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Response of Herbal Medicine to the Withdrawal of Bronchodilators and Corticosteroids in Bronchial Asthma (*Zeequn Nafas*) Patients

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Abstract Despite intensive ongoing research all over the world, satisfactory and safe treatment of *Zeequn Nafas* (Bronchial Asthma) still defies the modern medical world. Long-term use of corticosteroids and bronchodilators leads to suppression of immune system and other disorders. The present study was conducted to see the response of herbal formulation to the withdrawal of bronchodilators and corticosteroids and to see the efficacy of herbal drug in bronchial asthma.
Keywords *Herbal; Bronchial Asthma; Lung Function; Vital Capacity; Wheezing*

1. Introduction

Zeequn Nafas is diffused involvement of Bronchial system due to variety of influences resulting in chronic respiratory disability. This respiratory disability or Zeeq-un-Nafas (Bronchial Asthma) covers a broad clinical spectrum, ranging from readily reversible, and bronchospasm to severe chronic intractable obstruction to airflow. *Zeequn Nafas* is mentioned by the ancient physicians and philosophers like *Buqrat* (Hippocrates - 460 BC) and *Jalinoos* (Galen - 120-200 AD). *Buqrat* called this disease breathlessness or panting. Majoosi has also mentioned this disease in his book *Kamil-us-Sana* with reference to *Buqrat* and *Jalinoos*. Unani scholars have mentioned this disease under different headings in their treatises e.g. *Rabw*, *Buhar, Dama*, *Intasabun-Nafas,* etc. (Tabari, 1928; Razi, 1957; Ibn Sina, 1906; Majoosi, 2010; Jurjani, 1289H; Khan, 1978; Kabiruddin, 1960). *Zeequn Nafas* is a condition in which difficulty in breathing is caused due to accumulation of *Balgham Lazuj* (Viscous Phlegm) in *Urooq Khashna* (bronchioles).

In modern medicine *Zeequn Nafas* is described under the heading of bronchial asthma. The word Asthma is derived from Greek word meaning short drawn breath, panting or labored breathing. Asthma is a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role. The chronic inflammation is associated with airway hyper responsiveness that leads to recurrent episodes of wheezing, breathlessness, chest tightness and coughing, particularly at night or in the early morning. These episodes are usually associated with wide spread, but variable, air flow obstruction within the lung that is often reversible either spontaneously or with treatment (Kumar &

Clark, 2004; Stein, 1998). It has been identified as one of the five most pressing global lung problems (Barnes, et al., 1996). The prevalence of asthma is rising and 5-9% of general population in India is suffering from Bronchial asthma (Gupta, et al., 1999).

Bronchial asthma can be defined as a chronic inflammatory disorder of the airways, characterized by recurrent episodes of wheezing, breathlessness, chest tightness and cough that is often reversible, either spontaneously or with treatment. Different terms such as allergic or asthmatic bronchitis, wheezy bronchitis, intrinsic and extrinsic asthma are frequently employed in clinical practice.

2. Materials & Methods

2.1. Centre of Study

The study was carried out at Regional Research Institute of Unani Medicine, Srinagar. Total numbers of 2559 patients were registered from the general out patients department (GOPD) of the institute.

2.2. Subject Selection

Patients having breathlessness along with one or more of the following complaints were selected for the study

- Wheezing
- Tightness of chest
- Cough
- Cough with expectoration
- Impaired Lung Function Test

2.3. Inclusion Criteria

Patients with breathlessness, cough, and cough with expectoration, wheezing, of either sex age group between 10-70 years and also patients who were cortisone dependent and also using bronchodilator were included in the study.

2.4. Exclusion Criteria

Patients having COPD, Koch's infection, bronchiectasis pleuresy, endocrinological disturbance, chronic renal failure, pregnancy were excluded from the study.

2.5. Investigations

The following investigations were conducted for the inclusion, exclusion, grading of the patients and for the assessment of the efficacy of the test drug.

- Chest X-ray
- Lung function Test
  - Hematological and Biochemical Tests
  - Hb, TLC, DLC, & ESR
- Sputum test for AFB
- Blood Sugar
  - Fasting

  - Post Prandial
- Stool (Routine & Microscopic)
- Urine (Routine & Microscopic)
- E.C.G.

Drug Zn5 is an herbal formulation in the form of *Majoon* (Semi-solid preparation) containing Seer (*Allium Sativa* Linn.); Karanjwa (*Caesalpinia bonducella* Flem.); Hulba (*Trigonella foenum-graecum* Linn.); Katan (*Linum usitatissimum* Linn.); Chillbeenj (*Strychnos potatorum*); Karanj (*Pongamia pinnata* (Linn.) Pierre) and Honey. Zn5 was prepared and supplied by the pharmacy at Central Research Institute of Unani Medicine (CRIUM), Hyderabad. Most of the ingredients used in Zn5 are *Munaffis-e-Balgham* (Expectorant) and *Mukhrij-e-Balgham* (Phlegmagogue) (Ghani, 1998; Nabi, 1932; Lubhaya, 1977). Standardization and toxicity studies of drug Zn5 were conducted at DSRU, Srinagar.

2.6. Dosage

Coded Unani formulation Zn5 *Majoon* (Semi-solid preparation) was given in the dose of 10 gm twice daily with lukewarm water.

2.7. Duration of Protocol Therapy

Twelve weeks.

2.8. Sample Size

Two thousand five hundred and fifty nine (2559) cases of *Zeequn Nafas* were studied.

2.9. Parameters for Assessment of Safety

A. Clinical

Adverse event if any;

B. Laboratory

Biochemical and pathological parameters (Haemogram, LFT, KFT, etc.)

2.10. Parameters for Assessment of Efficacy

A. Clinical

Two thousand five hundred and fifty nine (2559) cases of *Zeequn Nafas* were registered for the study from the OPD of Regional Research Institute of Unani Medicine, Srinagar. Besides recording a thorough history, the cases were clinically examined and routine investigations conducted. Grading of the patients was done, and they were classified as per age, sex and duration of the diseases. The severity of the bronchial asthma was evaluated by spirometry. The study was designed to see the efficacy of Zn5 in improvement of clinical signs and symptoms with state of withdrawal of broