurvedic* classics. *Laksha* is an excellent remedy for skin diseases. *Laksha* is well known medicine for its *Vyanganahan*,*Varnya*, *Kusthaghna* and *Krimighna* activity. **Objective**- To evaluate the *Vyanghar Karma* of *Laksha (Laccifer lacca* Kerr.) which has been mentioned by various *Acharya*. To compare the *Vyanghar Karma* of *Laksha* obtained from Different host plants. **Material and Method- (i) Design** – Open, two armed, randomized and comparative clinical trial. **(ii) Settings** – OPD registered patients, **Participants** – 30 patients of either sex. **Intervention**– 3 groups, Group A- 10 volunteers have been given *Laksha* powder of *Ashwattha* plant. Group B- 10 volunteers have been given *Laksha* powder of *Palash* plant. Group C - 10 volunteers have been given *Laksha* powder of *Koshamra* plant. **Intervention Period -** 60 Days, **Outcome measures** – Photography. **Result-** All the three groups are observed on the basis of classical reference and size & Colour of patches. Statistically significant result was observed in group B and group A as compared to group C. **Conclusion**- The present study supports the use of *Laksha* of *Palash* and *Ashwattha* in treating *Vyanga*. With good acceptance by all treated patients.

Key word- *Vyanga, Laksha, Varnya.*

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Introduction

Vyanga is a common disorder affecting the face area and can be an embarrassing condition. It may affect the self-confidence of certain individual. It is personality damaging disease which affect on both psychic as well as somatic health. *Vyanga* is considered as a *Kshudra roga* by almost all *Acharya, Maharshi Sushruta*[1] and *Charaka*[2] considered, it also as *Raktaja Roga*. Concise description is available in classical text about *Kshudra Rogas* it is

characterized by *Shyava Varna* (Hyper-pigmentation), *Niruja* (Painless), *Tanu* (Thin), *Mandal* (Circular) etc.[3] it can be correlated to Melasma of modern medical science. *Maharshi Sushruta*[4] and *Vagbhatta*[5] have narrated some specific etiology and *Samprapti*. This disease is menifested by due to disturbed *Vata* and *Pitta Doshas* and *Rasa-Rakta Dushya*. The causative factors described in modern texts are useful to support above fact. All the causative factors like sun exposure, drug intake, hormonal changes at particular stages, vitamin deficiency, diet deficient in animal fat, green vegetables and fruits etc.[6] can be included under the broad heading of *Mithya Ahara* and *Vihara*. *Vyanga* (Melasma) is a disease has been around for centuries despite several treatment options. However, these agents have certain limitations, either due to poor efficacies or due to compliance issues. Hence in this study we tried to overcome this problem by holistic system of *Ayurveda*, through local and internal use of drug.

For the treatment of the *Vyanga* (Melasma), so many drugs are mentioned in *Ayurvedic* classics which are having *Vyangahar* action. *Laksha* is having classical references as *Varnya* and *Vyanganashan dravyas*[7].

In *Charaka Samhita Laksha is* mentioned in *Kushtha chikitsa adhyaya* for the treatment of *Kushtha*[8] and *Shivtra chikitsa*[4]. In *Sushruta Samhita* 1st time a group is mentioned of the title of *Lakshadi gana*. *Lakshadi gana* having *Kushthanashak, Kriminashak* and *Dushtavran vishodhak* property.[10] Regarding the properties of *Laksha* most of the classics has given it as *Kashaya* and *Tikta Rasa, Sheet Veerya, Laghu* and *Snigdha Guna, Katu Vipaka dravya*. *Laksha* is declared as *Kapha-Pitta Shamaka*[12] in most of the texts this may be due to its *kashaya* and *tikta rasa* and *sheet veerya*.

Aims And Objectives

1. To evaluate Pharmacognostical and Phyto-chemical study of *Laccifer lacca* Kerr.
2. To evaluate the clinical efficacy of *Laccifer lacca* Kerr. w.s.r to its effect on Melasma.
3. To provide a natural, economic, safe and easily available herb for anti- melasma of skin without any side effects.

Material & Methods

Collection of Drug

The exudates of *Laccifer lacca* Kerr of *Ashwattha* (*Ficus religiosa* Linn.) plant was collected from its natural habitat i.e. O.P.D. Garden of National Institute of Ayurveda, Jaipur. The exudate was collected in the month of June in morning time. The identification and authentication of plant material collected for study was done at Herbarium, Botany Department, Rajasthan University, Jaipur. Registration no. for *Laksha* of *Ashwattha* plant is **RUBL211469**. Other two sample viz *Palash & Koshamra* were collected from the Indian Institute of Natural Resins and Gums, (IINRG) Ranchi Jharkhand.

Method

Preparation of the drug

For the present study after the collection the drug was purified and dried in sun exposure by the scholar after that the drug was grinded and passed through fine piece of cloth to have uniform particle size. Powder of drug was prepared in the *Dravya guna* laboratory of the National Institute of Ayurveda, Jaipur.

Drug- *Laksha (Laccifer lacca* Kerr.)

Dose – Churna-1-2 gm. (twice daily) with milk for internal use, for external application paste of *Laksha* in milk was prescribed according to affected area.

Duration –Two months.

Groups:

All the volunteers were divided into three groups to compare the efficacy of the trial drug:

Group A- 10 volunteers will be given *Laksha* powder of *Ashwattha* plant.

Group B- 10 volunteers will be given *Laksha* powder of *Palash* plant.

Group C -10 volunteers will be given *Laksha* powder of *Koshamra* plant.

Consent of Volunteers:

All the volunteers selected for the trial were explained the nature of study and their consent was obtained on the Proforma before inclusion in the study.

Inclusion Criteria / Exclusion Criteria

Inclusion Criteria

- Volunteers willing to participate in the trial.
- Patients presenting with the signs and symptoms of *Vyanga* will be selected.
- Patients of either sex with the age group between 10- 50 years will be selected.

Exclusion Criteria

- Age <10 yrs and > 50 yrs
- Hyperpigmentation caused since birth like Nevus of Ota.
- Hyperpigmentation caused by tumor like malignant melanoma.
- Patients with secondary systemic involvement
- *Vyanga* along with *Kushtha roga* to be excluded.
- Patients suffering with other systemic disorders like renal failure, hepatic disorders and endocrine system related disorders.
- Associated with any other systemic and metabolic disorders are excluded because, they may alter the results of observation.
- Pregnant women's are excluded because even though the drug composition is herbal and safe still may be placental barrier and affect the foetus.
- Lactating mothers are excluded because even though the drug composition is herbal and safe still may have effect over food (milk) of infant.
- Women's using oral contraceptives are excluded because it may alter the results of observation.
- Hyper pigmentation caused since birth is excluded because, the prognosis is very bad in these conditions.

Discontinuation Criteria:

- Any sort of allergy caused by drug.
- Unable to follow the trial schedule.

Criteria of assessment

Objective Assessment: The difference in the size of the affected area will be noted. The change in complexion will be recorded by using digital camera in daylight.

Subjective Assessment: The improvement by the therapy was assessed on the basis of the following signs & symptoms. All the features were assigned score depending upon their severity to assess the effect of the drug. The detail of which is shown below.

Scoring Criteria: - For subjective parameter on the basis of classical reference

1. *Shyavata* (Darkening of the skin)

0 - Normal

1 - Mild

2 - Moderate

3 - Severe

2. *Parush-sparsh* (Dryness)

0 - Normal

1 - Mild dryness (not seen but felt by touch)

2 - Moderate dryness (stretching of the skin that person feels)

3 - Severe dryness (visible dryness and hardness of skin)

3. *Daha* (Burning sensation)

0 - No Burning sensation

1 - Mild Burning sensation

2 - Moderate Burning sensation

3 - Severe Burning sensation

4. *Kandu* (Itching)

0 - No itching

1 - Mild itching

2 - Moderate itching

3 - Severe itching

Scoring Criteria: - For subjective parameter on the basis of size and colour

5. On the basis of size of patches:-

1 - 0 -1cm - 1

2 – 1-3 cm - 2

3 - 3-6 cm - 3

4 - > 6 cm - 4

6. On the basis of colour of patches:-

0 - Normal colour

1 - Light brown

2 - Brown

3 - Dark brown

4 - Black

Observation And Result-

Assessment Of Therapy

Effect of therapy on Subjective Parameters on the basis of Classical reference -

Table No. I

Effect of *Laksha* of *Ashwattha* plant in Group A

Parameter	BT	15 days	30 days	45 days	60 days	Diff	Diff %	SD	SE	P value	Sig.
Shyavata	2.4	2.4	1.8	1.1	1.2	1.2	50	0.78	0.24	0.0039	S
Parush Sparsha	1.7	1.7	1.1	0.9	0.9	0.8	47.0	0.78	0.24	0.0156	S
Daha	0.8	0.8	0.7	0.3	0.3	0.5	62.5	0.52	0.16	0.0313	S
Kandu	0.6	0.6	0.4	0.2	0.2	0.4	66.6	0.51	0.16	0.0625	NS

Effect of *Laksha* of *Ashwattha* plant was found significant on *Shyavata, Parush sparsh, Daha* and only one parameter *Kandu* was found non-significant.

Table No. II

Effect of *Laksha* of *Palash* plant in Group B

Parameter	BT	15 days	30 days	45 days	60 days	Diff	Diff %	SD	SE	P value	Sig.
Shyavata	1.7	1.7	0.9	0.9	0.9	0.8	47.0	0.63	0.2	0.0011	S
Parush Sparsha	1	1	0.7	0.4	0.4	0.6	60	0.51	0.16	0.0119	S
Daha	0.8	0.8	0.6	0.1	0.1	0.7	87.5	0.67	0.21	0.0207	S
Kandu	0.9	0.9	0.8	0.5	0.5	0.4	44.4	0.51	0.16	0.254	NS

Effect of *Laksha* of *Palash* plant was found significant on *Shyavata, Parush sparsh, Daha* and only one parameter *Kandu* was found non-significant.

Table No. III

Effect of *Laksha* of *Koshamra* plant in Group C

Parameter	BT	15 days	30 days	45 days	60 days	Diff	Diff %	SD	SE	P value	Sig.
Shyavata	2.3	2.3	1.9	1.5	1.5	0.8	34.78	0.63	0.2	0.1038	NS
Parush Sparsha	1.4	1.4	1.2	0.7	0.7	0.7	50	0.48	0.15	0.0595	NS
Daha	0.7	0.7	0.5	0.4	0.4	0.3	42.85	0.48	0.15	0.4584	NS
Kandu	0.7	0.7	0.5	0.4	0.4	0.3	42.85	0.48	0.15	0.9141	NS

Effect of *Laksha* of *Koshamra* plant was found non-significant on all subjective parameter.

Table No. IV

Effect of Therapy by Inter group Comparison test on the basis of Classical reference between all three groups

Parameter	*Ashwattha*	*Palash*	*Koshamra*	P	Sig.
Shyavata	1.2	0.8	0.8	0.3467	NS
ParushSparsha	0.8	0.6	0.7	0.8499	NS
Daha	0.5	0.7	0.3	0.3398	NS
Kandu	0.4	0.4	0.3	0.8704	NS

After this statistical analysis of inter group comparison for subjective parameters (*Shyavata, Parush-sparsh, Daha* and *Kandu) shown* non-significant results.

Table No. V

Comparison of Effect of Therapy on the basis of Classical reference between all three groups

S. N.	Sign & symptoms	Relief in percentage		
		Group A	Group B	Group C
1	***Shyavata***	50	47.05	34.78
2	***ParushSparsha***	47.05	60.00	50.00
3	***Daha***	62.50	87.5	42.85
4	***Kandu***	66.66	44.44	42.85

On comparing the results of all three groups on the basis of all classical subjective parameters it was observed that *Laksha* of *Palash* (Group B) plant gave more relief as compared to *Laksha* of *Ashwattha* (Group A) followed by *Laksha* of *Koshamra* (Group C) plant.

Effect of therapy on Subjective Parameters on the basis of Size and Colour of patches-

Table No. VI

Effect of *Laksha* of *Ashwattha* plant in Group A

Parameter	BT	15 days	30 days	45 days	60 days	Diff	Diff %	SD	SE	P value	Sig.
Size	2.1	2.1	2.1	1.1	1.1	1	47.6	0.66	0.21	0.0039	S
Colour	2.5	2.5	2.1	1.2	1.2	1.3	52	0.94	0.30	0.0039	S

Effect of *Laksha* of *Ashwattha* plant was found significant on Size of patches and Colour of patches.

Table No. VII

Effect of *Laksha* of *Palash* plant in Group B

Parameter	BT	15 days	30 days	45 days	60 days	Diff	Diff %	SD	SE	P value	Sig.
Size	1.8	1.8	1.5	0.9	0.9	0.9	50	0.73	0.23	0.0151	S
Colour	2	2	1.6	1	1	1	50	0.81	0.25	0.0002	HS

Effect of *Laksha* of *Palash* plant was found highly significant on Colour of patches & significant on Size of patches.

Table No. VIII

Effect of *Laksha* of *Koshamra* plant in Group C

Parameter	BT	15 days	30 days	45 days	60 days	Diff	Diff %	SD	SE	P value	Sig.
Size	2.1	2.1	1.6	1.3	1.3	0.8	38.0	0.42	0.13	0.0758	NS
Colour	2.5	2.5	2.1	1.6	1.6	0.9	36	0.56	0.17	0.1572	NS

Effect of *Laksha* of *Koshamra* plant was found non-significant on Size of patches & Colour of patches.

Table No. IX

Effect of Therapy by Inter group Comparison test on the basis of Size and Colour of patches between all three groups

Parameter	*Ashwattha*	*Palash*	*Koshamra*	P	Sig.
Size	1	0.9	0.8	0.7909	NS
Colour	1.3	1	0.9	0.5783	NS

After this statistical analysis of inter group comparison in Size & Colour of patches shown non-significant results.

Table No. X

Comparison of Effect of Therapy on the basis of Size and Colour between all three groups

S. N.	Sign & symptoms	Relief in percentage		
		Group A	Group B	Group C
1	**Size**	47.61	50	38.09
2	**Colour**	52	50	36

On comparing the results of all the three groups on the basis of Size and Colour of patches. It was observed that *Laksha* of *Palash* (Group B) plant and *Laksha* of *Ashwattha* (Group A) plant were given almost equal relief whereas least improvement was seen in *Laksha* of *Koshamra* (Group C) plant.

Discussion-

Effect Of Therapy On Subjective Parameters On The Basis Of Classical Reference-

Effect of *Laksha* of *Ashwattha* plant in Group A

By applying Wilcoxan Signed Rank ('α' value) test following results were obtained

Effect of *Laksha* of *Ashwattha* plant on *Shyavata*: *Laksha* of *Ashwattha* plant had reduced the *Shyavata* by 50.00% which was statistically significant (p<0.0039).

Effect of *Laksha* of *Ashwattha* plant on *Parush Sparsh:* *Laksha* of *Ashwattha* plant had reduced *Parush Sparsh* by 47.05% which was statistically significant (p<0.0156).

Effect of *Laksha* of *Ashwattha* plant on *Daha*: *Laksha* of *Ashwattha* plant had reduced *Daha* by 62.50% which was statistically significant (p<0.0313).

Effect of *Laksha* of *Ashwattha* plant on *Kandu*: *Laksha* of *Ashwattha* plant had reduced *Kandu* by 66.66 % which was statistically non-significant (p<0.0625).

Effect of *Laksha* of *Palash* plant in Group B

By applying Wilcoxan Signed Rank ('α' value) test following results were obtained

Effect of *Laksha* of *Palash* plant on *Shyavata*: *Laksha* of *Palash* plant had reduced the *Shyavata* by 47.058% which was statistically significant (p<0.001).

Effect of *Laksha* of *Palash* plant on *Parusha sparash:* *Laksha* of *Palash* plant had reduced *Parusha sparasha* by 60% which was statistically significant (p<0.011).

Effect of *Laksha* of *Palash* plant on *Daha*: *Laksha* of *Palash* plant had reduced *Daha* by 87.5% which was statistically significant (p<0.0207).

Effect of *Laksha* of *Palash* plant on *Kandu*: *Laksha* of *Palash* plant had reduced *Kandu* by 44.44 % which was statistically non-significant (p<0.254).

Effect of *Laksha* of *Koshamra* plant in Group C

By applying Wilcoxan Signed Rank ('α' value) test following results were obtained

Effect of *Laksha* of *Koshamra* plant on *Shyavata*: *Laksha* of *Koshamra* plant had reduced the *Shyavata* by 34.782% which was statistically non-significant (p<0.1038).

Effect of *Laksha* of *Koshamra* plant on *Parusha sparash:* *Laksha* of *Koshamra* plant had reduced *Parusha sparasha* by 50% which was statistically non-significant (p<0.0595).

Effect of *Laksha* of *Koshamra* plant on *Daha*: *Laksha* of *Koshamra* plant had reduced *Daha* by 42.857% which was statistically non-significant (p<0.4584).

Effect of *Laksha* of *Koshamra* plant on *Kandu*: *Laksha* of *Koshamra* plant had reduced *Kandu* by 42.857% which was statistically non-significant (p<0.9141).

Laksha of *Palash* plant (Group B) was found to be more effective in subjective parameter like, *Parush-Sparsh* and *Daha* as compare to *Laksha* of *Ashwattha* (Group A) and *Laksha* of *Koshamra* (Group C) plant. *Laksha* of *Ashwattha* plant (Group A) was found to be more effective in subjective parameter like, *Shyavata* and *Kandu* as compare to *Laksha* of *Palash* (Group B) and *Laksha* of the *Koshamra* (Group C) plant.

Effect Of Therapy On Subjective Parameters On The Basis Of Size And Colour Of Patches

Effect of *Laksha* of *Ashwattha* plant in Group A

By applying Wilcoxan Signed Rank ('α' value) test following results were obtained

Effect of *Laksha* of *Ashwattha* plant on Size of patches: *Laksha* of *Ashwattha* plant had reduced size of patches by 47.61% which was statistically highly significant (p<0.0039)

Effect of *Laksha* of *Ashwattha* plant on Colour of patches: *Laksha* of *Ashwattha* plant had reduced the colour of affected area by 52 % which was statistically highly significant (p<0.0039).

Effect of *Laksha* of *Palash* plant in Group B

By applying Wilcoxan Signed Rank ('α' value) test following results were obtained

Effect of *Laksha* of *Palash* plant on Size of patches: *Laksha* of *Palash* plant had reduced the size of patches by 50% which was statistically significant (p<0.015).

Effect of *Laksha* of *Palash* plant on Colour of patches: *Laksha* of *Palash* plant had reduced the colour of patches by 50% which was statistically highly significant (p<0.0002).

Effect of *Laksha* of *Koshamra* plant in Group B

Effect of *Laksha* of *Koshamra* plant on Size of patches: *Laksha* of *Koshamra* plant had reduced the size of patches by 38.09% which was statistically non-significant (p<0.0758).

Effect of *Laksha* of *Koshamra* plant on Colour of patches: *Laksha* of *Koshamra plant* had reduced the colour of patches by 36% which was statistically non-significant (p<0.1572).

Laksha of *Palash* (Group B) and *Laksha* of *Ashwattha* (Group A) plant was found to be more effective in subjective parameter like Size and Colour of patches, compare than *Laksha* of *Koshamra* (Group C) plant.

Mode Of Action Of Mukhalepa:

The classical therapeutic management of *Vyanga* is described as *Shodhana* and *Shamana* Thearapy. For the management of *Vyanga Roga Shodhan* therapy like *Vaman, Virechana, Nasya, Raktamokshana* has been recommended. For the *Shaman* therapy purpose many single or compound formulations are advocated either internally or externally or both ways. The *Ayurvedic* pathogeneisis involves vitiation of *Dosha* starting at the *Koshtha* level and subsequent at *Srotas* level. *Pitta* is said to be a *Varn Prakashak* and therefore vatiation of *Pitta* leads to discoloration of skin but this is an associated etiological factor in *Vyanga* whereas *Vata* is the predominant *dosha* in the etiology of *Vyanga*. *Ruksha guna* of *Vata dosha* is the principal causative factor for disease process of *Vyanga*. The *Ruksha* guna of *Vata dosha* is manifested as *Rukshta* in skin. Therefore application of *Snigdha dravyas (Laksha)* as *Lepa* is postulated to reduce *Rukshata*.*Vata* and *Pitta* was pacified by the *Sheeta Veerya* of the drug used for *Lepa*.

Probable Mode Of Action Of Drug:

Vyanga is occur due to vitiation of *Vata* and *Pitta dosha*. The *Rasa* of drug is *Kashaya, Tikta*. Vitiated *Vata* and *Pitta* get localized on the face and gives rise to a patch on the skin, which is painless, thin and brown-black in colour. So *Kashaya and Tikta Rasa* subdues the *Pitta* which is the main cause of the disease. The *Guna* of drug is *Laghu-Snigdha*. Due to *Snigdha Guna* it alleviates the *Vata*. It breaks the etiology of *Vyanga* by subsiding *Pitta* & *Vata*.

- *Tikta Rasa* acts as *Agnideepaka, Krimighna,*

Kandughna, pacifies vitiated *Pitta* and is *Laghu* in property. Due to *tikta rasa,* and *sheeta veerya* it act as *Pittahara*.

- The drug has *Sheet Veerya,* which is beneficial for skin disorder like *Vyanga,* due to its *Pittashamak* property. *Sheet veerya* is *Prasadana, Kledana* and *Jeevaniya* as it promotes tissue firmness.
- *Laksha* has been mentioned in *Bhava Prakasha nighantu* as *Varnya*. *Shyavata* being the classical symptom of *Vyanga*, occurs due to *Vata* and *Pitta Dosha*. This symptom is treated by *Laksha* due to its *snigdha guna* and *tikta rasa*.
- *Parush sparsh* in *Vyanga* is due to *Abhyanga dvesha* and other *Vata* vitiating *Nidanas* which causes roughness of face. *Parush sparsh* is pacified by *Snigdha guna* of *Laksha*.
- *The Kandu* was found in some volunteers in the study. Which occurs due to *Kapha* dominant *dosha dushti*. *Laksha* have *kapha shamaka* due to its *kashaya, tikta rasa* and *katu vipak*.
- Aggravation of *Piita dosha* causes *daha* in *vyanga, Laksha does Pitta shaman* owing to its *tikta rasa and sheeta veerya*.
- *Laksha* has been used as *Balya* drug due to its *Snigdha guna* and *sheeta veerya*. It pacifies *vata* and *pitta dosha*, thus providing nourishment to the tissue and especially skin, causing restoration of skin lustre.
- The drug has *Laghu guna,* thus acting as *Srotoshodhaka,* and *Agnidipaka*.
- According to ayurvedic text *Laksha* is *Vishaghna, Krimighna, Vranaropak, Vranshodhak, Shothhar* and *Dahahar*.
- In modern aspect *Laksha* has cooling, astringent, haemostatic, anti-inflammatory, and anti-oxidant effect. So the drug *Laksha* is useful for skin diseases externally as well as internally.

Conclusion:

- The trial drug *Laksha* of *Palash* (Group B) and *Laksha* of *Ashwattha* (Group A) plant, (when given in powder form 1-2 gm. b.d. for 60 days for internal use and for local application paste of *Laksha* in milk was prescribed according to affected area), reduced the colour and size of patches in a statistically significant manner. *Laksha* of *Koshamra* (Group C) plant, (when given in powder form 1-2 gm. b.d. for 60 days for internal use and for local application paste of *Laksha* in milk was prescribed according to affected area) reduced the colour and size of patches but statistically non-significant manner.
- *Laksha* of *Palash* and *Ashwattha* plant reduced the color and size of patches more than *Laksha* of *Koshamra* plant.
- Therefore it is concluded that *Laksha* of *Palash* and *Ashwattha* when used in *Vyanga* patient it clear the affected area and is a safe and effective drug for treating *Vyanga*.
- *Laksha* of *Ashwattha, Palash* and *Koshamra* plant does not produce any ADRs in the prescribed dose and duration.
- The study reaffirms *Laksha* as a low cost, safe, effective, easily available and traditionally acceptable drug for the reducing *Vyanga* of the affected population.

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सारांश –

व्यङ्ग एक क्षुद्र रोग है जो कि दु:खद स्थिति उत्पन्न करती है। आयुर्वेद शास्त्र मे लाक्षा का वर्णन व्यङ्गहर द्रव्य के रुप मे उक्त है। त्वक विकरो के लिए लाक्षा एक उत्तम औषध है जो व्यङ्गहर, वर्ण्य, कुष्ठघ्न, कृमिघ्न द्रव्य के रुप मे लाक्षा उल्लेखित है।

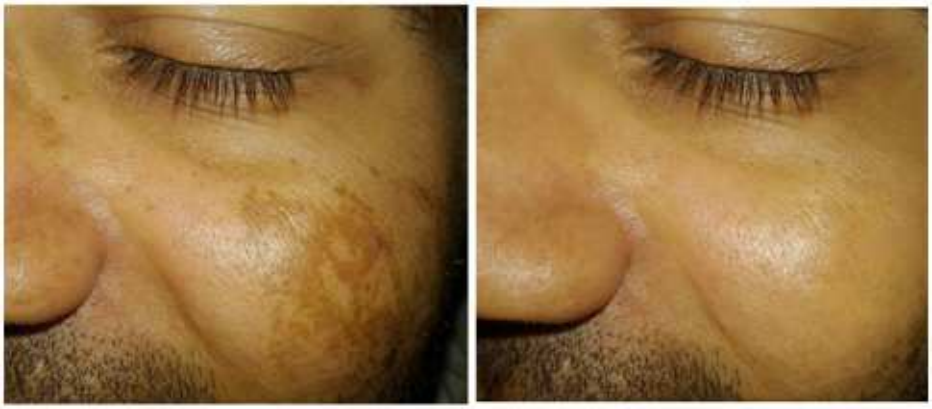
उद्देश्य– लाक्षा के व्यङ्गहर कर्म का अध्ययन जो की विभिन्न आचार्यो ने बताया है। तथा विभिन्न पादपो से प्राप्त लाक्षा के व्यङ्ग मे प्रभावकारिता का तुलनात्मक अध्ययन।

सामग्री और विधि – (i) डिजाईन – ओपन, द्वि–दिशीय, बिनाक्रमयुक्त और तुलनात्मक चिकित्सीय परीक्षण (ii) **सेटिंग्स** – ओपीडी पंजीकृत रुग्ण, **प्रतिभागी**– पुरूष तथा स्त्री वर्ग के रुग्ण, चिकित्सकीय वर्ग –3 समूहों, समूह ए– 10 प्रतिभागियो को अश्वत्थ की लाक्षा दी गई, समूह बी –10 प्रतिभागियो को पलाश की लाक्षा दी गई, समूह सी– 10 प्रतिभागियो को कोशाम्र की लाक्षा दी गई, **चिकित्सा अवधि** – 60 दिन, **परिमापन उपाय** – प्रभावित भाग की चित्रकरी।

परिणाम – सभी तीनो समूहों का अवलोकन शास्त्रोक्त लक्षण तथा आकार व वर्ण के आधार पर करने पर सांख्यिकीय रूप से महत्वपूर्ण परिणाम समूह बी और समूह ए मे लगभग समान पाया गया जबकि समूह सी मे तुलनात्मक रुप से कम पाया गया।

निष्कर्ष–वर्तमान अध्ययन से स्पष्ट होता है कि पलाश व अश्वत्थ की लाक्षा कोशाम्र की अपेक्षा श्रेष्ठ रुप मे व्यङ्ग व्याधि को दुर करती है साथ ही साथ सभी रुग्णो में अच्छा व्यङ्गहर कर्म करती है।

Group A

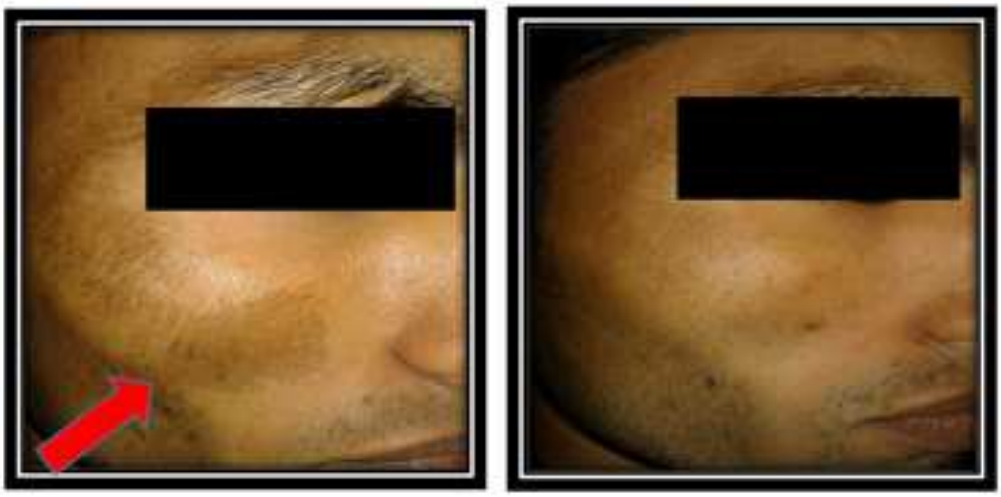


Before **After**

Before **After**

Before **After**

Group B



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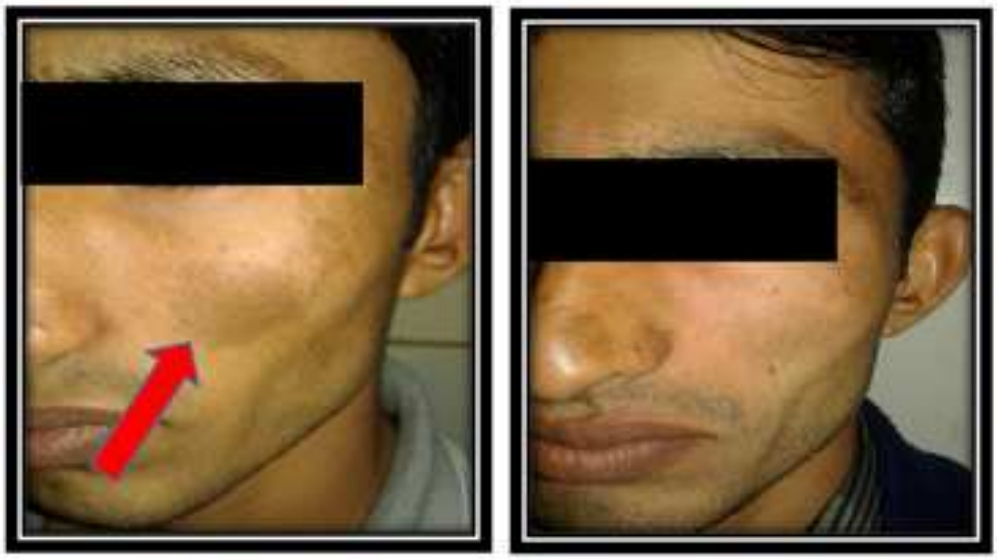

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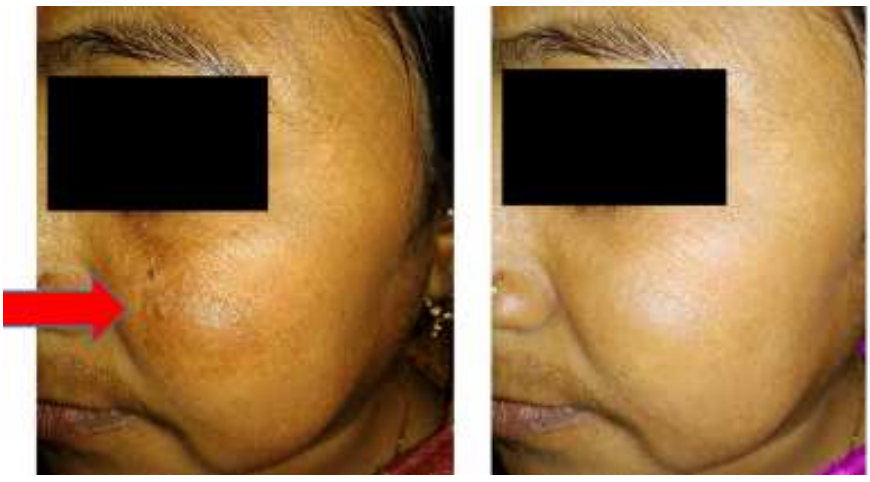

Before After

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ORIGINAL ARTICLE

Anti-Microbial Study on Different Samples of *Lavangadi Vati*

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ABSTRACT

Infectious diseases are a great challenge to human existence and the leading cause of death world-wide. Haemophilus influenzae is a small (1.0 × 0.3µm), gram-negative, non motile, non-sporing bacillus, exhibiting considerable pleomorphism. H. influenza is an exclusively human pathogen. Diseases caused by H. influenza may be categorized into two groups; they are- Invasive and Non-Invasive. In Non-invasive group, the bacillus spread by local invasion along mucosal surfaces and causes secondary or superadded infections, usually of the respiratory tract. Cough is the symptom which arises in Respiratory tract during this non-invasive infection. Lavangadi vati is the solid dosage form, comes under the *Vati kalpana* which is used in the treatment of cough. Because of its quick action in the treatment of cough, the object of the study is to evaluate the antimicrobial activity of 3 different formulation of *Lavangadi vati* against the H. Influenza. Antimicrobial susceptibility test was performed by well diffusion methods.

The result shows that in comparison with S1, S2 and S3; S2 formulation at \100mg/ml shows the best result against H. influenza i.e. 30mm ZOI comparative to 10 mg/ml Streptomycin.

Key Words:- Antimicrobial activity, Haemophilus influenza, *Lavangadi vati.*

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Introduction

Infectious diseases account for approximately one-half of all death in tropical countries. Infectious diseases are enchanted by factors such as inadequate sanitation, poor hygiene and overcrowding conditions. *Ayurveda* includes all type of diseases, for example indigestion-oriented (*Ajeernaja*), immune-compromised (*Oja-kshayaja*) and infectious diseases (*Aupsargaja*).

The term *Aupasargaja Vyadhi* is used for infectious and contagious diseases.[1] *Krimi* and *Bhoota*

are terms that may be co-related to microbes. From *Krimi*, *Raktaja Krimi* seems to be nearer to microbes because these are invisible and live in blood vessels. *Bhoota* are invisible, so they may be microbes.

Haemophilus influenzae is a small (1.0 × 0.3µm), gram-negative, non motile, non-sporing bacillus, exhibiting considerable pleomorphism. In sputum, it usually occurs as clusters of *coccobacillary* forms. *H. influenza* is an exclusively human pathogen. Diseases caused by *H. influenza* may be categorized into two groups; they are- Invasive and Non-Invasive. In Non-invasive group, the bacillus spread by local invasion along mucosal surfaces and causes secondary or superadded infections, usually of the respiratory tract. These include otitis media, sinusitis and exacerbations of chronic bronchitis and bronchiectesis. These are usually seen in adult and are often caused by the non-capsulated strains. Cough is the symptom which arises in respiratory tract during this non-invasive infection[2].

Now a days using antibiotics to subside infection produces adverse toxicity to host organs, tissues and cells[3]. Herbal molecules are safe, will overcome the resistance produced by the pathogens since they are in combined form or in pooled form of more than one molecule in the protoplasm of plant cell[4]. Some herbs have antibacterial and antifungal properties which will be useful to clinical use.[5] *Lavangadi Vati* is a most popular and effective medicine in the treatment of cough. It is an *Ayurvedic* solid dosage form prescribed for curative measure in all types of cough. One of the causative factor of cough is due to various infections in the upper and lower respiratory tract. As per *Ayurvedic* classics it may due to *Krimi*. Therefore the objective of the study is to evaluate the antimicrobial activity of this preparation against the pathogenic bacteria *Haemophilus influenza*.

Materials and Method:-

- The raw material used for the preparation of *Lavangadi vati* was procured from Pharmacy, NIA, Jaipur. All the raw material was authenticated and screened in *Rasasashtra* and *Bhaishajya kalpana* department, NIA before formulation development.
- The First sample (S1) was prepared as per specific reference of *Vaidya jivanam* written by *Loliambaraj*[6] with three times *Bhavana* of *Babbul Twaka kwatha*.
- The second sample (S2) was prepared with modified method of *Vaidya Jivanam*. Here *Bhavana* was given with *khadir Sara kwatha*, instead of *Babbul Twaka kwatha*. *Babbula Twaka Churna* was mixed with the other ingredients. All the materials were the same as mentioned in *Vaidya Jivanam*.
- The third sample (S3) was prepared same as per S1 only difference in seven times *Bhavana* of *Babbul Twaka kwatha* instead of three times.
- The antimicrobial susceptibility test performed by Well diffusion method on Muller Hinton (MH) agar[7] using 3 different samples of *Lavangadi vati* formulations against *Haemophilus influenza*.

Number of *Bhavana*:-

In the SOP of *Lavangadi vati*, the number of *Bhavana* is not mentioned in the *Vaidya jivanam*. So, the numbers of *bhavana* adopted here with were as general principle/average classical preparation.

Three numbers of *Bhavana* – No reference for giving three numbers of *Bhavana* was found in the classics in the preparation of *Lavangadi vati*. However, in the SOPs of various formulations like *Ajirnahara vati*, *Amritprabha vati*, *Agnikumar Rasa*, *Agnisandipan Rasa*, *Umasambhu Rasa*, *Khadiradi Gutika* [8] etc. three number of *Bhavana* has been carried out. Considering the above point of view, in the present research work, 3 number of *Bhavana* was done in the 2 batches of *Lavangadi vati* (S1 & S2).

Seven numbers of *Bhavana*[9]- *Vaidyaka Paribhasa Pradipa* clearly mentioned the procedure for seven times of *Bhavana*, where no such reference of number of *Bhavana* is available for a particular formulation. Considering this reference the seven times of *Bhavana* was given in one batch of *Lavangadi vati* (S3) in the present research work.

Preparation of *Babbula Twaka kwatha* (Ref.- *Rasatarangini* 2/50-51)

In the preparation of *Babbul Twaka kwatha* (Decoction) for *Bhavana* process, fresh *kwatha* was prepared by using coarse powder boiled with distilled water in the ratio of 1:8 times[10] each time for each *Bhavana*. Showing of ingredient proportion of *Drava Dravya* in Table I.

Table No.1- Showing Ingredient and proportion of *Drava dravya*

S. No.	Name	Part used	Quantity	Proportion
1	*Babbul*	Bark	300 grams	1:8
2	Distilled Water	——-	2400 ml.	

Procedure: -

Before starting the process all equipments were cleaned. Coarse powder of *Babbul Twaka* was soaked with Distilled water in a medium size stainless steel vessel and kept it for overnight. Next morning the soaking mixture in vessel was put on mild fire using gas stove at the temperature in between 76°c to 78°c. The quantity was then reduced to 1/8th (300ml) part of the initial (2400ml). This was then filtered through a clean cotton cloth and stored in a glass beaker for *Bhavana* process. Various observations during the preparation of *Babbul Twaka kwatha* are shown in the following table.

Table No.II- Showing various observations during and after the preparation of *Babbul Twak Kwatha*

***Kwatha* (Kw) sample**	**Kw 1**	**Kw2**	**Kw3**	**Kw4**	**Kw5**	**Kw6**	**Kw7**	**Kw8**	**Kw9**	**Kw10**
Time spent for preparation of *kwatha* (in hour)	2.45	2.45	2.56	2.54	2.50	2.45	2.45	2.50	2.55	2.45
Amount of *Kwatha* (in ml)	300	300	300	300	300	300	300	300	300	300
Residue	1/8th	1/8th	1/8th	1/8th	1/8th	1/8th	1/8th	1/8th	1/8th	1/8th
Colour	Dark Brown	Dark Brown	Dark Brown	Dark Brown	Dark Brown	Dark Brown	Dark Brown	Dark Brown	Dark Brown	Dark Brown
Odour	Plea-sant	Plea-sant	Plea-sant	Plea-sant	Plea-sant	Plea-sant	Plea-sant	Plea-sant	Plea-sant	Plea-sant
Taste	Astring-ent	Astring-ent	Astring-ent	Astring-ent	Astring-ent	Astring-ent	Astring-ent	Astring-ent	Astring-ent	Astring-ent
PH	3.7	3.7	3.8	3.7	3.7	3.7	3.8	3.7	3.7	3.7
Refractive Index	1.344	1.344	1.345	1.344	1.344	1.344	1.345	1.344	1.344	1.344
Bricks value	7	7	8	7	7	7	8	7	7	7
Specific gravity	1.028	1.028	1.026	1.028	1.028	1.028	1.026	1.028	1.028	1.028

Preparation of *Khadir Sara* solution for *Bhavana* process: -

As the second sample of the study was a modified one, here *Bhavana* was given by *Khadir Sara kwatha* instead of *Babbul Twaka kwatha*. In this preparation, *Khadir Sara* powder was dissolved in distilled water and converts it to liquid form to perform easy and comfort trituration (*Bhavana*). Freshly prepared *Khadir Sara kwatha* was made each time for each *Bhavana*. In preparation of *Khadir Sara kwatha* the ratio of water and ingredient was the same as in case of preparation of *Babbul Twaka kwatha*.

Table No.III- Showing the ingredient and proportion of *Drava Dravya*

S. No.	Name	Part used	Quantity	Proportion
1	*Khadir*	*Sara*	50 grams	1:8
2	Distilled Water	——	400 ml	

Procedure: -

Before starting the process all equipments were cleaned. *Khadir Sara powders were kept first in a small size stainless steel vessel and then add* distilled water into vessel with *khadir Sara*. Stir the whole mixer of vessel slowly until the *khadir Sara* dissolved completely in water. When *Khadir Sara* was completely dissolved, the solution kept in beaker. This method was adopted three times for making three preparation of *khadir Sara kwatha* for three times *Bhavana* in second sample.Various organoleptic and physiochemical observation found in *Khadir Sara kwatha* shown in Table no-IV.

Table No.IV- Showing various observations during and after the preparation of *Khadir Sara kwatha*

***Khadir Sara kwatha* (Kh)**	**Kh 1**	**Kh 2**	**Kh 3**
Colour	Pink	Pink	Pink
Odour	Odorless	Odorless	Odorless
Taste	Astringent	Astringent	Astringent
P^H	5.7	5.7	5.7
Refractive Index	1.412	1.412	1.412
Bricks value	46	46	46
Specific gravity	1.00769	1.00769	1.00769

Preparation of *Lavangadi Vati* sample-

Three samples of *Lavangadi Vati* were labeled as S1, S2 and S3 respectively. In all the 3 samples the quantity of chief ingredients *Lavanga, Maricha, Bibhitaka* and *Khadir Sara* were the same. But *Babbul Twaka* was used as *kwatha* form in S1 and S3. Whereas *Babbula Twaka* was used in fine powder form in S2 sample. Prepared each handmade *Vati* weighed~ 1gm dose according to AFI[11].

Preparation of *Lavangadi vati* sample S1-

50 gram of fine powder of each ingredient (*Lavang, Maricha* and *Bibhitaka*) were weighed and kept separately. Equal to the total quantity of above drugs i.e. 150 grams of *khadir Sara* were weighed and kept separately. All the powder of ingredients was then mixed thoroughly and makes a homogenous mixture in a steel tray. Then this homogenous mixture was shifted into a medium size *Khalva*

Yantra and three times *Bhavana* was given with *Babbul Twak kwatha*. It requires 170ml, 106ml and 100ml of *Babbul Twak kwatha* for first, second and third *Bhavana* respectively.

Preparation of *Lavangadi Vati* sample S2-

50 grams of fine powder of each ingredient *Lavanga, Maricha* and *Bibhitaka* were weighed and kept separately. Equal to the total quantity of above drug i.e.150 grams of *Babbul Twaka churna* were weighed and kept separately. All the above mentioned powder of the ingredients was then mixed thoroughly to make a homogenous mixer in a stainless steel tray. The mixer of the powder was then shifted to a medium size *khalva Yantra* and three times *Bhavana* was given with *khadir Sara* solution. Each *Bhavana* was given with 400 ml of *khadir Sara kwatha.*

Preparation of *Lavangadi Vati* sample S3-

50 gram of fine powder of each ingredient (*Lavanga, Maricha* and *Bibhitaka*) were weighed and kept separately. Equal as total quantity of above drugs i.e. 150 grams of *khadir Sara* were weighed and kept separately. All the powder of ingredients was mixed thoroughly and makes a homogenous mixture in a steel tray. Then this homogenous mixture was shifted into a medium size *khalva Yantra* and seven times *Bhavana* was given with *Babbul Twaka kwatha*. It requires 170ml, 110ml, 100ml, 100ml, 100ml, 90ml, 90ml of *Babbula Twaka kwatha* for 1st, 2nd, 3rd, 4th, 5th, 6th and 7th *Bhavana* respectively.

Anti-microbial susceptibility test:

The *anti-haemophilus* activity of different formulations of *Lavangadi vati* was performed. *H. influenze* was used for testing *in-vitro* antimicrobial activity. Identification of microbial strain was based on morphological, cultural and biochemical tests. *In vitro anti-haemophilus* activity was performed by well diffusion method on bacteria seeded Muller Hinton agar, wells of 6 mm were made on seeded agar by using pre-sterilized cork borer. Aliquot of 60µl of each formulation S1, S2 and S3 (1, 10 and 100 mg/ml in DMSO) and standard antibiotic Streptomycin (10 mg/ml) was added into labeled wells on seeded medium and allowed to stand for 1 hour on the bench for proper diffusion thereafter incubate for 37±2°C for 24 hour. The resulted inhibition zones were measured in millimeters (mm). Negative control of 60 µl of DMSO was also run in a same manner and parallel to the treatments. Zone of inhibition of samples were compared with corresponding concentration of standard drug.

Results:-

Table No.V- Showing the Antimicrobial susceptibility test result of the 3 samples of Lavangadi Vati against Haemophilus influenza.

S. No.	Sample	Standard and Dilution	Sample Inject	ZOI Result
1	*Lavangadi Vati* S1	Standard (10mg/ml)	60 µl	28mm
		1mg/ml	60 µl	17mm
		10mg/ml	60 µl	19mm
		100mg/ml	60 µl	25mm
2	*Lavangadi Vati* S2	Standard (10mg/ml)	60 µl	34mm
		1mg/ml	60 µl	17mm
		10mg/ml	60 µl	22mm
		100mg/ml	60 µl	30mm

3	*Lavangadi Vati* S3	Standard (10mg/ml)	60 µl	31mm
		1mg/ml	60 µl	13mm
		10mg/ml	60 µl	22mm
		100mg/ml	60 µl	27mm

Figure No.- 1, Showing the Antimicrobial activity of *Lavangadi vati* against the bacteria *Haemophilus influenza*. at 100 mg per ml constraction.

Discussion:-

Three different formulations of *Lavangadi Vati* (S1, S2 and S3) were prepared using classical and modified method to check their *in-vitro anti-haemophilus* activity (shown in table no V). The antimicrobial susceptibility test performed for M.H. agar using different concentration of *Lavangadi Vati* formulations (Figure shown study plates in Figure no.1). In comparison with S1, S2 and S3; S2 formulation at 100 mg/ml shows the best result against *H. Influenza* i.e. 30mm Zone of Inhibition comparative to 34 mm of Streptomycin (10 mg/ml). This results confirm that sample drug possess 88% of activity comparative to standard antibiotic at specific concentration. S2 formulation shows higher susceptibility against *H. Influenza*, possibly *Khadir Sara trituration* may synergistically improve the antimicrobial property of other ingredients of *Lavangadi vati*.

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सारांश:

संक्रामक रोग मानव मृत्यु का एक प्रमुख कारण है जो विश्व के लिए बड़ी चुनौती है। हीमोफिलस इन्फ्लुएंजा ग्राम निगेटिव, नॉन मोटाइल, नॉन-बेसिलस समूह का जीवाणु है, जो बहुरूपता प्रदर्शित करता है। एच इन्फ्लुएंजा विशेष रूप से मानव रोग उत्पत्ति कारक है। इसके कारण होने वाले रोगों को दो समूहों में वर्गीकृत किया जा सकता है -इनवेसिव और नॉन-समूह में, बेसिलस का आक्रमण स्थानिक से म्यूकोसल सतहों में फैलता है और प्राय:श्वसन तंत्र के संक्रमण में सहायक होता है अथवा सुपर ऐडेड कारण बनता है। इस नॉन इनवेसिव संक्रमण में श्वसन तंत्र में कास एक लक्षण के रूप में उत्पन्न होता है। लवंगादी वटी, वटी कल्पना के अंतर्गत आता है। जिसका उपयोग कास की चिकित्सा में किया जाता है। लवंगादी वटी कास की चिकित्सा में शीघ्र प्रभावकारी होने के कारण लवंगादी वटी के 3 अलग-फॉर्मूलेशन्स का निर्माण करके एच इन्फ्लुएंजा के विरुद्ध रोगाणु प्रतिरोधी प्रतिक्रिया का मूल्यांकन किया गया। रोगाणुप्रतिरोधी संवेदनशीलता की परीक्षा वेल डीफुजन विधि द्वारा किया गया। तीनो फॉर्मूलेशन 1, 2 और 3 की तुलना में; एस-2 का परिणाम 100/mg/ml पर एच इन्फ्लुएंजा के विरुद्ध सबसे अच्छा अर्थात ZOI 30mm रहा।

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ORIGINAL ARTICLE

In-Vitro Evaluation of Anti-Microbial Effect of Herbal Formulation

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ABSTRACT

Surgical infection, particularly surgical site infection (SSI), is a major concern of surgery. Micro-organisms contaminate these wounds and delays wound healing, Use of anti-microbial agents are very important for prevention of sepsis. The aim of this study was to investigate the anti-microbial potential of different extracts of flowers of *Hibiscus rosa sinensis* Linn., leaves of *Melia azedarach* Linn. and leaves and stem of *Jatropha curcas* Linn. in combination in a suitable formulation (ointment) against *S. aureus*, *E. coli*. *Klebsiella sp.* and *P.aeruginosa*. Majorly responsible for surgical wound infection, using agar well diffusion technique. Aqueous and alcoholic extracts of *Hibiscus rosa-sinensis* Linn. showed antimicrobial activity against *Klebsiella* sp and *P. aeruginosa*, while the alcoholic extracts of *Melia azedarach* and *Jatropha curcas* showed activity with different microorganisms individually. In ointment form, the combination did not exhibit significant activity. This is indicative of fact that the combination might nullify each other's effect resulting in loss of effectiveness. Thus, the ointment prepared from combination of test substances does not possess anti-microbial activity.

Keywords:- Anti-microbial, Herbal, *Ayurveda*, Hibiscus, *Melia azedarach*, *Jatropha curcas*

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Introduction

Ayurveda is a holistic system of medicine nurturing human lives since ancient times. Drugs in Ayurveda plays important role not only as dietetics but also in treatment of various diseases and disorders by being an integral part of *Chikitsa Chatushpada*.[1] According to Ayurveda, diseases develop due to imbalance of *Tridosha*. Apart from this, concept of micro-organism affecting the human being is also present in Ayurveda texts as is evident in *Charak samhita*.[2] *Dalahana* in his commentary on

Sushruta samhita indicated towards the infectious diseases.[3] There is abundant material available regarding *Krimi* in *Vedic* literature like *Atharvaveda* and *Rigveda*. *Krimi* are mentioned in Ayurveda literature as *Sukshma krimi, Rakshash, Bhoot, Adrashta, Durnama* etc. Along with *Vata, Pitta* and *Kapha, Krimi* plays an important role in pathogenesis of various infective diseases.

Infections have long been a major health concern to entire human population, more so in under developed & developing countries of the world like India, especially the infection of post-operative wounds. In surgical procedures, break in the continuity of skin occur leading to formation of surgical wound. As it is an unavoidable part of surgery, surgical wounds needs to be taken care of, from any infections for proper healing. This creates space for the development of suitable herbal anti-microbial formulation to be used topically for prevention of wound infections.

In Ayuveda, many drugs have been mentioned having *krimighna* activity i.e. these plants kill or inhibit the growth of harmful microorganisms. Various researches done on *Japa, Mahnimba* and *Vyaghra eranda* in modern science explore the anti-microbial activity of their parts. These parts can be used to produce effects on both systemic and topical use. P Ruban et al reported antibacterial activity of hibiscus flowers against the human pathogens such as *E. coli*, *B. subtillis*, *P. aeruginosa*, *S. aureus*, *Streptococcus* sp. *Salmonella* sp.[4] while Sen et al reported activity of Ethanol, Methanol, Petroleum ether and aqueous extracts of *M. azedarach* against the locally isolated human pathogens like *Escherichia coli*, *Staphylococcus aureus*, *Bacillus cereus*, and *Pseudomonas aeruginosa*.[5] Stem bark of *Jatropha curcas* shows effective anti-bacterial activity in its methanolic extract against different pathogenic bacteria.[6]

Material and methods:-

Collection and preparation of plant parts:

Fresh flowers of *Hibiscus rosa sinensis* Linn. (*Japa*), Leaves of *Melia azedarach* Linn. (*Mahanimba*), leaves and stem of *Jatroha curcas* Linn. (*Vyaghra eranda*) were collected from the field area of NIA, Jaipur, Rajasthan. Their identities were confirmed with the available literature and authenticated by the Department of the Botany, Rajasthan University.

Table No. I:-

Sr. No.	Plant Name	Herbarium Account No.
I.	*Hibiscus rosa-sinensis* Linn.	RUBL211533
II.	*Melia azedarach* Linn.	RUBL211534
III.	*Jatropha curcas* Linn.	RUBL211535

The plants parts were cleaned, air-dried at room temperature (28 ± 2 °C), blended to powder and stored at room temperature in sterile bottles prior to use.

Preparation of Plant Extract:

Macerate 10 g of the air dried drug, coarsely powdered, with 100 ml each of distilled water and alcohol separately, the specified strength in a closed flask for twenty-four hours, kept on a rotatory shaker at 190-220 rpm shaking frequently during six hours and allowing standing for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tarred flat bottomed shallow dish and dry at 100 °C, to constant weight and weigh. This was followed by the dilution of the crude extract with mother solvent to produce a stock solution of 300mg/ml; from which a series of dilutions were made to obtain solutions of 20, 50, 100 and 200mg/ml concentrations.

Culture and Maintenance of microorganisms:

Pure cultures of all experimental bacteria were obtained from the Microbial Type Culture Collection and Gene Bank (MTCC), Institute of

Microbial Technology (IMTECH), Chandigarh. The pure bacterial cultures were maintained on nutrient agar medium. Each bacterial culture was further maintained by sub culturing regularly on the same medium and stored at 4°C before use in experiments.

Table No. II:-

Sr. No.	Bacterial strains	MTCC NO.
I.	*Exsherichia coli*	10239
II.	*Pseudomonas aeruginosa*	1034
III.	*Klebsiella Subsp. Pneumonia (aerogenes)*	39
IV.	*Staphylococcus aureus*	6908

Antibacterial activity:

The antibacterial activity of the crude extracts was determined in accordance with the agar-well diffusion method described by Perez et al. (1990).[7] The bacterial isolates were first grown in a nutrient broth for 18 h before use. Standardized cell suspensions were spread on a Mueller-Hinton agar (Oxoid). Wells were then bored into the agar using a sterile 5 mm diameter cork borer. Approximately 20 ìl of the crude extract at concentration of 20, 50, 100, 200 and 300 mg/ml-1 were introduced into the wells as single samples and in concentration of 100, 200 and 300 mg/gm as mixture of alcoholic and aqueous extracts of all four samples in liquid extract and in ointment form, then allowed to stand at room temperature for about 2 h and then incubated at 37°C. Controls were set up in parallel using the solvents that were used to reconstitute the extract. The plates were observed for zones of inhibition after 24-48 h. The effects were compared with standard Povidone Iodine solution at a concentration of 5%w/v solution.

Ethical clearance:-

Ethical clearance was not required in this work as this research work was done in-vitro on micro-organisms and does not involve any human or animal trial.

Observation and result:

In the present investigation, the inhibitory effect of different extracts (viz. Methanol, Aqueous) of flowers of *Japa*, *Mahanimba* and *Vyaghra eranda* were evaluated against bacterial strains individually and in combination in ointment form. The antimicrobial activity was determined using agar well diffusion method summarized in Table III- IX. The activity was quantitatively assessed on the basis of inhibition zone.

Table No. III: Table showing ZOI of test drugs in different extracts of *Japa*:-

Extracts (w/v)	Zone of inhibition (in mm)			
	S.aureus	***E. coli***	***P.aeruginosa***	***Klebsiella sp.***
Aqueous 10%	0	0	6	6
Alcohol 10%	7	7	6	9
Aqueous 20%	0	7	11	9
Alcohol 20%	6	0	6	14
Aqueous 30%	8	8	14	20
Alcohol 30%	6	7	7	21

Table No. IV: Table showing ZOI of test drugs in different extracts of *Mahanimba*:-

Extracts (w/v)	Zone of inhibition (in mm)			
	S.aureus	***E. coli***	***P.aeruginosa***	***Klebsiella sp.***
Aqueous 10%	7	0	0	7
Alcohol 10%	0	6	0	7
Aqueous 20%	0	0	6	9
Alcohol 20%	0	8	6	10
Aqueous 30%	0	0	0	17
Alcohol 30%	7	8	16	20

Table No. V: Table showing ZOI of test drugs in different extracts of *Vyaghra eranda* Leaf

Extracts (w/v)	Zone of inhibition (in mm)			
	S.aureus	***E. coli***	***P.aeruginosa***	***Klebsiella sp.***
Aqueous 10%	0	6	0	8
Alcohol 10%	0	7	0	10
Aqueous 20%	0	8	0	11
Alcohol 20%	0	0	10	13
Aqueous 30%	0	9	6	12
Alcohol 30%	7	10	0	22

Table No. VI: Table showing ZOI of test drugs in different extracts of *Vyaghra eranda* Stem

Extracts (w/v)	Zone of inhibition (in mm)			
	S.aureus	***E. coli***	***P.aeruginosa***	***Klebsiella sp.***
Aqueous 10%	7	0	6	8
Alcohol 10%	6	6	6	9
Aqueous 20%	0	6	6	8
Alcohol 20%	6	8	7	13
Aqueous 30%	8	6	7	0
Alcohol 30%	6	0	0	21

Table No. VII: Table showing ZOI in different concentration of Mixture

Conc. (w/v)	Zone of inhibition (in mm)			
	S.aureus	***E. coli***	***P.aeruginosa***	***Klebsiella sp.***
Mixture 10%	0	0	6	6
Mixture 20%	0	0	7	6
Mixture 30%	6	7	7	6

Table No. VIII: Table showing ZOI in different concentration of Ointment

Conc. (w/v)	Zone of inhibition (in mm)			
	S.aureus	***E. coli***	***P.aeruginosa***	***Klebsiella sp.***
Ointment 10%	0	0	0	0
Ointment 20%	6	6	0	0
Ointment30%	0	0	0	6

Table No. IX: Table showing ZOI in Standard Povidone iodine (+ve control), Water, Alcohol and Ointment base (-ve control)

Controls (w/v)	Zone of inhibition (in mm)			
	S.aureus	***E. coli***	***P.aeruginosa***	***Klebsiella sp.***
Povidone Iodine 5%	13	0	0	28
Water (Aqueous)	0	0	0	0
Alcohol (99.5%)	0	0	0	6
Ointment Base	0	0	0	0

Discussion:-

In case of *Japa*, both Aqueous as well as Alcoholic extracts were found highly effective in 30% conc. against *Klebsiella sp.* with ZOI of 20mm and 21mm respectively but was less as compared to Standard Povidone Iodine of 28mm. For *P.aeruginosa*, aqueous extract was found effective in 30% with 14mm and in 20% conc. with 11mm ZOI while they show mild response against *E.coli* and *Staphylococcus aureus*.

In case of *Mahanimba*, Alcohol extract shows highest activity in 30% conc. as 20 mm and in 20% conc, as 10mm while Aqueous extract shows ZOI of 17 mm in 30% conc. against *Klebsiella sp.* Alcoholic extract was found effective with 16 mm ZOI against *P.eruginosa* in 305 w/v conc., while both the extract were not much effective against the remaining two organisms.

In case of *Vyaghra eranda* leaf, Alcoholic extract is much effective in all its conc. of 30%, 20% and 10% with 22mm, 13mm and 10mm of ZOI respectively while Aqueous extract shows effectiveness of 12mm and 11mm in 30% and 20% conc. for *Klebsiella sp.* Alcoholic extract of 30% conc. shows activity of 10mm against *E.coli* and in 20% conc. with 10mm ZOI against *P.aeruginosa*.

In case of *Vyaghra eranda* stem, only Alcoholic extract shows good activity of 21mm and 13mm in 30% and 20% conc. respectively against *Klebsiella sp.*

Different extracts of *Japa, Mahanimba* and *Vyaghra eranda* exhibited various degree of zone of inhibition against different bacteria (Gram positive as well as Gram negative), they were taken as mixture

to test in liquid and ointment form to test their collective efficacy.

Mixture in both liquid and ointment forms in all the concentrations were found ineffective to show considerable zone of inhibition.

This shows that although individual drugs have satisfactory effect in certain bacteria but when used together, they fail to elicit this effect. The hypothesis of individual effect will lead to summative total effect does not hold good for these test substances.

The individual components might be negating the effects of each other (due to *Prabhava*) or the lowering of effective concentration of the effective substance might be another reason for less effect.

Conclusion:-

Japa, *Mahanimba* and *Vyaghra eranda* individually possess variable degree of anti-microbial activity against different strains of bacteria but the herbal formulation i.e. ointment prepared from the combination of test substances does not exhibit anti-microbial activity against targeted micro-organisms.

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सारांश:

शल्यचिकित्सा में संक्रमण,विशेष रूप से शल्य स्थानगत व्रण का संक्रमण (एस एस आई) शल्य चिकित्सा के लिये प्रमुख चिन्ता का विषय है। सूक्ष्म जीव इन व्रणो को दूषित करके व्रण रोहण की प्रक्रिया को प्रभावित करते है। व्रण को दूषित होने से बचाने के लिये क्रिमिघ्न द्रव्यो का प्रयोग अत्यन्त आवश्यक है। इस अध्ययन का उद्देश्य जपापुष्प, महानिम्ब पत्र और व्याघ्र एरण्ड पत्र तथा काण्ड के विभिन्न सत्वो के सम्मिश्रण से उपयुक्त कल्पना (मरहम) निर्मित कर उसकी क्रिमिघ्न कर्म कि क्षमता की जाँच एस.औरियस, इ.कोलाइ, पी.ऐरुजिनोसा तथा क्लेबसिएला स्पि., जो कि शल्य स्थानगत व्रण के संक्रमण हेतु प्रमुख रुप से उत्तरदायी है, के विरुद्ध करना है। इसकी जाँच अगार कूप प्रसरण विधि से की गयी। जपापुष्प के जलीय तथा एलकोहल सत्व पी.ऐरुजिनोसा तथा क्लेबसिएला स्पि. के विरुद्ध, महानिम्ब पत्र और व्याघ्र एरण्ड का एलकोहल सत्व विभिन्न सुक्ष्म जीवो पर व्यक्तिशः प्रभावी साबित हुए। उपरोक्त द्रव्यो के सत्वो से निर्मित मलहम कल्पना क्रिमिघ्न कर्म में प्रभावी साबित नही हुई। इसका कारण द्रव्यो का एक-के प्रभावो को शून्य कर क्रियाहीन होना हो सकता है। अतः उपरोक्त द्रव्यो से निर्मित मरहम कल्पना क्रिमिघ्न कर्म हेतु अप्रभावी है।

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ORIGINAL ARTICLE

An in-vivo study of toxicological effects of *Shudha Dhatura Beej* and its therapeutic efficacy w.s.r. to *Jwar*.

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ABSTRACT

Upvishas are *gaun vishas*, one among them is *Datura Metal* which is unanimously accepted as *Jwarhara* by all *Nighantus* of medieval and modern era. On the other hand, in toxicological text of modern era it is said to be causing dry hot skin. So we have selected it as test drug and *Jwar* as disease & expect there will be a plenty of experience which will make us enable to know whether it is higher doses or impurities which causes contrary effects or it is *Shodhana* process which deprive *Dhatura* of its serious toxic properties.

Though, *Jwar* is most common & having high mortality rate in its different varieties. In *Ayurveda* it has been considered such a disease which supposes to be present at the time of birth and death. Therefore, it has been termed as kings of disease, *Vikar-Raj Punarvasu Atreya* also supported this thought or observation of *Acharya Shushruta* and stated that:-

सर्वेप्राणभृत:सज्वराएवजायन्तेसज्वराएवम्रियन्ते। (च.नि. 1/35)

And started to write diagnostic and treatment chapters in *Samhita*, *Nidana* and *Chikitsa* keeping *Jwar* at no.1. Doubtlessly, it is common and most important disease.

Key words: *Upvisha, dhatura* metal.

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Introduction

Dhatura is included in the group of *Upvisha*.[1] There are differences in the number of *upvisha* in ayurvedic books but *Dhatura* has been considered *upvisha* by all ayurvedic authors of medieval era and also in modern era. It is also considered by almost all authors that every *visha* has 10 *gunas* in different quantity and ratio which makes them special & more

effective and dangerous some time, depending on different factors, dose & time of intake, method of use, preparation of use, physical condition of user etc.

For the purpose of identification of *Rasa, Guna, virya, vipaka* etc. of *dhatura,* we have surveyed about nine *Ayurvedic Nigantu*. In almost 21 major diseases, they have mentioned use of *dhatura*, the *Jwar* is only one where its utility, usability has been accepted or indicated by all nine *Nigantu*. Therefore we have decided to study its *Jwarahara* effect only where all *Nigantu* were having same opinion about its usability in fever.[2]

On the other hand, it is described as poison (in Parikh's textbook of medical jurisprudence, forensic medicine and toxicology) which causes 9D's symptoms, among which one is dry hot skin or pyrexia which is contrary to its so called therapeutic use in ayurvedic texts/*Nigantu* as anti-pyretic.

But it is also very interesting to know that there are some *visha* and *upvisha* which are creating or producing a disease if they are taken in *ashodhita* form. That same *visha* or *upvisha* can even treat or eradicate the very same disease if taken in proper dose and if it is used in *shodhit* form. *Dhatura* represent the *upvisha varga* which can cause fever as its toxic effect if taken in *ashodhita* form.[3] And it can also subside or reduce the body temperature if it is taken after subjection of *shodhana*. The other one is *Hartala,* which can cause *Kushtha* disease by its toxic effect if taken in *ashodhita* form and also can treat it, if taken in *shodhit* form[4].

It created lot of curiosity in mind. Therefore, we have selected *Dhatura beej* for this study and *Jwar* as disease where its effect can be assessed and also to find out some possibilities to create a new experimental model to produce high temperature in lab animal as an *Ayurveda* model. Because up to this time no *Ayurveda* model is available by which one can produce fever in lab animal in controlled scientific conditions.

We also decided to perform toxicity study in *ashodhita* form *dhatura* seeds as well as its toxicity after its *shodhana by Godugdha in dola-yantra* according to the purification method given *in rasa tarangini* 24/346-347, So that we can assess impact of *Shodhana* on toxicity.

Because it is not advised by *Agad Tantra* to take poison in their original form in which they occur in nature as these are mixed with a lot of toxic impurities which are toxic for our body. Various pre-pharmaceutical processes have been described in the *Ayurveda* or especially in *Rasagranthas* to render them useful to incorporate in medicines. They also suggested various methods of administration and do's and don'ts. When followed all these as suggested then there will be no scope for such symptoms to develop.

Aims & objectives:

- ✓ The aim of the present research work is to evaluate the antipyretic effect of powder of *Shodhit Dhatura* seeds in different doses and compare of these effects with the effect of antipyretic drug paracetamol.
- ✓ To Study the acute toxicity of *Shodhit Dhatura* seeds after *shodhana* and to evaluate effect of *shodhana* on the toxicity of *Dhatura beej*.
- ✓ To find out the antipyretic efficacy of *Datura* metel seeds in Brewer's yeast induced pyrexia in lab animals in different doses.
- ✓ To evaluate effect of *shodhit and ashodhita dhatura beej* on the temperature. It may be taken as model to create this.
- ✓ To calculate average weight of seed of *dhatura*.
- ✓ To calculate average fatal dose given in text in term of weight.
- ✓ To compare the effects of *Shodhit & Ashodhita dhatura* on weight of rats.

Materials & methods:

➢ **Materials**

These articles/items have been included in the study as materials-

Seeds of *Dhatura* metel, Apparatus for *shodhana* & liquid media to be used, Laboratory utensil, Trial equipment, Consumable items, Chemical reagents and drugs, Gadgets & software, Rat

animals, Food materials and water for rats. Detail of these items are given below-

➢ **Seeds of *Dhatura metel:*** We had used powder of *Shodhit dhatura* metel for toxicity study & antipyretic study while toxicity study with *Ashodhita dhatura* was also performed. For this we had collected 4 different samples and mixed them all. One Sample of which was fresh ripped fruits of *Dhatura metel* were collected on November 3, 2014 and were dried in sunlight for 4 days to separate the seeds while 3 other samples were collected from Jaipur market. The detail of which has been described later in method used for calculation of fatal dose.

➢ **Methods:** These following methods has been adopted for an easy and smooth transaction of work regarding to the topic of research-

- Methods of preparation of *Shodhit and Ashodhita dhatura beej powder*
- Method Adopted for *shodhana* of seeds of *Dhatura metel in present study*
- Method adopted for Preliminary phytochemical screening
- Methods for preparations of stock solutions to be used further, in experimental study
- Method adopted for calculation of fatal dose in unit of mg. or gm. instead of no. of seeds
- Method for formation of Doses for acute toxicity studies

(i) Doses formation for acute toxicity study with *Shodhit dhatura beej* powder

(ii) Doses formation for acute toxicity study with *Ashodhita dhatura beej powder*

- Evaluation method in toxicity study
- Laboratory methods: fixation, tissue processing, section cutting and staining
- Method of setting three different Test Doses level for human being and its conversion into the doses (in mg) for Experimental Albino Rats
- Methods for liquid doses formation for antipyretic study

(i) Doses of brewer's yeast solutions to all groups at 0:0 hr.

(ii) Liquid doses of different item mentioned as per plan in antipyretic study at 18:00 hr.

- Procedure of recording of per hour temperature
- Method used in Presentation of result
- Method of Statistical analysis

➢ **Inclusive criteria**

- The animals having 38°C rectal temperatures will only be included as a subject for this study.

➢ **Exclusive criteria**

- Animal which are having temperature less than 38°C will not be included.

➢ **Method adopted for calculation of fatal dose**;

the fatal dose of *datura metel* is 100-125 seeds for human being.

Total weight of seeds= 4 gm. or 4000 mg.

Total number of seeds= 350

So weight of one seed= total weight of seeds/ no. of seeds= 4000 mg/350= 11.43 mg.So we can put the fatal dose given in term of no. of seeds into the fatal dose in term of weight as follow-

Fatal dose (in mg) = fatal dose (in term of seeds) X weight of 1 seed.

Fatal dose (in mg) = (100-125 seeds) X 11.43 mg = 1143-1429 mg.

➢ **Calculation of fatal doses for rats-**

We have calculated fatal doses for rats by multiplying fatal doses for human being to the conversion factor for rat which is .018 for rat weighing 200 gm.

So fatal dose for a rat weighing 200 gm. = fatal dose for human being X .018

And fatal dose (in mg/kg) = fatal dose for 200 gm. rat X 5

➢ Method for formation of Doses for acute toxicity studies-

Acute single dose toxicity of *dhatura beej* powder according to OECD guidelines-423, was carried out-

Ashodhit (non-purified) & *Shodhit* (purified) *Dhatura seed churna* was administered orally in single dose of 50 mg/kg body weight; 300 mg/kg body weight and 2000 mg/kg body weight to 6 groups of Albino Rats for both toxicity study. For this the rats were randomly selected in 7 groups with 3 rats in each group. The first 3 groups were given *Shodhit Dhatura seed churna* in the dose of 50 mg/kg body weight, 300 mg/kg body weight and 2000 mg/kg body weight respectively while the other three groups were given same doses of *Ashodhit Dhatura seed churna* and last group was placed as control group and only given distil water. Dose of particular rat was calculated according to its body weight and then dissolved in 1% CMC solution to make drug suspended.

➢ Protocol for antipyretic study:

The animals were fevered by injection of 10 ml/kg Brewer's yeast suspension subcutaneously in the back, below the nape of the neck and the site of injection was massaged in order to spread the suspension beneath the skin. The room temperature was kept at 22-24°C. Immediately after injection, the food was withdrawn but allowed free access to drinking water. 18hr post challenge, the rectal temperature was recorded using digital clinical thermometer. Only animals with a rectal temperature at least 38° C (100.4 °F) were taken into the test and split into five subgroups (N=8); placebo control, standard control, test group-A, test group-B and test group-C marked the rats as given in plan of study.

We have recorded and presented Rectal temperature of rats in different groups at 0, 60, 120, 180, 240,300, 360 (at 18:00, 19:00, 20:00, 21:00, 22:00, 23:00 and 24:00 hr. of commencement of study) minute after administrating distil water to placebo control group, paracetamol to standard control group and test drug to 3 test groups as per plan at 18:00 after yeast administration.

OBSERVATION & RESULTS

Observation on experimental study:

1. Observation on *Shodhan* of *Dhatura Seeds*:

It was observed that after compeletion of *shodhan* process the colour of *Godugdha* (cow's milk) was changed from white to Brownish.

2. Observation on Acute Toxicity Studies:

Observation on toxic effects & behavioural changes:

In observation of toxic effect and behavioural change in group given *shodhit dhatura beej* powder inhibition in salivary secretion, dryness of eyes, mucous membranes and dilation of pupil and tremor were observed, in which most of these sign& symptoms were in generally present in first 24 hr. of administration of test drug doses and then automatically disappeared but more higher doses made the rats more lethargy and more drowsy for a long period which was even up to 14th day in 2000 mg/ kg dose.

In other groups which were administrated *Ashodhita dhatura beej* powder, with these signs & symptoms there were many other severe toxicity signs & symptoms were observed such as; inflammation and redness of eyes, dysphagia, drunken gait, urine retention, severe dryness of mouth, skin, eyes and mucous membrane. These effects were followed by increase in temperature, convulsion and even mortality in the end. These signs & symptoms not only occurred early but also persist for a long time at higher doses of *ashodhita dhatura beej*.

Observation on mortality:

In toxicity study of *Ashodhit dhatura* seeds 1 out of 3 rats in 300 mg/kg body weight group and 2 out 3 rats in 2000 mg/kg body weight group were observed dead in 24 hr. after administration of test drug.

Analysis of change in weight:-

In control group and in groups administrated 50 mg/ kg body weight of test drug, the % increase

in body weight was 2.7%, 4.97% and 2.79 % respectively for control, *shodhit* and *ashodhita* drug. Which means the *shodhit dhatura* is more effective in increasing body weight.

Analysis of haematological Parameters:

In rats given *ashodhita dhatura beej* powder, in toxicity study, the increase of lymphocytes and decrease in neutrophils were both very significant in comparison to those same doses, in rats given *shodhit dhatura beej* powder. Which also indicate and proves about the inflammation happened and its fever causing ability.

Analysis of histopathological study:

The pathological data indicated that the plant constituent (s) affected mainly in brain, kidneys and liver causing hepatocellular fatty vacuolation, fatty change and dilatation and alteration of glomeruli of kidney and cerebral neuronal vacuolation and lymphocytic infiltration. This toxicity of *Datura metel* seeds might be related to the compounds in *Datura metel* seeds.

1. Observation on Antipyretic study:

Table showing temperature (°F) presented as MEAN±SEM at 18-19-20-21-22-23 & 24th hours after inducing yeast at 0 hr. to all groups & different item as per plan in different group i.e. placebo-pcm-test drug in different doses in different group.

GROUP	18 HR	19 HR	20 HR	21 HR	22 HR	23 HR	24 HR
Placebo control group	100.79±.12	100.91±.21	100.89±.25	100.89±.19	100.88±.21	100.85±.19	100.84±.18
Standard control group	100.82±.15	99.78±.14	99.21±.13	99.00±.15	98.90±.16	98.70±.15	98.58±.12
Test group-A	100.80±.22	100.59±.22	100.40±.23	100.19±.20	100.08±.20	99.99±21	99.96±.22
Test group-B	100.64±.19	100.38±.13	100.34±.14	100.18±.16	99.99±.09	99.82±.09	99.79±.11
Test group-C	100.74±.19	100.34±.18	99.89±.16	99.68±.16	99.55±.13	99.30±.14	99.25±.18

Discussion:

Our study shows that *Shodhana* of *dhatura* has tremendous effects on depriving Dhatura of its some of serious toxic properties which looks prominent given the fact that even 2000 mg/ kg dose or 22.22 gm. human dose of *Shudha Dhatura* (17.5 times of average textual fatal dose, as given in Parikh's text book of medical jurisprudence, forensic medicine and toxicology i.e. 100-125 seeds) didn't cause any fatality while *Ashudha Dhatura* causes 1 Mortality (33.33%) even at 300mg/kg or at 3.33 gm. human dose (2.6 times of textual fatal dose for human being), which is 1/8.5 times of maximum dose given of *Shudha dhatura* in this study. In 2000 mg/ kg of *Ashodhita Dhatura* the mortalities are 66.66%.

However, beside effect on temperature some of other signs & symptoms of toxicity are not fully deprived (although attenuation of severity is significant in term of mortality causing effect and the time they remain present) by *shodhana*. This is exactly what *Nighantus* say; which mentions it antipyretic unanimously and also mentioned some of its toxic effects like *Bharma* etc.[5]

All three test doses (4.22, 5.625 & 7.03 mg/ kg body weight of *Shodhit Dhatura)* although, continually reduce the increased body temperature but the effectiveness has been changed with time. In first 3 hour of treatment pcm did extremely well by reducing 1.05 °F, 0.56 °F and 0.21 °F of increased body temperature. In 1st, 2nd and 3rd hr., Temp reduction in test groups A, B, C were [-0.21 (20%), -0.19 (33.93%), -0.21 (100%)], [-0.26 (24.76%), -0.04 (7.14%), -0.16 (76.19%)], [-0.40 (38.10%), -0.45 (80.35%), -0.21 (100%)] respectively, in comparison to pcm. But in 4th and 5th hr. of treatment, temp

reduction in pcm group are 0.10 °F and 0.20°F but in comparison to test drug A [-0.11 (110%), -0.09 (45%)], B [-0.19 (190%), -0.16 (80%)] and C [-0.12 (120%), -0.25 (125%)] it is less by-en-large.

Which means mathematically, test drug-C reduced temp equal or more effectively than pcm during 4th and 5th hr. of treatment.

Statistically, effect of pcm is found significant in comparison to effects of test dose 4.22 & 5.625 mg/kg body weight but it is insignificant or Ns in comparison to test dose 7.03 mg/kg body weight.

Conclusion:

1. *Shodhana* has tremendous effects on depriving *Dhatura* of its serious toxic properties which looks prominent given the fact that even 2000 mg/ kg dose or 22.22 gm. human dose of *Shudha Dhatura* (17.5 times of average textual fatal dose, as given in Parikh's text book of medical jurisprudence, forensic medicine and toxicology i.e. 100-125 seeds) didn't cause any fatality while *Ashudha Dhatura* causes 1 Mortality (33.33%) even at 300mg/kg or at 3.33 gm. human dose (2.6 times of textual fatal dose for human being), which is 1/8.5times of maximum dose given of *Shudha dhatura* in this study. In 2000 mg/ kg of *Ashodhita Dhatura* the mortalities are 66.66%.

2. Toxicity study shows that higher doses of *Shudha Dhatura* also made rats drowsier and lethargy & it increases with increased doses, thus it also has toxic effect at much higher doses.

3. All three doses of *Ashudha Dhatura* (i.e. 50, 300, 2000 mg/kg body weight) have considerable pyrogenic effect

4. In toxicity study of *Ashudha Dhatura*, percentage increase in body temperature according to different doses given, isn't considerably different, so even low doses can be used to create pyrexia in lab animal (Model) as these doses don't have mortality effect.

5. All three test doses (4.22, 5.625 & 7.03 mg/kg body weight of *Shodhit Dhatura)* although, continually reduce the increased body temperature but the effectiveness has been changed with time. In first 3 hour of treatment pcm did extremely well by reducing 1.05 °F, 0.56 °F and 0.21 °F of increased body temperature. In 1st, 2nd and 3rd hr., Temp reduction in test groups A, B, C were [-0.21 (20%), -0.19 (33.93%), -0.21 (100%)], [-0.26 (24.76%), -0.04 (7.14%), -0.16 (76.19%)], [-0.40 (38.10%), -0.45 (80.35%), -0.21 (100%)] respectively, in comparison to pcm. But in 4th and 5th hr. of treatment, temp reduction in pcm group are 0.10 °F and 0.20 °F but in comparison to test drug A [-0.11 (110%), -0.09 (45%)], B [-0.19 (190%), -0.16 (80%)] and C [-0.12 (120%), -0.25 (125%)] it is less by-en-large.

   Which means mathematically, test drug-C reduced temp equal or more effectively than pcm during 4th and 5th hr. of treatment. Statistically, effect of pcm is found significant in comparison to effects of test dose 4.22 & 5.625 mg/kg body weight ($p<0.01$) but it is insignificant or Ns in comparison to test dose 7.03 mg/kg body weight.

6. Temperature in placebo control remained almost stable when we have calculated average change of temperature in whole period of study but there was considerable decrease in increased temperature by all three test doses in comparison to placebo control.

   Statistically, test dose-A, test dose-B, and test dose-C are Ns, significant and significant (Ns, $p<0.05$ and $p<0.01$) respectively in comparison to placebo control. It means middle and higher doses are effective in reducing pyrexia.

7. As per our study, average weight of one seed of *Datura metel,* which is calculated through 4 different samples collected randomly, is 11.43 mg and one gram of weight contains 87.5 seeds. As per Parikh's text book of medical jurisprudence, forensic medicine and toxicology 100 seeds weigh about 1 gram.

8. Fatal dose which is being calculated on the basis of number of seeds (i.e. 100-125 seeds for human being), is 1143 mg- 1429 mg when expressed in unit of weight but as per conclusion of our study

22.22 gm. (2000mg/kg for rat) of *shudha Dhatura* has no fatal effect. Even though this dose is higher than mentioned in text.

9. *Shudha* form of *dhatura* has *Brhana* effect and can be used as weight gainer.

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सारांश:

उपविष गौण विष हैं उन्हीं में से एक धत्तूर है, जो मध्यकाल एवं आधुनिक लगभग सभी निघण्टुओं द्वारा सर्वसम्मति से ज्वरहर कहा गया है वहीं दूसरी ओर आधुनिक विष विज्ञान द्वारा इसे डी लक्षण समूह में से एक शुष्क तप्त त्वक कारक कहा गया है। इसलिये हमने धत्तूर को test drug के रुप में एवं ज्वर को ही रोग के रुप में चुना है और उम्मीद करते हैं कि हमारा अनुभव हमें यह बताने में समर्थ होगा कि (कितनी अधिकतम औषधीय मात्रा) या अशुद्धियां हैं जो इस विपरीत प्रभाव के लिये जिम्मेदार हैं या शोधन इस रुपान्तरण के लिये जिम्मेदार हैं।

हालांकि ज्वर सर्वसामान्य एवं अपने विभिन्न रुपों में प्रकट होता हुआ उच्च मृत्युदर के लिये भी जिम्मेदार है। आयुर्वेदिय धारणा कहती है कि यही वो बीमारी है जो हर समय और मृत्यु के समय भी उपस्थित पायीं जाती हैं इसलिये आचार्य सुश्रुत ने इसे रोगराज की संज्ञा दी है और जैसा कि पुनर्वसु आत्रेय ने भी कहा है–

सर्वेप्राणभृत:सज्वराएवजायन्तेसज्वराएवम्रियन्ते। (च.नि.1/35)

निदान और चिकित्सा स्थान की शुरुआत भी ज्वर से की है इसलिये नि:संदेह यह सबसे महत्वपूर्ण रोग भी है।

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ORIGINAL ARTICLE

A Study of *Asthi Sharir* In Context of Various Types of *Asthi* Described In *Ayurvedic Samhitas*

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ABSTRACT

Ancient seers of Ayurveda have classified the elements of the body under three fundamental components- *Dosha, Dhatu* and *Mala*. According to *Acharya Sushruta* the pioneer of *Ayurveda*, Asthi is last part of body to be destroyed. Knowledge of *Asthi* can be traced back from *Vedas* passing chronologically down to *Samhitas*. *Asthi* plays the role of kernel of body on which whole system depends. Profound description is illustrated in classical texts about nomenclature, enumeration, types, *Bhagna* and its treatment. Especially types and nomenclature are to be discussed in light of modern and classical grammar. Here main aims are Analytical discussion about *Sankhya and* nomenclature of *Asthi*, *Asthi Prakaras* and grammatical validation. As knowledge about *Asthi* dates from Pre-*Vedic* period concepts, believes, methods, usefulness etc have changed from time being. The nomenclature of *Asthi* and *Bhagna* and *Prakar* is also same as in the contemporary knowledge and profoundly described.

Keywords: *Asthi Bhagna, Asthi Sankhya, Asthi Prakara*

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Introduction

It is very clearly apparent from the admonitions of Galen how great is the usefulness of a knowledge of the bones, since the bones are the foundation of the rest of the parts of the body and all the members rest upon them and are supported, as proceeding from a primary base. Thus if anyone is ignorant of the structure of the bones it follows necessarily that he will be ignorant of very many other things along with them."

Niccolo Massa, 1559.

Being an eternal science, '*Ayurveda*', the science of human life deals with physical, psychological as well as spiritual well being of an individual. It covers all the spheres of human life. As we all know that, this entire world can be divided into two types of material i.e. soft and hard. Soft and hard though are antonyms yet are equally important for sustainability. This division is also evident in human body. Here several parts are soft organs and rest hard. Hard part of body is skeleton system which provides support and shape. Thus, parts which provide support, shape, helps in locomotion, protection to soft organs are hard parts forming nutshell of human body, comprising bones, teeth etc.

According to *Acharya Susruta* the pioneer of Ayurveda explained, the organs of the body destroy after death except the *Asthi*. *Asthi* is the last to be destroyed, even after death when body is buried or burnt the remnants left are bones. Knowledge of *Asthi* can be traced back from Vedas passing chronologically down to *Samhitas*. Considering its history of description and importance many methods and thought can be visualized in classical texts. Each explains their own way of enumeration and nomenclature.

Literal Review

In Atharva Veda, *Narayana* is author of the *Atharva* hymn which takes us back to that period of prehistoric or semi-mythical age of the medicine men who combined the functions of priest and physician. *Narayana* is representative of this Indian medicinal tradition. He is also author of famous ***"Purusha Sukta"*** (RV.X.90=AV.XIX.6), which contains many anatomical references. The hymn X.2.1-8 is reported to show how *Artharva* mentioned bones of human body.

It is a hard substance which remains even after most part of body has been decayed. According to *Susrutha*[1] it is substance which remains even after else very part like flesh, muscles etc. are shattered even after burying the body after death. It remains as last identity of person even after demise. According to *Shabdastomkara*- it is part of body which remains till long period even after death of body. "*Hada*" is synonym of *Asthi*.[2]

Though every substance is made of all five *Mahabhutas (Akasha, Vayu, Agni, Jala and Prithivi),* but *Asthi* has predominance of *Prithivi and Vayu Mahabhuta*.[3] The *Asthi Karmas* are as follows *Deha Dharan., Majja Pushti and* supporting the *Mamsa, Sira and Snayu*.[4] The numbers of *Asthi* in the *Sharira* according to different *Samhitas* are as follows-

Table No.I:
Showing the Numbers of *Asthi* [5,6,7]

S.No	Text books	Numbers
1.	*Charaka Samhita*	360
2.	*Susruta Samhita*	300
3.	*Astanga Hrudaya*	360
4.	*Astanga Sangraha*	360
5.	*Bhavaprakasha*	300
6.	*Kashyapa Samhita*	360
7.	*Bhela Samhita*	360

Depending upon size, shape, position[8] of *Asthi* in the body total *Asthi* is divided into five types. These are tabulated below

Table No II: Showing the Types of *Asthi*

S.No	Types	Su.S	As.S	As.H.	B.P
1	*Kapala*	+	+	+	+
2	*Ruchaka*	+	+	+	+
3	*Taruna*	+	+	+	+
4	*Valaya*	+	+	+	+
5	*Nalaka*	+	+	+	+

Kapala-Asthi[9]- These are flat in nature. The above and below layer is separated and hollowed parts are made. Red *Majja* is filled in it. *Asthi's* present in the *Janu, Nitamba, Amsa, Ganda, Talu, Shankha, Vankshana and Madhyashira* are known as *Kapalasthi*.

Valaya-Asthi[10] - These are round in shape. The ribs of the chest are of this type. *Asthi* in *Ura, Parshva* and *Prustha* are *Valayasthi*.

Taruna-Ashthi[11]- These are soft in nature.[12] They are mainly in between joint of vertebrae, two vertebrae there is a circle of *Tarun Asthi*. Hence, any jolt to the body, till it reaches the brain becomes mild. *Asthi's* present in the *Ghrana, Karna, Greeva* and *Akshikuta* are called as *Tarunasthi*.

Ruchaka-Asthi[13] - the bones which help in taste or which are to enjoy food with taste. The *Dashanas* are known as *Ruchak Asthi*. These are 28 or 32 in all. It is also considered as *Updhatu* of *Asthi* by *Sharangdhar*.

Nalika-Asthi[14]- These are long like tubes and hollow from within. They are stuffed with *Majja*. Till the age of 20 years, the color of this is red, and then it turns yellow. These types of bones are in the hands and legs. *Asthi* which remains from above description are listed in this type.

Discussion-

Enumeration i.e. *Sanhkya* of human parts is as important as the knowledge particular organ as stated by *Acharya Charaka*. According to *Chakrapani* – knowledge of enumeration of parts *(Avayavaas)* of human body is important in Clinical practice as it is prime source of evidence. *Acharya* states that *Prayogan* of *Adhayaya Sharir Sankhya Shariram* is simply to know the whole body *Sankhya Pramana*. Limitation of *Pramana* of *Avayavaas* is *Sankhya Pramana*. Importance of knowledge of *Sharir Sankhya* is given very efficiently in end of seventh chapter of *Sharir Shtana*[15]. It illustrates – the Clinician who has knowledge about human body with its all parts with their enumeration never gets distracted as the distraction faced by Clinician who doesn't have *Tatwapurna* (analytical) knowledge about *Sharir Sankhya*.

According to modern anatomy, there are about 206 bones in the adult human skeleton. The early Indian anatomist, on the other hand, count either 360 (*Aterya*) or 300 (*Susrutha*) bones. This large excess is principally due to the fact that (besides including the teeth, nails, and cartilages) they counted prominent parts of bones, such as are now known as 'processes' or 'protuberances', as if they were separate bones. Their reasons for counting in this manner were mainly three.

- Sometimes processes or protuberances of bones were popularly known by special names, and regarded as special bones. Examples are the malleoli, or ankle bones and the styloid processes or wrist-bones.
- In other cases the separate enumeration of process or protuberances was due to an exaggerated regard for the homological principle. For example the right and left halves of the skeleton were regarded as homologous.
- Sometimes, again it was a fancy for artificial symmetry which led to the multiplication of bones. This can be cause of assumption of the existence of a third joint in the thumb and great toe, and of twelve costal tubercles instead of ten.

We can trace this variation in nearly all *Asthi Sankhya* but major variations can be traced in enumeration of ribs, vertebraes, phalanges etc. Like while enumerating ribs *Charaka* states that there are 24 *Parsvaka* or ribs, 24 *Sthalaka*, sockets, and 24 *Arbuda* (tubercles) and of course as indicated by *Susrutha* manner of counting, it is to be understood that there are 12 of such kind, that is, altogether thirty six, on each side.

As in *Greeva Charaka* makes the number of neck-bones to be fifteen. The *Susrutha* makes it to be only nine, while the list of *Vagbhata* makes it to be thirteen. As a matter of fact, the number of the cervical vertebrae is seven. *Susrutha* counts nine neck-bones, each of the six upper vertebrae as single bone; but the seventh he treated in the same way as he treated the thoracic vertebrae, that is to say, he counted it as consisting of three bones; viz. a body plus spine and two transverse processes. He thus obtained 6+3=9, bones.

Charaka obtained his total of fifteen bones by treating the cervical column somewhat similarly to the vertebral column. As regards the count of *Vagbhata*, his total of thirteen bones probably represents, as usual, a compromise between the systems of *Charaka* and *Susrutha*.

Likewise several other *Asthi* and their *Sankhya* can be discussed and it can be seen though the enumeration was varied but each one satisfied their own principle and thus no major controversy can be drawn.

Now talking about types or *Prakara* as per *Samhita*, we can see that division was basically on the terms of *Shalya Tantra* and is uniformly pentad type. Asthi can be divided in these five divisions as follows-

Table No. III Presenting division of *Asthi* as per their type (*Susruta*)

S.No	*Asthi Prakara*	Number	Names
1	*Tarunasthi*	14	● *Ghrana-3* ● *Karna-2* ● *Griva-9* ● *Aksikosa*
2	*Valayaasthi*	110	● *Parsva-72* ● *Prstha-30* ● *Uras-8*
3	*Nalakaasthi*	125	● *Padanguli (3x5)-15x2=30* ● *Padatala* ● *Padakurcha* } 20 ● *Gulpha* ● *Parsni-2* ● *Jangha-4* ● *Uru-2* ● *Hastanguli(3x5)-15x2=30* ● *Hastatala* ● *Hastakurcha* } 20 ● *Manika* ● *Karpurasthi-2* ● *Prakosthasthi-4* ● *Bahunalaka-2* ● *Trikasrita-1* ● *Amsaphalaka-2* ● *Kanthanadi-4* ● *Hanwasthi-2*

4	*Kapalasthi*	19	● *Janu-2* ● *Nitamba-4* ● *Amsa-2* ● *Ganda-2* ● *Talu-1* ● *Sankha-2* ● *Sira-6*
5	*Ruchakasthi*	32	● *Danta-32*
	Total	**300**	**300**

On using *Tarka* and *Pramana* we can understand that the particular five types defined are just symbol for major division. In fact these merely are not just types but these are basically five ways of divisions of bones on different basis.

First division can be on the basis of hardness or completion of ossification. On the basis of hardness this is first type of *Asthi*, thus other can be its antonym that is *Asthi* or *Pakva-Asthi* (normal or hard) or *Jirna-Asthi* (fully developed or hard). Next division is on basis of surface area. (*Kapala-Asthi)*- This is based on surface of bone. *Kapala* as described is flat or which has more area than thickness. Other bones mainly are slender or cylindrical here surface area is comparatively less (*Nalaka-Asthi*). Next division is on basis of specific shape *(Vartulakara)*. This type bones are for specific functions of providing support as well as helping in inspiration and expiration i.e. providing elasticity as well as support for specific function. Thus, this can be basis for division into two groups i.e. bones with round shape and others without it i.e. *Avartulakara*.

Next division is on basis of length and end points *(Nalaka-Asthi)*. Main function of these is to help in locomotion as these bones are mainly found in extremities. Thus, bones can be called as functioning in locomotion can be separated from others with function of protection mainly like *Kapala or Valaya-Asthi or Analakakara*. Next division is really interesting type as sense organ (*Ruchaka-Asthi*)- *Acharya Susrutha* have divided next variety specially on power of teeth as '*Ruchaka*', i.e. one which can sense or know the taste of food during chewing process.

So, total types can be summarized in five group's like-

1. *Tarunaasthi* (undeveloped) and *Pakvaasthi or Ghanasthi* (fully ossified)
2. *Kapalaasthi*-(great surface area) and *Akapalaasthi* (less surface area).
3. *Vartulakara (Valayasthi* elastic and round) and *Avartulakara* (not round in shape).
4. *Nalakaasthi* (long and for movement) and *Analakaasthi. (other than cylindrical)*
5. *Ruchaka* (with sense power) and *Kharasthi* (normal bone).

The bones sustain trauma in different ways. *Acharya Susruta* has paid due attention to this fact and observed that all the bones do not show similar type of effect due to trauma. As we already know that *Acharya* have particularly described the types of fractures occurring in each type of bone[16] mentioned as below-

1) *Tarunasthi - Namayante*

2) *Nalkasthi - Bhajayante*

3) *Kapalasthi - Vibhidhyante*

4) *Ruchkasthi - Sphutayante*

5) *Valayasthi – Sphutayante*

On profound analysis on literal basis of the words denoted as fracture types a clear picture can be drawn on relation of specific fracture with the specific type of bone. Firstly let us dissect word on basis of *Dhatu Pada* and its meaning as per *Panini Vayakarana* in *Ganakaastadhyayi*. Results can be tabulated as-

Tables No. IV showing *Asthi Prakara*; it's *Dhatu Pada* and their meanings.

Type of bone	Defination[17]	Type of *Bhagna*	*Sandhi*	*Dhatupada*	Meaning of *Dhatupada*	English meaning
Taruna	यानि घनता न प्राप्नुवान्ति तानि तरुणास्थिनि	नम्यन्ते	नमे अन्ते	नम्	नाम प्रतिवत्वे शब्दे चा	To bow , to bend, curve, bow down, sink
Kapala	कं नाम शिरः तं पालयति इति कपाल	विभिध्यन्ते	विभिदि अन्ते	विध्, भिद्	विध् विधाना, भिदिर् विदारणे, खण्डशो भिधन्ते (चन्द्रट)	Perforating, fissure, gap, cleaving
Valaya	वर्तुलाकाराणि वर्तुल अर्धवर्तुल सदृशानि	स्फुटयन्ति	स्फुट अन्ते	स्फुट्,	स्फुट विकासने स्फुट भेदने	Brust, split, cracked
Nalaka	नल इव प्रतिशतिः नलकं नलाकारकस्थिविधयेत इति	भज्यन्ते	भजि अन्ते	भञ्ज् भुज्	भञ्जो आमर्दने भुज् कौटिल्ये	Shatter, break to pieces

Table No. V showing comparison of word meanings of *Asthi Bhagna;* and type of fractures.

Asthi prakara	*Bhagna*[18]	Meaning of *Bhagna*	Bone example as per modern	Common fracture[19]	Word meaning/ meaning of fracture
Taruna	*Namayante*	To bow, to bend, curve.	Cartilaginous or bones of child (which are not fully ossified)	Green Stick Fracture	bone bends and breaks
Valaya	*Sphutayante*	Burst, split, cracked.	Ribs	break in the rib (detach)	Separation, cracking
Kapala	*Vibhidhyante*	Fissure, gap, cleaving.	Flatbones like Skull bones, hip bone, scapula	Linear, Depressed, Diastatic, Basilar	widen the suture, displaced inward, transverse break in the full thickness of the skull

Nalaka	*Bhajayante*	Shatter, break to pieces.	Various Long Bones like Femur, Humerus etc.	Transverse, Oblique, Spiral, Comminuted.	Perpendicular to the long axis, at an angle, bone fragments scatter

By these tables it is clearly visualized that our *Acharaya* had given principle of *Asthi Bhagna* and *Asthi Prakara* on clinical basis as is proved here merely by meanings of root word. This knowledge can be used in vice a versa way that the particular type of fracture occurs in particular type of bone as. which means bones which tend to bend or curve can be a type of *Tarunaasthi,* bones in which linear fractures or fissure is commonest type of fracture can be a type of *Kapalasthi,* bones which commonly breaks into pieces or detaches (having semi circular shape) from its attachment can be a type of *Valayaasthi* and bones in which fracture are mainly perpendicular to axis, transverse to axis or at angle can be a type of *Nalakaasthi.*

Conclusion

As knowledge about *Asthi* dates from Pre-*Vedic* period concepts, believes, methods, usefulness etc. have changed over time. As per basic definition of *Asthi* according to *Susruta* "it is substance which remains as the last identity of person even after demise." Whereas in modern science it is simply defined as connective tissue i.e. hard in texture and characterized by the presence of Haversian system. Thus, a major difference arises as per definition so is the differences are seen in enumeration, types and function.

The pentad division of *Asthi Prakara* was given mainly in accordance with *Shalya Tantra* especially for dislocation and fracture of bones. Basically this pentad division is not the types of bone, but actually these are principles for division which can be further elaborated like as *Tarunasthi* and *Ghanasthi, Vartulakara* and *Avartulakar* etc. This proves that classification of bones based on shape, size and texture was given firstly in *Samhita* not in modern text as per popular belief.

Leaving *Rucaka*, as a type especially for *Danta*, rest can be classified under rest four as *Tarunasthi*-14, *Valayasthi*-110, *Nalakasthi*-125 and *Kapalasthi*-19; as per *Acharya Susrutha.* Type of bone and type of fracture in it, are in accordance with its modern counterpart as proved by literal grammatical study of *Dhatupada* and their *Artha.*

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सारांश

आयुर्वेद के आचार्यो ने शरीर को मुख्यत: दोष,धातु एवं मल से निर्मित बताया हैं। यही तीनो शरीर के निर्माण में एवं क्रियाशील होने में कारण होते हैं। आचार्य सुश्रुत के अनुसार अस्थि ही शरीर का वह भाग है जो सब कुछ नष्ट होने के बाद भी बचा रहता है। अस्थि का वर्णन वेदों से ही मिलता है जो की संहितायो में और भी स्पष्ट होता है। अस्थि शरीर का आधार कारण है। जिसके पूरे शरीर के अन्य अवयव आधारित रहते है। संहिताओं में अस्थि के नामकरण, संख्या, प्रकार,भग्न एवं उसकी चिकित्सा का विस्तार से वर्णन मिलता है। अलग ग्रन्थो में नामकरण, संख्या एवं प्रकार में अनेको मतभेद मिलते है, जिनका निराकरण आचार्यो ने अपने-अपने ढंग से किया है, फिर भी अर्वाचीन दृष्टि से इनका और आधिक विश्लेषणात्मक अध्ययन आवश्यक है प्रस्तुत लेख में अस्थि के नामकरण, संख्या एवं प्रकार पर प्राचीन एवं अर्वाचीन मतानुसार व व्याकरण के उपयोग से इन मतभेदों का निराकरण किया गया है। इस प्रकार प्राचीन मत भी आजकल के सिद्धान्तों के अनुसार ही पूर्ण एवं चिकित्सा उपयोगी है।

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ORIGINAL ARTICLE

Comprehensive approach of Lifestyle Modification in Diabetes Mellitus w.s.r. *Prameha*

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ABSTRACT

Diabetes mellitus (DM) is a progressive chronic metabolic disorder characterized by hyperglycemia associated with long-term micro vascular complications like retinopathy, nephropathy, neuropathy and macro vascular (cardiovascular) complications. Pharmacological interventions i.e. medicines are not always necessary to control diabetes, but emphasis should also be given to non-pharmacological management. *Prameha* explained in *Ayurveda* texts bears resemblance to Diabetes.

There is detailed explanation in ayurveda texts regarding dietary modification and physical activities for prevention and management of *Prameha*. This article is compiled with an aim to commemorate various references of lifestyle modification in *Ayurveda* texts and researches supporting them. Principles of *Dinacharya, Aahara, Vihara, Sadvritta, Rasayana* when applied in daily routine plays major role in prevention as well as better management of Diabetes.

Keywords- Diabetes, Microvascular complications, *Prameha*, Lifestyle Modification.

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Introduction

Diabetes mellitus (DM) is a progressive, chronic metabolic condition characterized by hyperglycemia associated with long-term micro vascular complications like retinopathy, nephropathy, neuropathy and macro vascular (cardiovascular) complications. *Premeha* is a syndrome which includes all those clinical conditions which are characterized by increased quantity of urine associated with or without the increased frequency of micturition. Poly urea and Turbidity of the urine are the cardinal presenting features of this diseased state.[1]

It is one of the common problems facing our modern era, resulting in numerous complications, which can be effectively managed by simple measures, such as lifestyle modifications. Pharmacological interventions i.e. medicines are not always necessary to control diabetes, but emphasis should also be given to non-pharmacological management. Evidence has clearly shown that lifestyle variables are highly associated in determining the relative risk of diabetes mellitus. Lifestyle variables include meal habits, exercise state, drinking state and smoking state. Modification in these factors would result in improved compliance towards hypoglycemic agents.[2]

Need of Study

There are several factors that increase the risk of developing T2DM (Type 2 Diabetes Mellitus), some of which include Obesity, Family history of DM in a first-degree relative, Increasing age, Polycystic ovarian syndrome, Physical inactivity, Low-fiber, high-fat, energy-dense diet, Urbanization.[3] The management of T2DM is multifactorial, taking into account other major modifiable risk factors, like obesity, physical inactivity, smoking, blood pressure (BP) and dyslipidemia. Therefore preventive aspect of Ayurveda explained as *Dinacharya, Aahara Visheshaayatana, Sadvritta, Rasayana* etc needs to implemented in practice to prevent and manage Diabetes.

Literature Review

Ayurvedic classical texts ie. *Bruhatrayee* and others were screened for various references that can be directly or indirectly understood to frame lifestyle guidelines in Diabetes. Various Research paper published in peer reviewed journals were studied and screened for role of lifestyle modification in terms of diet and exercise in Diabetes. Comprehensive management of diabetes includes multifactorial approach as there is no single etiological factor involved instead there is cluster of factor responsible in causation of DM.

Ayurveda suggests individualised approach in preventive and curative medicine. In case of individuals who are at risk of T2DM or suffering from it, lifestyle modification has to be as per their *Prakriti* (Body Constitution), *Saatmaya* (Accustomisation of food habits), working nature i.e. Occupation etc. Patient preferences, values, objectives, and priorities should be respected, and these should then guide the shared clinical decision-making process. This is the patient-centered approach to DM management that is advocated by the American Diabetes Association and European Association for the Study of Diabetes.[4] It encourages the individuals to own their lifestyle goals and action plans.

Dietary Modification

Diet plays an important role in causation of T2DM. *Ayurveda* says excessive consumption of sweet, heavy food like milk, curds, sugarcane, meat of *Anoopa Desha* animals leads to increase in *Kapha Dosha* and eventually causes *Prameha* or Diabetes. The key principles include calorie restriction, low-fat diet, portion control, and increasing fruit, vegetable, and fiber intake. Dietary habits of patient should be modified to encourage regular meal times and healthy eating habits. *Asthahaaravidhi Visheshayatana* explained in *Vimaana Sthaana* of *Charaka Samhita*.[5]

These are 8 specific factors of method of dietetics which are discussed in detail further more and are summarized briefly below.

1. *Prakriti/ Swabhava*- Nature of food/ Qualitative characteristics of food.
2. *Karana* – Processing of food.
3. *Samyoga* – Combination/mixing of different food items.
4. *Rashi* – Quantity of food.
5. *Desha* – Habitat of food i/e. place of origin.
6. *Kaala* – Time and seasonal variation.
7. *Upayoga Samstha* – Rules for dietetics.
8. *Upayokta* – The person who consumes the food.

Prakriti/ Nature of food

Major cause of *Prameha* is *Kapha* aggravating diet that is *Guru, Snigdha Guna Aahara* hence diet advised should be *Laghu, Rooksha* in case

of Kaphaja Prameha which in general can be taken as Type 2 Diabetes Mellitus associated with obesity.

One should opt food items that are mainly of *Kledahara guna* (which reduces the kleda) like *Yava* (Hordeolum vulgare) *Sarodaka*, *Chanaka* (Green gram), *Kulattha* (Horsegram). One year aged grains like wheat, barley are to be preferred over newly harvested . *Yava* is rich in fibre content and has very low glycemic index too. Diabetic patients should eat in moderation and at regular time intervals. Drinks like *Sarodaka* (Acacia cathechu 12 gms boiled with approx 700 ml water to be taken for drinking throughout the day), *Kushodaka*, *Madoodaka* (Honey with warm water) are advisable for diabetics.[6]

Substitution of energy-dense foods with foods rich in fiber, like fruits, vegetables, and whole grains, and with low-glycemic index is appropriate. Diabetics should go for calorie restriction to upto 1,500 kcal/day and saturated fat intake should be minimised. Vegetables of *tikta rasa* are to be preferred. Fruits like pomegranate, *Amla*, Kharjura (dates), *Kalingaka* (Watermelon) can be taken.[7] Spices like pepper, fennel seeds, asafoetida are of great importance as they increase the digestive fire and thus improves metabolism. Ginger neutralizes the heavy quality of the food thus adding ginger will convert the property of heavy food into a lighter state.

Karana/Processing Methods

Various method involved in cooking like soaking, boiling, steaming, deep frying, marinating etc bestows different properties to the food item being cooked. So only there are various cooking methods that are highlighted in classical *Ayurvedic* texts that change the original nature of the food items. Keeping grains for a period of one year increases *Laghutva* i.e. makes them easily digestible. Yava (Barley) when overnight soaked in *Triphala Kashaya* is comparatively more *Rooksha* in nature and easy to digest.[8] Similarly when grains are dry roasted before use they become more easy to digest. Roasted Bengal gram is very good choice for diabetics. Meat cooked in tandoor that is Shooli Mamsa (explained in *Ayurvedic* text) is more beneficial for Diabetic patient, probably because it has reduced *Kleda* as compared to meat curries.[9] Even through proper washing grains like rice prior to cooking and removing the supernatant water also increase their digestibility. Green gram soaked in *Triphala Kashaya* to prepare Daals or soup also has more suitability to diabetic patient. In case of *Vata* dominant *Prameha* where *Nidaana* is *Apatarpana* (Nutritional deficiency), nourishing diet is advised. So oils like *Atasi Taila, Sarshapa Taila, Kharjoor* are also indicated in *Prameha*.[10]

***Samyoga* (combination/ mixing)** - *Samyoga* (combination) is aggregation of two or more substance. This exhibits peculiarities which are not seen in case of individual substances.[11] Combinations like fish with milk, hot pizzas with cold drinks etc is *Viruddhaahara* as per *Ayurveda* and is contraindicated for diabetics also.[12]

Rashi/ Quantity of food

Quantity to be taken depends on individuals *Agni* (Appetite). It may vary depending upon time and season even in same person. So one must assess it and eat accordingly. *Ayurveda* advocates *Langhana* (Fasting) in *Kaphaja* disorders. It means either fasting or reducing the quantity of food intake so that there is *Kapha Kshaya*. Individual should eat optimum quantity at proper time. One should eat cautiously and avoid overeating.

Desha (Habitat)

Desha denotes place relating to growth as well as distribution of the substances and also the suitability in respect of place. It is a geographic region. Food substances differs in quality due to difference in soil and climate. Foods grown in *Anoopa Pradesh* i.e. cold, rainy places are heavy to digest and not to be preferred for Diabetics whereas food grown in *Jaangala Pradesh* (Region of dryness, less rainfall, *Vata* predominant) are *Laghu* and *Rooksha,* hence more suitable to Diabetics.

Kaala (Time and Seasonal variation)

To maintain proper health in both healthy and diseased condition the seasonal regiment must be followed. *Kala* is eternally moving (time) as well as conditional. *Ritucharya* mentioned in *Vasanta* and *Varsha Ritu* has strong resemblance to the *Pathya*

Apathy mentioned in Prameha.[13]

Upayoga samstha (Classical rules of dieting)

It denotes the rules for dieting. This depends on the digested food. One should eat light, warm, at proper time and in a calm environment. Heavy diet at night time is to avoided by Diabetics. Frequent small meals can be taken where fluctuations in glucose level is more.

Upayokta (The person who takes the food/user)

Upayokta is that who consumes the food. Dietary regimens cannot be same for individuals of different *Prakruti*. For eg Preparation of *Yava* in form of chapati and pancakes will be preferred to *Kapha* & *Vata Prakriti* respectively. So physician needs different approach in each individual. Here Role of *Saatmaya* (Accustomisation to certain food) is very important. Before withdrawing any particular food habit and introducing any new habit, one should take time and try with modifications of existing diet first. Drastic changes are not accepted well, may lead to *Asatmaya Janya Vyadhis*.

Daily Regimens

Dinacharya regimens which are of immense importance to diabetics are *Brahma Muhurata Jaagrana* (Early Rising), *Udvartana, Utsadana, Snaana, Vyayama* etc. *Udvartana* is dry powder massage all over body in opposite direction of body hairs. It reduces *Kapha* and *Kleda*. *Udvartanam* with *Tvaka* (Cinnamomum zeylanicum), *Ushira* (Vetiveria zizanioides), Ela (Cinnamomum zeylanicum) , *Agaru* (Aquilaria agallocha), *Rakta chandan* (Pterocarpus santalinus) along with takra all over body followed by bath in *Vijaysara Sadhita Jala* (decoction of Pterocarpus marsupium).[14]

Udvartana is especially indicated for *Kapha Prakruti* as it reduces weight and peripheral fat. In case of *Vata Prakruti* Diabetic patients can be advised to do massage of exteremities with supti tailam or pinda tailam on daily basis before taking bath. *Vyayama* leads to *Kapha* & *Meda Kshaya*. It creates *sthairya* in *Dhatus* (Compactness in Tissues) of body.[15]

Exercise helps in weight control. *Vyayama* should be done to certain limit by each individual mentioned as *Ardhashakti* in *Ayurveda* that is till the appearance of sweat on forehead, axilla and increased breathing rate. Basically there is *Dhatu Shaithilyata* in *Prameha, Samhanana* of body is reduced so one should not go for vigorous exercise instead Yoga is very beneficial .Yoga postures like *Paschimottanasana*, *Halaasana, Vajraasana*, *Shalabhaasana, Vakraasana* are effective in reducing the blood glucose levels in patients with T2DM.[16]

The beneficial effect of yoga in T2DM has been attributed to increased insulin sensitivity at target tissues which decreases insulin resistance and consequently increases peripheral utilization of glucose.[17] It has also been postulated that yoga can rejuvenate or regenerate beta cells of pancreas.[18] In addition, *yoga* has positive effect on general well-being and stress.[19]

Samyaka Nidra (Adequate Sleep)

Due to proper and adequate sleep body tissues and *Doshas* remain in balanced state of health both physically and mentally. *Ayurveda* states that, happiness and sorrow, obesity and emaciation, strength and weakness, virility and impotence, knowledge and ignorance, life and death are all depends on adequate and inadequate sleep.[20] Repeated disruption of Circadian System, Pineal Gland, Melatonin suppression by exposure to light. Sleep deprivation causes impairment of the immune system plus metabolic changes favouring obesity. Poor sleep can be an important indicator of emotional stress. On the one hand, emotional stress can easily affect different aspects of sleep, such as initiation of sleep, sleep duration, and sleep quality.[21] Conversely, sleeping problems may not only be a consequence of emotional stress, but are often experienced as a significant source of stress. Studies reveals that habitual sleep disturbances were associated with a higher incidence of type 2 diabetes.[22]

Diabetics should wake up early so that hormonal flow is regular. Sleeping early at night reduces mental stress and restores energy too. One should strictly avoid Day sleep as it viciates *Kapha* and *Pitta Dosha*. Day sleep decreases *Agni* and causes

deranged metabolism that may cause increase in weight. In case of individuals working during night, they are advised to sleep during day time upto half of their normal duration at night time. Also one must take care not to sleep just after having food.

Sadvritta / Behavioural Modification

According to Ayurveda, to maintain a healthy and disease free life everyone should follow *Sadvritta* mentioned in *Ayurveda* texts. *Sadvritta* plays key role in the maintenance of health and prevention of disease. *Sadvritta* are regarded as one of the measures to prevent various types of diseases. It also plays important role in personal cleanness of body and mind. Continues practicing these principles gives balance and peace to the mind. This is code of conduct for keeping good and balanced condition of body and mind. By following these, the person can achieve two aims together such as Arogya (health) and *Indriya Vijaya* (control over the sense organs).[23]

One should not indulge in any activity without proper examination and should not postpone the things to be done at the proper time. One should not feel excessively exhilarated in achievements and depressed in loss. Should always remember normal modes of events happening since the cause of all things are definite and their effects are also definite. These all modifications helps in better management of stress.[24] Stress has long been suspected as having important effects on the development of diabetes. More than 400 years ago, the famous English physician Thomas Willis noted that diabetes often appeared among persons who had experienced significant life stresses, sadness, or long sorrow.[25] Chronic stress can also initiate changes in immune system activity. There is experimental and clinical evidence that a rise in the concentration of pro-inflammatory cytokines and glucocorticoids, particularly cortisol, in response to chronic stress and often in depression, both contribute to the behavioral changes associated with depression.[26] In addition, activation of the immune system can provoke neuroendocrine and neurotransmitter changes that are similar to those provoked by physical or psychological stressors. Sleep disturbance and depression were also associated to hypercytokinemia and activated innate immunity.[27]

Rasayana (Rejuvenating herbs & Minerals)

The *Ayurvedic* texts describe *Shilajatu* as a *Naimittika Rasayana* for *Prameha* and hence it is advisable to use *Shilajatu* in prediabetics or in diabetic management as an adjuvant therapy for promotive and preventive measure. Classically *Shilajatu* is well known for its *Naimittika Rasayana* effect, *Ojovardhaka* and *Pramehaghna* property. *Dalhana's* commentary on *Sushruta* considered *Shilajatu* as the best *Naimittika Rasayana* (Adjuvant therapy) for *Prameha*[28] *Nisha Aamalaki* prayoga is highly beneficial for diabetics.

Table I- Showing Behavioural measures & Diet advised in T2DM

Behavioural Modification/ *Sadvritta*	**Daily Regimens/ *Dinacharya***	**Dietary Modification Cereals & Pulses**	**Advisable Vegetables & Fruits**	**Oils**
Should control the urges of *Bhaya* (Fear), *Chintan* (excessive thinking), *Krodha* (Anger) etc	*Brahma muhurta Jagarana Vyayama*	*Purana Yava(Barley) Bajra(Millet) Purana Godhuma (Wheat) Shastika Shaali (Paddy ripened in 60 days)*	*Patola(Parvala) Vastuka(Bathua) Moringa Giloya(Tinospora cardifolia) Karela(Momordica)*	Mustard oil
One should not control urges of urine, faeces, hunger, thirst, sleep etc.	*Udvartana Snaana Samyaka Nidra*	*Mudga*(Green gram) *Aadhaki*(Pigeon pea) *Chanaka*(Chick pea) *Kulattha*(Horsegram)	Pomegranate *Amla, Kapitha Jambu Kharjoora*	Flax seed oil

Conclusion

Lifestyle strategies are cost effective, at least in delaying the onset of DM. Lifestyle strategies, unlike pharmacotherapy, are not limited by side effects and tolerability. In contrast to medications, which typically address only one risk factor, lifestyle modification simultaneously addresses obesity, glycemic control, BP, and lipid abnormalities. Furthermore, behavioral strategies, such as stress management and self-monitoring of food and exercise can be instituted.

Ayurvedic dietary and behavioural modification needs to be incorporated so that Prediabetics and Diabetics can be effectively managed. Diabetes is a complex condition so all aspects of its management need to be brought together in a complementary fashion incorporating treatment of acute complications while preventing long-term complications.

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सारांश

डायबिटीज मेलिटस (डीएम) एक पुरानी, प्रगतिशील चयापचय संबंधी विकार है, जिसकी विशेषता हाइपरग्लाइसेमिया है, जिसमें लंबे समय तक माइक्रोवास्कुलर (रेटिनोपैथी, नेफ्रोपैथी और न्यूरोपैथी) और मैक्रोवास्कुलर (हृदय) जटिलताएं होती हैं। औषधीय हस्तक्षेप यानी दवाएं हमेशा मधुमेह को नियंत्रित करने के लिए आवश्यक नहीं हैं, लेकिन गैर–औषधीय प्रबंधन पर भी जोर दिया जाना चाहिए। प्रमेह को आयुर्वेद ग्रंथों में बताया गया है कि यह मधुमेह के समान है। प्रमेह की रोकथाम और प्रबंधन के लिए आहार संशोधन और शारीरिक गतिविधियों के बारे में आयुर्वेद ग्रंथों में विस्तृत विवरण उपलब्ध है। यह लेख आयुर्वेद ग्रंथों में जीवन शैली संशोधन के विभिन्न संदर्भों को जीवन में लागू किए जाने पर, दिनचर्या, आहार, विहार, सद्वृत्त, रसायन के सिद्धांत रोकथाम में प्रमुख भूमिका निभाते हैं और साथ ही साथ मधुमेह के बेहतर प्रबंधन में भी सहायक होते हैं।

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ORIGINAL ARTICLE

Conceptual study on *Aartavakshaya*

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ABSTRACT

In the modern world the sedentary life style associated with stress increased menstrual disorders. Among menstrual disorders oligomenorrhea or hypomenorrhea is the most common gynaecological problems. Ratio of menstrual disorder is rising in gynaecological practice which is a precursor of infertility associated with various metabolic disorders, so it requires more attention. Menstrual disorder affects mental state of women. Modern medical science gives Hormonal therapy for menstrual disorders which have many side effects if continued for long time. So, in contemporary era it is very important to provide a particular etiopathology and treatment for "*Aartavakshaya*". Present article aims at elaborating details of *Aartavakshaya* mentioned in *Ayurveda* classics.

Keywords: *Aartava*, *Aartavakshaya*, Hypomenorrhea, Menstrual disorders, Oligomenorrhea.

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Introduction

Mother is the most blessed and beautiful word in the world; in this universe only females have been bestowed the power of creation next to the enormous God. This is why women are considered as reflection of the God in this world. But the root of the importance of women lies in their capacity of creation. This is the reason why the question of fertility is most important for women. In *AyurvedaAartavadushti* is one of the cause behind it.The word *Aartava* denotes two meanings one of them is *Antah Pushpa* and another one is *Bahir Pushpa*. Both *Antah* and *Bahir Pushpa* are interrelated. *Bahir Pushpa* is outward manifestation of appropriate work of *Antah Pushpa* which is necessary for conception. Here, the present studies deal with *Bahir Pushpa* that is Menstrual Blood.

Aim and Objectives: -

1. To review and compare literary data available on *Aartavakshaya* in different Ayurvedic

and modern classical texts.

Materials & Methods:

Only literary material from available Ayurvedic classical texts and commentaries were reviewed, compared and analysed on classical background to find similarities, dissimilarities and clinical approach in accordance to modern science.

Literary Review:-

There are no direct references regarding *'Aartavakshaya'* in *Veda*. Shri Keshava Dutta Shastri, the author of *'Atharvediya Karmaja Vyadhi Nirodha'* has mentioned the etiopathogenesis of *Anartava* and its management. In '*Vandhya Kalpadruma'* the author has mentioned the etiopathogenesis of '*Nyunartava*' and its management.

Here, in *Nyunartava* word '*Nyun*' means less quantity. In '*Aartavakshaya*' word '*Kshaya*' means less quantity.

Acharya Sushruta described *Lakshanas* and *Chikitsa* of '*Aartavakshaya' i*n brief.[1] While describing the *'Aartavadosha'* he has mentioned *'Kshinartava'. Kshinartava* is one of the symptom of '*Aartavakshaya*'[2]

In both *Vagabhata* – I, II, The word '*Aartavakshaya*' is not clearly used but the word *'Kshinartava'* has been used which is actually a synonym of '*Aartavakshaya.*'[3]

Bhel – *Acharya Bhel* has described '*Alpartava*' and '*Vikritaartava*' but here also they are synonymous of '*Aartava-kshaya*'.

Sharangadhara – He has mentioned '*Kshinartava*' as synonyms of '*Aartavakshaya.*'[4]

Defination of *Aartava*:

Ruturbhavamaartavam...[5]

Aartava means monthly vaginal bleeding. Here word '*Rutubhavam*' indicates the particular time. That is monthly menstrual blood flow.

The word 'Menstruation' has its origin from the Greek word 'men' meaning month. It's literally meaning is the periodic discharge of a bloody fluid from the uterus. Thus, both words '*Aartava*' and 'Menstruation' convey same meaning i.e. belonging or confirming to seasons or periods of time.

Synonyms:

Our ancient *Acharyas* have described certain words for menstrual blood.

(1) *Aartava* (2) *Shonita* (3) *Asrik* (4) *Raja* (5) *Rakta* (6) *Lohita* (7) *Rudhir* (8) *Pushpa*

These words are used to indicate menstrual blood as well as ovum.

It is therefore necessary to consider reference to context before interpreting them exactly for menstrual blood or ovum or even ovarian hormones.

In modern texts, period, menses or catamenical flow are the words used as synonyms of menstrual blood.

Properties of *Aartava*:

First we have to consider physiology of *Aartava* before coming to conclusion of *'Aartavakshaya'.*

Physiology of *Aartava* is described in Ayurvedic classics under the heading of '*Shuddha Aartava Swarupa'.*

(1) *Varna*

According to *Acharya Charaka* normal colour of menstrual blood is like *Gunjaphala*, *Lal Kamala* (Red lotus flower), *Indragopa* (An Insect) and *Alaktaka.*[6]

Acharya Sushruta explained that the colour of *Shuddhartava* should resembles with the *Shasha Asrik* (Rabbit blood) and *Laksha Rasa.*[7]

According to modern text menstrual blood is bright red in colour.

(2) *Gandha*

Menstrual blood has specific odour. According to *Madhukosha Vyakya*; *Aartava* is *Madhu Gandhi.*

Acharya Sushruta says '*Rakta*' has *Vistrata* (*Amagandhitva*) due to *Prithvi Mahabhuta* same can be consider for *Aartava*.[8]

The menstrual blood has a characteristic odour caused partly by bacterial action degeneration; partly by the accompanying secretion of sebaceous and apocrine gland on vulva.

(3) *Matra*

Acharya Vagabhata denotes *Aartava Pramana* measuring to four *Anjali*.

According to modern medical science measurement of Menstrual blood loss is also varies from individual to individual. The amount of blood loss is estimated to be 20ml to 80 ml with an average of 50ml.

(4) *Aartava Srava Kala*

Aartava Srava Kala means duration of menstrual bleeding. *Aartava Srava Kala* varies with individuals. *Ayurvedic* classics have different opinion regarding duration of menstruation. It describes three *(Vagbhata & Bhavamishra)* to five (*Charaka*) days and rarely up to seven (*Harita&Bhela*) days.

(5) *Aartavapravritti Chakra Kala*

Aartava Pravritti Chakra Kala means interval between two menstrual cycles.

According to modern science, once the menstruation starts, it continues cyclically at intervals of 21 to 35 days with a mean of 28 days (Text book of gynecology by D.C. Dutta)

If inter menstrual period is exceed up 35 days, it is known oligomenorrhea.

***Aartava Vaha Srotas*:**

Aartavavahasrotasa is one of the part of the Anatomy of female genital tract and since *Aartavakshaya*is also connected with *Aartava Vaha Srotas*, it is very important to discuss about *Aartavavahasrotas*.

"*Aartavavahedwetayormulam Garbhashaya*"[9]

Aartava Vaha Srotas are two in number, having roots in *Garbhashaya* and *Aartava Vahi Dhamanis*, injury to these produces infertility, dyspareunia and amenorrhoea. *Acharyas* have different opinion regarding modern concept of '*Aartava Vaha Srotas'*. *Pandit Gangadhar Shastri* denotes *Aartava Vahi Srotas* as Uterine mucosa.

Acharya Ghanekarji cite uterine arteries as, "*Aartava Vaha Srotasa*"

Aartavakshaya as Disease:

Acharya *Sushruta* quoted *Aartavakshaya* as a disease as it is known that disease is a combination of sign and symptoms.

1) Yathochit Kale Adarshanam

2) Yoni Vedana.

3) Alpata

1) Yathochit Kale Adarshana: It means increase or decrease menstrual cycle or dysfunctional uterine bleeding.

2) Yoni Vedana: pain during menstruation / dysmenorrhea.

3) Alpata: It may be hypomenorrhea or oligomenorrhra.

Hypomenorrhea means scanty menses in normal menstrual cycle (25 to 35 days)

Oligomenorrhea means increased menstrual cycle ≥ 35 days to 6 month.

The word *Aartava* denotes two meanings one of them is *Antah Pushpa* and another one is *Bahir Pushpa*. Both *Antah* and *Bahir Pushpa* are interrelated. *Bahir Pushpa* is outward manifestation of appropriate work of *Antah Pushpa* which is necessary for conception. Here, the present studies deal with *Bahir Pushpa* that is menstrual blood.

Aartavakshaya is more related to internal genital organs. To evaluate the disease *Aartavakshaya* genital organs are very important. To understand the pathology of internal genital organ, anatomy of this organ must be understood. Normal menstrual pattern depend upon ovulation so it is necessary to understand ovum according to *Ayurveda* as *Antah Pushpa* term frequently used in the context of ovum in *Ayurveda*.

Beejagranthi:-

- While describing *Viddhalakshana* of *Aartavavaha Srotas*, *Acharya Sushruta* has enlightened the functions of ovary.
- *Tatraviddhaya Vandhyatva Maithunasahishnuta Aartavanashash*[10]

Means, any trauma to the *Aartavavaha Srotas* may leads to *Vandhyatva, Maithunaasahatva* and *Aartavanasha*. However, he has not given any description about The Anatomy Of Ovary.

Beeja Nirmana:-

*Aahara*is the most important entity for survival. The *Aahara,* composition of *Panchamahabhuta,* is acted upon by *Jatharagni, Bhutagni* and *Dhatvagni* and the resultant nutritious material is made available up to cellular level. In this course, *Ayurvedic* texts mentioned the formation of *Dhatus, Upadhatus, Malas,* and *Doshas*etc.

The formation of the factor responsible for *Garbhadharana* occurs from *Rasadhatu*. The *Aahara Rasa* derived from the consumed *Aahara* by the action of *Jatharagni* is subjected to *Rasa Dhatvagni* to produce the *Aartava*. The process of *Pravartana* of *Aartava* is governed by *Apana vayu* as mentioned by *Acharya*s in the *Prakrita Karma* of *Apana vata*.[11]

***Swarupa* of *Beeja*:**

The *Swarupa*as described by *Acharya*s in various contexts are:

Rakta Lakshanam Aartavam Garbhakruttacha...|[12]

Aartavam Agneyam|[13]

Aartava is *Agneya*, has characteristics of *Rakta*, forms *Garbha*and also essential for creation of life.

Kala* of *Beeja Nirmana:

The *Aartava* becomes *Vyakta* in a female body from the age of twelve years and persists up to fifty. Thus it is physiologically absent before twelve years and after fifty years. The *Aartava* is manifested from *Rasa* in the female body within a month. The production of both menstruation and ovum is monthly[14] so, this reference can be true for the meanings of *Aartava*. The term *Rutukala* is defined as period most suitable for achievement of conception. The *Rutukala* in which, the seeds deposited are likely to bear fruits. This directly refers to the period of ovulation wherein the chances of conception are most. *Acharya Kashyapa* has also explained *Rutu Kala* as the *Beeja Kala*.[15]

***Aartavakshaya Chikitsa*:**

Chikitsa is nothing but '*Samprapti Vighatana' Chikitsa* mainly divided into two segments.

1. *Shamana* or *Abhyantra*
2. *Samshodhana* or *Sthanika*

Acharya Sushruta said '*Aartavakshaya*' should be treated by the use of purifying measures (*Samshodhana*) and *Agneya* substance. *Dalhana* says that for purification, only emetics should be used not the purgatives, because purgation reduces *Pitta*, which in turn decreases *'Aartava'* while emesis removes *Saumya* substances, resulting into relative increase in *Agneya* constituents of the body consequently '*Aartava*' also increase.

Commentator *Chakrapani* says that by use of purifying measures *Srotas* are cleared. Emesis and purgation clear upward and downward direct *Srotas* respectively, thus both should be used, giving due consideration to the dosages of drugs used for purification and fitness of the woman.

Acharya Kashyapa says *Aartavakshaya* is *Anuvasana Sadhya Vyadhi*.[16]

Acharya Vagabhata –I – II, recommend *Pitta Vriddhi Kara* and *Rakta Vriddhi Kara Chikitsa*

Abhyantara Chikitsa

No.	Name of Preparation	Name of *Yoga*	Reference
1	*Kwatha*	*Tila, Karvi, Guda, in Form of Decoction* *Krishna Tila Kwath* with *Guda Mishreya* *Methikamuli, Garjara, Shatpushpa* Etc. in Form Decoction	Bha. Pra. Chi 70/22-24. Yog Ratna. Yoni Vyapada Chikitsha Adhyaya Harihar Samhita
2	*Churna*	*Shatpushpa*	*Kashatpushpa-shatavariKal.*
3	*Vati*	*Rajah Pravartini Vati Rituvari Vati* *Kanyalohadi Vati* *Boladivati* *Nastapushpantaka Rasa*	Bhai. Rat. 67/58-60. *Rasoddhara Tantra* *Rasoddhara Tantra* *Rasoddhara Tantra* Bhai-Rat. 67/51-59.
4	*Modaka* etc.	*Aswathamuladi Modaka Agashti* *HaritakiModaka*	Bhel. Chi – 4 H.S. Sutrsthana – 9/63-66.
5	*Ghrita*	*Phala Ghrita* *Brihata Shatavari Ghrita* *Kumar Kalyana Ghrita Shitakalyana Ghrita* *Maha Kalyanaka Ghrita*	Bha.Pra. Chi 70./54-56, 58, 81 Yog.Rat.Yo. Vya. Chi -2 Ch.chi 30-36-64, A.S. Utt 39/55 A.H. Utt 34/36-39 Bhai Rat 67/92-108 Yog Rat Prada chi-2 A.S.Utt – 9/19 A.S.Utt – 9/20

Sthanika Chikitsa

No.	Name of Preparation	Name of *Yoga*	Reference
1	*Basti*	*Anuvasana Basti* Shatavaryadi Uttar Basti Taila of Jivaniyadigana Dravya Shatpushpa Taila Arkapushpa Tail Uttarbasti	*Ch.si* 12/18 *Ch.chi* 30/102 Ka.Kalpa-*shatpushpa* *Shatarvari Kalpa.* *Bha.bhai.rat*-4
2	*Varti*	*Ikswaku-Bija,* *Danti, Chapala,* *Madana Phala, Guda, Surabija, Yavashuka,* *Snuhikshira in Form of Varti*	*Bha.Pra.chi 70/22-24* *Yog. Rat.Yo.Vya. chi* – 2

(**Abbrevations**:

Bha. Pra. Chi: Bhavprakash Samhita chikitsasthan

YogRatna: Yog Ratnakar

Ka: Kashyap Samhita

Bhai. Rat.:Bhaishajya Ratnavali

Bhel. Chi :Bhel Samhita Chikitsasthan

H.S. Sutrsthana :Harita Samhita Sutrasthana

Yog.Rat.: Yogratnakar

Ch.chi: charaka Chikitsasthan

A.S. Utt: Ashtang Sangrahauttersthan

A.H. Utt: Ashtang Hridyamuttersthan

Ch.si: charaksiddhisthan

Ch.chi:Charakchikitsasthan

Ka.Kalpa: Kashyap Samhita Kalpasthan

Bha.bhai.rat: Bharat Bhaishajyaratnakar)

***Sadhyasadhyata* (Prognosis)**

In *Ayurvedic* classics, there is no description about prognosis of *Aartavakshaya* but prognosis of *Kshinartava* is described in *Ashtartava Dusti*. Here, *Aartavakshaya* is synonyms of *Kshinartava*, so we can take it.

Sushruta says that *Kunapa-gandhi*, *Granthi-bhuta*, *Putipuya*, *Kshina* and Mutrapurishagandhi disorder are incurable[17]

Vagabhata – I, corroborating *Sushruta* has accepted *Kshinartava Dusti* as curable one.[18]

Physiological Consideration Of *Aartava*:

Each and every process of human body depends upon rhythmic phenomenon. Some processes of rhythmic phenomenon of human body are heart rate and menstrual bleeding. These phenomena are most rhythmic because it is noticed externally. Here our subject is related to menstruation. Menstruation depends on the cyclic release of the steroid hormones estrogen and progesterone. If this cyclic phenomenon is normal then everything goes normally. It is therefore very essential to know physiology of menstruation to diagnose abnormality of menstrual disorder.[19]

For understanding of menstrual disorder

according to *Ayurveda* it is necessary to understand normal menstrual pattern.

The Normal Menstrual Cycle

The menstrual cycle is divided into a follicular or proliferative phase and a luteal, or secretory, phase. The secretion of FSH and LH is fundamentally under negative feedback control by ovarian steroids (particularly estradiol) and by inhibin (which selectively suppresses FSH), but the response of gonadotropins to different levels of estradiol varies. FSH secretion is inhibited progressively as estrogen levels increase—typical negative feedback. In contrast, LH secretion is suppressed maximally by sustained low levels of estrogen and is enhanced by a rising level of estradiol—positive feedback. Feedback of estrogen involves both the hypothalamus and pituitary. Negative feedback suppresses GnRH and inhibits gonadotropin production. Positive feedback is associated with an increased frequency of GnRH secretion and enhanced pituitary sensitivity to GnRH. The length of the menstrual cycle is defined as the time from the onset of one menstrual bleeding episode to onset of the next. In women of reproductive age, the cycle averages 28 - 30 days and the mean duration of flow is 4 -2 days. Longer menstrual cycles (usually characterized by anovulation) occur at menarche and near the onset of menopause. At the end of a cycle, plasma levels of estrogen and progesterone fall and circulating levels of FSH increase. Under the influence of FSH, follicular recruitment results in development of the follicle that will be dominant during the next cycle. After the onset of menses, follicular development continues, but FSH levels decrease.

Approximately 8 to 10 days prior to the midcycle LH surge, plasma estradiol levels begin to rise as the result of estradiol formation by the granulosa cells of the dominant follicle. During the second half of the follicular phase, LH levels also begin to rise (owing to positive feedback). Just before ovulation, estradiol secretion reaches a peak and then falls. Immediately thereafter, a further rise in the plasma level of LH mediates the final maturation of the follicle, followed by follicular rupture and ovulation 16 to 23 h after the LH peak. The rise in LH is accompanied by a smaller increase in the level of plasma FSH, the physiologic significance of which is unclear. The plasma progesterone level also begins to rise just prior to midcycle and facilitates the positive feedback action of estradiol on LH secretion. At the onset of the luteal phase, plasma gonadotropins decrease and plasma progesterone increases. A secondary rise in estrogens causes further gonadotropin suppression. Near the end of the luteal phase, progesterone and estrogen levels fall, and FSH levels begin to rise to initiate the development of the next follicle (usually in the contralateral ovary) and the next menstrual cycle. Inhibin A levels are low in the follicular phase but reach a peak in the luteal phase. Inhibin B levels, in contrast, are increased in the follicular phase and low in the luteal phase. The endometrium lining the uterine cavity undergoes marked alterations in response to the changing plasma levels of ovarian hormones. Concurrent with the decrease in plasma estrogen and progesterone and the decline of corpus luteum function in the late luteal phase, intense vasospasm occurs in the spiral arterioles supplying blood to the endometrium, causing ischemic necrosis, endometrial desquamation, and bleeding. This vasospasm is caused by locally synthesized prostaglandins. The onset of bleeding marks the first day of the menstrual cycle. By the fourth to fifth day, the endometrium is thin. During the proliferative phase, glandular growth of the endometrium is mediated by estrogen. After ovulation, increased progesterone levels lead to further thickening of the endometrium, but the rapid growth slows. The endometrium then enters the secretory phase, characterized by tortuosity of the glands, curling of the spiral arterioles, and glandular secretion. As corpus luteum function begins to wane in the absence of conception, the sequence of events leading to menstruation is again set into action.[20]

Discussion:

Aartavakshaya is one of the important diseases pertaining to *Aartava*. It is explained in *Brihatrayee* i.e *Sushruta, Charaka, Vagbhata* & in *Laghutrayee* like *Bhavaprakasha,Sharangadhara*. It is characterised by delayed, scanty menstruation associated with pain along reproductive tract.

Ayurvedic literature, advocates *Shodhana* & *Agneya Dravya Upayoga*. *Aartavakshaya* described as the most common menstrual disorders have become a challenging problem may cause functional disturbance associated with complaint of infertility and other metabolic disorder etc. *Aartava* is related to reproductive life of woman as well as it helps to restore the normal rhythmic pattern of body. In modern medical science it is treated with hormone replacement therapy (HRT), having long terms use and produces many side-effects. But *Ayurveda* describes various treatment modalities and drugs to treat *Aartavakshaya* with better responses and without causing any side-effects.

Conclusion:

Ayurveda has given various aspects of physiology of menstruation in microlevel than that of modern science which are helpful to aware of menstruation. In *Ayurveda* all menstrual irregularities associated with decrease menstrual flow comes under broad heading of *Aartavakshaya*.As menstruation is goverened by *Doshas* their imbalance causes abnormality. Therefore, it is necessary to have balance state of *Dosha, Dushya, Dhatu* and *Mala*.

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सारांश:

आधुनिक युग में आसीन जीवन एवं तनाव से जुडी शैली के कारण मासिक धर्म संबंधी विकार में वृद्धि हुई है। मासिक धर्म संबंधी विकार जैसे कि अल्प रज सबसे आम स्त्रीरोग की समस्या है। मासिक धर्म विकार के अनुपात में लगातार वृद्धि हो रही है, जो की बांझपन एवं उससे संबंधित विभिन्न चयापचय विकारों का कारण है। इसलिए इस समस्या की ओर अधिक ध्यान देने की आवश्यकता है। मासिक धर्मविकार महिलाओं की मानसिक स्थिति को प्रभावित करता। आधुनिक चिकित्सा विज्ञान में मासिकधर्म संबंधी विकार की चिकित्सा में हारमोन्स थेरेपी दी जाती है, जिसके लंबे समय के लिए जारी रखने से कई दुष्परिणाम होते है। तो, समकालीनयुग में इसके लिए एक विशेष हेतु विज्ञान और उपचार प्रदान करना बहुत जरुरी है। अत: वर्तमान लेख में, आयुर्वेदशास्त्र में उल्लेखित आर्तवक्षय के विवरण का विस्तार से वर्णन किया गया है।

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ORIGINAL ARTICLE

An Analytical Study on *Tamra Patra Sthita Jala*

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ABSTRACT

The World Health Organization (2006) estimates that 88% of diarrhoeal disease is attributed to un safe drinking water. Therefore, it becomes necessary to treat water before consumption. Household-level methods of drinking water treatment are commonly referred as PoU (Point of Use). There are many PoU available in market which is effective but they have some shortcoming like expensive maintenance, need electricity etc.

Ayurveda recommends many methods of water storage and purification like boiling; filtration sun light etc. Use of *Tamra Patra* for storage of drinking water is recommended in different *Ayurvedic* treaties. The aim of present study was to explore the facts behind the traditional use of *Tamra Patra* for storage of water and its use as a PoU. A complete analytical study of effect of copper in purification of drinking water was done in this study.

Keywords: Copper, Copper treated water, PoU, *Tamra Patra,* Unsafe water, Water purification.

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Introduction

Water is fundamental to better health and community development. According to the United Nations, over 1.1 billion people lack access to safe drinking water, of which nearly two thirds live in Asia. The intermittent and infrequent supply of water also results in need for storage of water at homes for drinking Storage practices of water in various containers that are not properly covered, inadequate cleaning of storage containers, unhygienic storage conditions that lead to biofilm formation and unhygienic handling and dispensing activities

contribute to contamination of water. Therefore, it becomes necessary to further treat water at point of consumption or at the household level. In *Ayurveda*, procedures of *Jalshodhana* (purification of water) are boiling, sun exposure, quenching the hot earthen ball in water, sieving, use of *Katak, Sphatika,* pearl, gems etc. Metals such as copper, silver and gold are used for making utensils to keep drinking water; they are also used traditionally in India. Use of *Tamra Patra* for storage of drinking water is not only recommended in different *Ayurvedic* treaties but also practiced for generations.

Material and Method:

The aim of present study was to explore the facts behind the traditional use of *Tamra Patra* for storage of water and to evaluate its role in changing the quality of drinking water. To fulfil this target water was assessed on physical, chemical and biological parameters according to IS standards. Sample collection bottles of glass were used to collect samples from source of supply for chemical and physical analysis. Each bottle was of two liter capacity. Sterile sample collection bottles were used to collect the samples for microbiological analysis and transfer of samples to lab after experiment. Before collecting samples bottles were rinsed well three times with water filling it each time about 1/3 full. These samples were collected from a tap which was in regular use and tap was left open for two minutes. Before collection of samples tap was cleaned properly and flamed to avoid any contamination. While collection of sample bottle was held near the vase with one hand and stopper and paper cover were held in other hand. The stream was gentle to avoid splashing. Then bottles were filled with water and stoppers were tied with a cloth over it. Copper pots of 3 L capacity with a surface area of approximately 750 cm^2 were purchased from a kitchenware shop. These vessels were non-reactive utensils made up of copper and used to store water for overnight before transferring to lab.The pots were cleaned each time before use with citric acid to get a clean shiny surface and rinsed thoroughly with water. This was then autoclaved and used for the study. All reagents and equipment as per Indian standard guidelines was used to analyse different parameters.

Observation and Result:

The analytical study has been conducted in standard government lab. The sample was analysed on test protocols as per India Standards. The observations are comprehended in Table No. I.

Table No.I: observed values of different parameters before and after the experiment

Sr. No.	Test	Observed Values		Specific values
		Before	After	
1	Colour hazen units	Colourless	Colourless	5 max
2	Odour	Objectionable	Aggreable	Aggreable
3	Turbidity (NTU)	2.6	1.2	1 max
4	pH	7.79	8.04	6.5 to 8.5
5	Total dissolved solids, mg/l	2918	2948	500 max
6	Copper (asCu), mg/l	<.01	1.42	.05 max
7	Total Coliform per 100 ml	Present	Absent	Absent

In this study significant changes have been observed in copper, turbidity, pH, TDS value

Discussion:

The water quality monitoring results obtained during 1995 to 2011[1] indicate that the organic and bacterial contamination are continued to be critical in water bodies. This is mainly due to discharge of domestic wastewater mostly in untreated form from the urban centers of the country. Although community water supplies providing safe drinking water after disinfection, they may be prone to contamination during transport or handling[2]. Approximately 72.2% of rural populations consume untreated water owing to various reasons including taste (in the case of chlorine) or cost[3]. Many studies have demonstrated that PoU water purification methods significantly improve the physiochemical and microbial quality of water. Many simple methods are recommended in Ayurveda for enhancing the quality of drinking water.

Water purification in Ayurveda:

Several methods of water purification are explained in *Ayurveda* classics. During Samhita period water was not as polluted as at present due to lack of industrialization and less population. Hence we can classify the methods in three categories as we explained earlier in *Ayurveda* review. When water is not much polluted and contain only physical impurities at lesser extent it may be purified with simple filtration (*Garh Vastra Parisrav*). Water with physical impurities with lesser extent of biological impurities could be made potable with moderate application of heat (*Nirvapan*). When water is highly impure and contains all kind of impurities physical as well as biological it could be made potable with boiling process (*Agni Kwathan*). So it is proved that methods explained in classics are sufficient to fulfil the purification requirements of that period.

Potential of Copper device as a low-cost water purifier:

This study has demonstrated that the copper pot not only changed the physical chemical properties of water but also inactivate bacteria, thus demonstrating its potential as a PoU water purifier. Copper pots for treating one liter of water would cost INR.500 - 600/- for a life time. Its functioning is not dependent on fuel, electricity, replaceable filters, intensity of sunlight, etc. to operate or maintain it. It also reduces recontamination due to handling. It is simply a passive storage of water. In this study significant change has been observed in following parameters.

1. pH values:

In this study pH values has been analyzed as per I.S. (Indian Standard) protocol. The pH was within normal permissible limits and increased after storage in copper pot.

2. Turbidity:

A significant decrease in turbidity was observed. The change in turbidity might be due to formation of sediments. Further study is required to find the effect of copper on turbidity of water.

3. Copper:

WHO (World Health Organization) (1996) estimated that average copper requirements are 12.5 ìg/kg of body weight per day for adults and about 50 ìg/kg of body weight per day for infants. The IOM (Institute of Occupational Medicine) recommended 10 mg/day as a tolerable upper intake level for adults from foods and supplements. In most foods, copper is present bound to macromolecules rather than as a free ion.Food and water are the primary sources of copper exposure in developed countries. In general, dietary copper intakes for adults range from 1 to 3 mg/day. Drinking water contributes 0.1–1 mg/day in most situations. Thus, daily copper intakes for adults usually range from 1 to 5 mg/day. Concentration of copper increased after storage in copper pot. Although these values are within limits as per WHO guideline. Probable cause of this leaching might be due to cuprosolvency. Further clinical study on effect of continuous use copper containing water is needed to know the effect of water stored in copper pots. Study to evaluate the effect of copper containing water in humans is required, in both long as well as short duration.

4. Total dissolved solids:

TDS (Total dissolved solids) value have increased due to storage in copper pot, but this increase was not very significant.

5. Total coliform bacteria:

Coliform bacteria was not recovered after storage in copper pot. The antimicrobial activity of copper is well established. Copper exhibits antibacterial activity against a range of Gram positive and Gram negative bacteria, including spores.

Conclusion:

- Copper leaching occur in water stored in coper pot in significant levels.
- Odour of water improved after storage in copper pots.
- pH changes occur in water after storage in copper pots.
- Quality of water improves.
- Microbial contamination reduced as an effect of copper on water.

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सारांश:

विश्व स्वास्थय संगठन का अनुमान है कि 88 प्रतिशत डायरिया रोग के लिए असुरक्षित पेयजल जिम्मेदार है। इसलिए प्रयोग से पहले जल का शोधन आवश्यक हो जाता है। पीने के पानी के शोधन के घरेलू तरीकों को आमतौर पर पी.ओ.यू. (प्रयोग पूर्व उपाय) कहा जाता है। बाजार में कई पी.ओ.यू. संसाधन उपलब्ध हैं जो प्रभावी हैं, लेकिन सभी में कुछ न कुछ कमी है, जैसे कि महंगा रख रखाव, बिजली की आवश्यकता आदि। आयुर्वेद में पानी के शुद्धिकरण के कई तरीकों का वर्णन है जिसमे से ताम्र के प्रयोग का वर्णन कई संहिताओ में मिलता है. इस अध्ययन का उद्देश्य पानी के भंडारण के लिए ताम्र पत्र के पारंपरिक उपयोग और पी.ओ.यू. के रूप में इसके उपयोग के पीछे के तथ्यों का पता लगाना था। इस अध्ययन में पीने के पानी के शुद्धिकरण में तांबे के प्रभाव का एक संपूर्ण विश्लेषणात्मक अध्ययन किया गया है।

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ORIGINAL ARTICLE

Ayurvedic Management of Obstructive Uropathy with Vesico-Ureteral Reflux : A Case Study

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ABSTRACT

Ayurveda offers a different approach for the diagnosis and treatment of obstructive uropathy. In present case study, a male patient, 17 years old with symptoms like painful micturition, pain in lower abdomen, anorexia, weakness etc. Diagnosed with obstructive uropathy with vesico-ureteral reflux by contemporary medical science and *Mutraghata* according to *Ayurveda*. The *Ayurveda* treatment included *Mutravirechaneeya* drugs, vatanuloman and *Virechan* and symptomatic treatment. The patient showed remarkable relief clinically and laboratory parameters also significantly came close to normal.

Key words: Obstructive uropathy, vesico- ureteral reflux, *Ayurveda*

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Introduction

Obstructive uropathy is functional and structural hindrance of normal urine flow, sometimes leading to renal dysfunction (obstructive nephropathy)[1]. This condition in some cases results in vesico-ureteral reflux. Obstructive uropathy in Ayurveda is mentioned under *Mutraghata* which encompasses thirteen different conditions.[2] The present case is of bladder outlet obstruction for which treatment given by contemporary medical science was indwelling catheter for long term but no absolute treatment was recommended. *Ayurveda* suggest the drug therapy for the condition which act on the disturbed equilibrium of *Dosha* and affected *srotas* and *Dushy*.

Case History:

A patient male, 17 admitted to the IPD of *Maulik Siddhanta* Dept of National Institute of Ayurveda, Jaipur. He was experiencing painful micturition, scanty urine, pus in urine, pain in both the flanks (*Katigrah),* pain in lower abdomen, fever

(*Jvar)*, anorexia (*Aruchi*), weakness (*Daurbalya*), constipation (*Vibandh*) since 2 months.

Past History: The patient, since childhood didn't have proper sensation for micturition. He only experienced urge for maturation when he felt heaviness in the lower abdomen and used to take longer time in maturation. Patient was in the habit of taking very spicy food and 3 to 4 glasses of tea daily. Two months back, the patient experienced pain in both the flanks (*Katishula*), fever (*Jvar*), painful maturation, oligoanuria, anorexia, and weakness. Patient consulted to allopathic hospital and was suspected with obstructive uropathy (bladder outlet obstruction) with vesico-ureteric reflux. He was catheterized and given the antibiotic cover. The symptoms were relieved. Later, patient again developed the same problems and this time the catheterization was obstructed and could be done with difficulty. Patient was advised for clean intermittent bladder catheterization for lifetime. The patient, then came for *Ayurvedic* consultation. The investigation history is as follows

USG (26/07/2018)

Hydrouretero nephrosis, tortuous dilated uterus, paper thin renal parenchyma

Pre-voiding urine volume: 700ml

Post void residual urine volume: 650 ml

NCCT KUB (27/07/2018)

Both kidney enlarged, dilatation of bilateral pelvicalyceal system, thinned out renal cortex, bilateral toutous ureters with over distended urinary bladder

USG (03/08/2018)

Gross dilated PCS and ureters, sludge and thickening in Urinary bladder, lower ureter sludge

Pre-voiding urine volume: 120ml

Post void residual urine volume: 40 ml

Table I

Investigation name	27/07/2018	3/08/2018	10/08/2018	28/08/2018	8/09/18 (during ayurvedic treatment)
RBS	130.5	78		155	
S.urea	131.87	106	98	86	25
S. Creatinine	4.02	3.08	2.94	3.33	0.6
Na^+	138.4		137	179	
K^+	6.22		5.15	4.04	
Cl^-	107.7 mMol/L		117	116	
Urine	Sugar, protein –nil Pus cells 18-20				WBC- full field
PTH	302.8				
Hb	6.8	8.2	8.6		11.5
ALP	NAD			268	

Diagnosis: The symptoms of patient in *Ayurvedic* terms can be understood as following

Table - II

Symptom in patient's language	Symptoms according to *Ayurveda*
Micturition with pain	*Sakashtamutrata*
Scanty urination	*Mutrasanga*
Turbid urine	*Shwetasandra mutra*
Pain in both flanks	*Katigrah*
Pain in lower abdomen	*Udara shula*
Anorexia	*Apakti*
Weakness	*Daurabalya*
Constipation	*Vid sanga*

The symptom painful maturation suggest primarily *Mutrakrichchha*[3]. The obstruction of urine has been resulted in the backflow of urine and the pain by virtue of *Vimrgagaman* of *vata* and this symptom is suggestive of *Mutrajathar*, a condition of *Mutraghata*[4]. The other associated symptoms like *Mutravitsanga*, *Apakti* also confirms the diagnosis[5]. The appearance of turbid urine can be taken for superimposed *Kaphaja Mutrauksada* which is also a condition of *Mutaghata*[6]. The condition vesico urteric reflux can be considered congruent with "*Mutrajathara*".

Treatment given:

The aim of the treatment was to ease the maturation process, increase the urine outflow, pacification of *vata* and subsiding the other symptoms. The *Ayurvedic* line of treatment for obstructive uropathy is facilitating the urination (*Mutavirechan)*, pacification of *vata* (*Vatanuloman*) and symptomatic treatment.[7] The treatment prescribed was *Trunpanchmula kashayam* 50 ml BD plus 250 mg *Shwetaparpati* BD, *Gokshur paneeyam*, *Gokshuradi guggulu* 2 tab BD, *Godanti bhasma* 250 mg BD. The treatment was continued for one week. The complains like pain in flanks and pain during maturation were very mildly relieved. The amount of urine increased. Fever and constipation was persisting on and off. The pus appearance in urine was persisting. Then, *Varunadi Kashayam* 20 ml, *Dashmoola Kashayam* 50 ml BD and *Sanjeevani* vati 2 tab BD were added to the previous treatment and *Godanti bhasm* was omitted. The treatment continued for one more week. The complain of fever subsided. Then, the patient was given five *basti* viz. first *Anuvasan Basti* with *Dashmoola tailam*, after that three *niruha basti* of *Varunadi Kashayam*, *Trunapanchmula kashayam* and then again a *Anuvasan Basti* with *Dashmoola tailam* and *Panchtiktaghritam*. The pain in flanks and complain of constipation were relieved and pain during maturation got relieved to a greater extent. *Shilajatu* 250 mg was added to the prescription. After one week the turbidity of the urine was also reduced. Then the patient was discharged. The discharge prescription was *Shilajatu* 125mg OD, *Dashmoola kashyam* 50 m BD, *Sanjeevani vati* 2 tab BD, *Varunadi kashyam* 50ml BD, *Trunapanchmula kashyam* 50 ml BD. The investigation results during the treatment have been mentioned in table1 (08/09/2018).

Discussion

It is evident from the symptoms that the *Basti Marma* of the patient is affected.[8] In text, the treatment of *Basti Marma* has been mentioned as *Basti Karma*, *Virechana* and *Vatanuloman*.[9] As per the line of treatment *Gokshur churna* along with *Shweta parpati* were given. These drugs have *Mutravairechanik* effect so it decreses the post

voidal urine volume.[10] The *Trunpanchmula kwath* facilitates micturition and cleanses the urinary bladder. *Godanti Bhasm* was given to combat fever condition. The other preparation *Gokshuradi guggulu* further worked as adjuvent in facilitating the urine out, to relieve pain and have rejuvenating effect on excretory system. Later, *Sanjeevani vati* was added for subsiding the indigestion and anorexia and to relieve *Jvar*. *Dashmoola kashayam* which added for pacification of *Vata* and to relive the pain[11]. *Varunadi Kashyam* which is indicated for *Antarvidradhi*[12] (internal suppuration) was added to stop the pus appearance in urine as the stagnation and back flow of urine have resulted in the suppuration and appearance of pus. After sometime *Basti* therapy was given which is the best therapy for *Basti marma* and *vata* shaman as indicated in the text[13]. After that *Shilajatu* was added which is considered as best *Rasayan* for diseases of *Mutravaha srotas*[14]. The functional abnormalities of excretory system came to normal in terms of laboratory parameters. The patient didn't feel for the artificial evacuation of urine during the treatment.

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सारांशः

आयुर्वेद में मूत्रावरोधजन्य विकारों के निदान एवं चिकित्सा हेतु एक अपनी विशिष्ट अवधारणा है। उसी के अनुसार प्रस्तुत रोगीवृत अध्यनन में एक 17 वर्षीय पुरुष में शूल युक्त मूत्र प्रवृत्ति, उदरशूल, अरोचक, दौर्बल्य आदि लक्षण पाए गए, जिसका निदान आयुर्वेदानुसार मूत्राघात तथा आधुनिक विज्ञान के अनुसार ऑब्सट्रिक्टव यूरोपैथीविथवैसिको–यूरेट्रलरिफ्लक्स किया गया। इसमें मूत्रविरेचनीय, वातानुलोमन, विरेचक तथा लक्षणों के आधार पर अन्य आयुर्वेदीय चिकित्सा उपक्रम का प्रयोग किया गया, जिसके फलस्वरूप रोगी को एक सराहनीय लाभ मिला था चिकित्सकीय एवं प्रयोग शाला से सम्बन्धित परिणामों में भी सकारात्मक प्रभाव देखने को मिला।

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ORIGINAL ARTICLE

Functional Outcome of *Basti Karma* in Avascular Necrosis of Femoral Head – A Case Report

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ABSTRACT

Avascular necrosis (AVN) is the disease characterized by collapse of bone, joint pain, bone destruction and loss of function mainly due to temporary or permanent suppression of the blood supply. AVN of the femoral head is the most common type among all AVN. Modern treatment modalities like arthroplasty, femoral head graft, hip compression, hip replacement, osteotomy, etc. having higher failure rate. Most of the surgical treatments are cost worthy and having poor prognosis. Hence an effort has been made to evaluate the efficacy of *Panchatikta Ksheer Basti* in the management of the AVN of femoral head.This is single case study of 35 years old male suffering from pain and stiffness in bilateral hip joints, difficulty in walking and restricted movement of both legs. It was diagnosed case of avascular necrosis of femoral head based on MRI report. As per *Ayurveda* the case was diagnosed as *Asthimajjagata Vata Vikara* and was admitted in the male ward of *Panchakarma*, NIA and Jaipur. The whole treatment includes *Sarvanga Abhyanga, Swedana* for 16 days, *Panchatikta Ksheer Basti*along with *Shamana Chikitsa*. Assessment was done on the basis of sign and symptoms.The therapy provided remarkable symptomatic relief with increase in functional activities in avascular necrosis of femoral head. On the basis of this case study it can be concluded that *Basti Karma* along with *ShamanaChikitsa* is effective in the management of AVN of femoral head. Since the single case is not enough more rooted study in this is required.

Keywords : Avascular necrosis, *Basti Karma, Asthimajjagata Vata Vikara*

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Introduction

Avascular necrosis (AVN) is the disease characterized by collapse of bone, joint pain, bone destruction and loss of function mainly due to temporary or permanent suppression of the blood supply.[1]The etiological factors of AVN includes trauma, genetic factors, metabolic factors, use of glucocorticoids, alcoholism, gout, disease that

promotes hypercoagulable states etc.[2, 3,4] AVN is difficult to diagnose in early stages from clinical findings and plain radiograph so early MRI should be done to verify clinical suspicion.[5]In early stages AVN is asymptomatic but as the disease progress there is constant pain in affected joints with decrease in the function of joints.. Factors like pain in lower limbs, alcohol history, hidden diseases, disease of lower limbs etc may lead to the misdiagnosis of the AVN.[6] Modern treatment modalities like arthroplasty, femoral head graft, hip compression, hip replacement, osteotomy, etc. having higher failure rate.[7,8,9]

On the basis of sign and symptoms avascular necrosis resembles with *Asthimajjagata Vata* in *Ayurveda*. Symptoms such as pain in joints, wasting of muscles and bones, disturbed sleep, constant body ache are caused due to vitiation of *Vata* residing in *Asthi*nd *Majja*.[10]*AsthimajjagataVata* can be cured if treated in acute stage but it becomes difficult for the complete recovery in chronic stages.[11]Treatments of AVN are cost worthy and having poor prognosis so an effort is made to evaluate the efficacy of *Panchatikta Ksheer Basti* in the management of the AVN.

Case Report

This is a case study of 35 years old health workerwho visited to OPD of *Panchakarma* Department, NIA, Jaipur (Reg. no. 26614022019) with complaints of pain and stiffness in bilateral hip joints, pain radiating to bilateral knee joint, restricted movement of both lower limbs and difficulty in walking for past 2 years. Since past year, pain has gradually deteriorated and his daily activities such as walking, standing, working etc have been hampered. Sleep was disturbed due to pain. Symptoms were aggravated by cold climate, supine posture and during night hours and got relieved by warm weather. Patient consulted to orthopaedic department where he was diagnosed asavascular necrosis of bilateral femoral head from MRI and was advised for surgical intervention. Then he came at *Panchakarma* Department, NIA for the *Ayurveda* treatment. Past history reveals road traffic accident 5 years back. There was no any significant past history of DM, STDs, HIV, addiction, etc. *Astavidha Pariksha* and Systemic examination was done. [Table 1, Table 2]. Ficat and Arlet classification was used and diagnosed as 3rd stage avascular necrosis of head.[12] Patient was admitted tomale IPD ward of *Panchakarma* Department, NIA. The patient was treated on the line of management of *Asthimajjagata Vata Vikara*.

Table I "*Astavidha Pariksha*"

Astavidha Pariksha	
Nadi	84 bpm
Mala	*Samayak*
Mutra	*Samayak*
Jivha	*Niram*
Shabda	*Spasta*
Sparsha	*Samshitoshana*
Drik	*Spasta*
Akriti	*Madhyam*

Table II "Systemic Examination"

Systemic Examination	
BP	130/70 mm of hg
Temp	98.6 F
Pulse	84 bpm
Sleep	Disturbed
Gait	Changed
Pain in B/L Hip joints	Present
Stiffness	Present
Pain during walking	Present
Movements of joints	Restricted
Power of lower limbs	Grade 4 bilaterally

Involuntary movements	Absent
Trendelenburg sign	Positive
Raising of lower limbs	Right leg up to 15 degree and left leg 20 up to degree

Interventions- *Panchatikta Ksheer Basti* [Table 3]along with *Shamana Chikitsha* was given [Table 4].10 *Anuvasan* and 6 *Ksheer Basti* was given as per *Kaal Basti* schedule [Table 5]. Initially 50gm of honey was taken for *Ksheer Basti* along with 5 gm of *Saindhava Lavana* and was stirred well. 50ml of *Tikta Guggulu Grihtam* was added and mixed well. *Panchatikta Ksheer Kwath* was prepared by *Ksheerpaka Vidhi*. Finally 400 ml of prepared *Panchatikta Ksheer Kwatha* was added, mixed well and homogenous mixture was obtained. It was filtered, kept in *Basti Putak* and was made luke warm before adminstration. Both *Anuvasana* and *Ksheera Basti* was given in left lateral position as mentioned in the *Ayurveda* texts. *Pathya*diet was advised to the patient during and after the treatment.

Table III : Ingredients of *Panchatikta Ksheer Basti*[13]

***Dravya* (Materials)**	**Qty.**
Madhu (Honey)	50 ml.
Saindhav Lavana (Rock Salt)	5 gm.
Tiktagugglugrhitam (Medicated Ghee)	50 ml
Shatpuspa Kalka	10gm
Panchatikta Kwatha + *Ksheer* (Milk)	400ml

Table IV: " Interventions"

Date	Drug	Dose	Frequency
14/02/2019	*Yograj Guggul*	2tab	Thrice a day
	Rasna saptak kwath	20ml	Twice a day
	Ashwaghanda Churna +	2gm	Twice a day
	Nagradhya Churna +	1gm	
	Chopchini Churna	1gm	
	Panchasakar Churna	5gm	Once during bed time
15/02/2019	*Panchatikta Ksheer Basti*	400ml	In *Kala Basti* Format
	With *Dasmool Taila Anuvasan Basti*	60ml	
	after *Sarvanga Abhyanga Swedana*		

Table V: "*Basti* Pattern"

Days	1	2	3	4	5	6	7	8
Type of *Basti*	A	A	K	A	K	A	K	A
Days	9	10	11	12	13	14	15	16
Type of *Basti*	K	A	K	A	K	A	A	A

A= *Anuvasan Basti*, K = *Panchatikta Ksheer Basti*

Assessment Criteria - Assessment was done on the basis of subjective parameters. [Table 6]. Pain and stiffness was markedly reduced after *Basti Karma*. After completion of the treatment patient was able to walk freely, walking distance was increased, sleep was occasionally disturbed, leg raising to 40° and trendelenburg sign was negative[Table 7]. On discharge patient was advised to continue the *Shamana Aushadh* for 3 months.

Table VI. Grading of Subjective Parameters

S.N	Symptom	Criteria	Grade
1.	**Pain**	No pain while walking	0
		Mild Pain while walking	1
		Moderate Pain while walking	2
		Severe pain while walking	3
2.	**Stiffness**	No stiffness	0
		Stiffness for 10-30 min	1
		Stiffness for 30 – 60 min	2
		Stiffness for more than 1 hr	3
3.	**Movement of joints**	Normal	0
		Mildly restricted	1
		Moderately restricted	2
		Severely restricted	3
4.	**Radiating pain**	Pain never radiates	0
		Occasionally radiating	1
		Mostly radiating	2
		Radiating all the time	3
5.	**Gait**	Unchanged	0
		Occasionally changed	1
		Walk with support	2
		Unable to walk	3
6.	**Sleep**	Normal	0
		Occasionally disturbed	1
		Frequently disturbed	2
		Unable to sleep due to pain	3

Table VII "Assessment before and after treatment"

	Before treatment	After Completion of *Basti Karma*	After follow up of 15 days
Pain	3	1	1
Radiating pain	3	1	0
Stiffness	2	1	1
Movement of joints	2	1	1
Gait	2	1	1

Sleep	3	1	1
SLR	Rt leg-15°, Left leg-20°	Rt leg-30°, Left leg-40°	Rt leg-40°, Left leg-40°
Trendelenburg sign	Positive	Negative	Negative

Discussion:

Avascular necrosis is bone tissue death due to cessation of blood supply causing collapse of the bone, leading to pain, loss of joint function and ultimately damage of the joint.[14] Avascular necrosis is usually of traumatic and non traumatic causes. In traumatic injury blood supply is interrupted due to injury in the femoral artery. Some non traumatic AVN are found to be associated with corticosteroid usage, alcoholism, infections, storage disorders, coagulation defects and some autoimmune disease.[15]

Here the Avascular necrosis of femoral head on the basis of sign, symptoms, *Dosha* and *Dushya* is treated on the line of *Asthimajjagata Vata Vikara*. *Snehana* and *Swedana* is considered as the 1st line treatment of *Vata Vyadhi*.[16] In *Asthimajjagata Vata Vikara Snehan* either internal or external is indicated.[17]*Swedana* helps in reducing the heaviness, stiffness and increases the blood circulation.[18] According to *Acharaya Gangadhar* for vitiated *Vata Basti* Should be the choice of treatment and administered *Vata* below *Nabhi Pradesh* (Umblical region).[19] *Basti* by its action on *Pakwashya* and *Purishdhara Kala* helps in the treatment of *Vata Vyadhis*. For the treatment of *Asthi Dhatu Acharya Charaka* clearly indicated *Tikta Dravya Siddha Grihta* and *Ksheera*. There is *Tikta Rasa* dominancy in *Tikta Guggulu Grihta*. *Tikta Dravyas* are *Akash* and *Vata Mahabhoota* dominant drugs hence they directly acts on *Asthi* and *Majja Dhatu*. *Grhita* is *Balya* in nature having *Vata-Pitta Shamak* property and also contains vitamin D hence it helps in the regeneration of *Asthi Dhatu*. *Ksheer* (Milk) have *Madhur* and *Snighdha* property which helps in the nourishment of *Asthi* (joints and bones). *Panchatikta Ksheer Basti* having predominence *Tikta rasa* helps in treatment of *Asthi* and *Majja Vikara* and also balances the *Apana Vayu* through its *Vatanulomana* Property. *Ashwagandha* acts as *Balya*, *Rasayana* and *Dhatuposhaka* drug. *Chopchini* having property of *Shothahara* (anti-inflammatory) *Vedanahara* (analgesic) and acts on the *Sukshma Srotsas* of the body. *Nagradhya Churna* having anti- inflammatory and neuroprotective action due to its *Madhur*, *Ushna* and *Snigdha* property. *Dasmool Taila* having *Vatahar*, *Balya* and *Brihman* properties due to its *Sneha Guna*. *Rasna Saptak Kwath* having *Vatahara* G*una* and anti-inflammatory in action. Thus *Basti Karma* along with *Shamana Aushadha* shows significant improvement in the avascular necrosis of femoral head.

Conclusion:

Panchatikta Ksheer Basti along with *Anuvasana Basti* shows remarkable symptomatic relief with increase in functional activities in avascular necrosis of femoral head. The results need to be studied in more numbers of populations for the better assessment.

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There is no conflict of interest.

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सारांश

Avascular necrosis (AVN) में मुख्यत: रक्त परिसञ्चार की अस्थाई या स्थाई रूप में आपूर्ति बंद होने या कम होने के कारण हड्डियाँ टूटने लगती है। संधियों में रुजा व नियमित कार्यों में कमी आने लगती है। आधुनिक चिकित्सा में arthroplasty, femoral head grafting, hip compression, hip replacement, osteotomy आदि उपचार उपलब्ध है। आधुनिक चिकित्सा में शल्य क्रिया द्वारा उपचार बहुत महंगा है। शल्य क्रिया की असफलता अधिक होने के कारण, आयुर्वेद संहिताओं में वर्णित 'पञ्चतिक्त क्षीर बस्ति' का प्रयोग व इसके प्रभाव का मूल्याङ्कन करने का प्रयास किया गया है। प्रस्तुत शोध में एक 37 वर्षीय पुरुष जो कि चलने में कठिनाई जोड़ों में दर्द, जकड़ाहट (hip joints) के साथ राष्ट्रीय आयुर्वेद संस्थान, जयपुर की पञ्चकर्म इकाई में पञ्जीकृत हुआ। MRI की रिपोर्ट के अनुसार रोगी femoral head का (AVN) केस था। रोगी को पञ्चकर्म इकाई के अंतरङ्ग विभाग में भर्ती किया गया। पञ्चकर्म चिकित्सा के अन्तर्गत रोगी को 16 दिन तक अभ्यङ्ग–स्वेदन व पञ्च तिक्त क्षीर बस्ति द्वारा चिकित्सा दी गई। संशोधन चिकित्सा के साथ शमन औषधि भी दी गई। इस चिकित्सा द्वारा नियमित कार्यों को करने में आयी कमी में प्रभावशाली सुधारपाया गया व पाया गया कि बस्ति कर्म व शमन चिकित्सा इस व्याधि के नियन्त्रण में प्रभावशील है। यह शोध भविष्य में (AVN) के रोगियों के लिए पर्याप्त नहीं है, इसलिए अधिक रोगियों पर इसका अध्ययन किया जाना आवश्यक है।

Annexure I

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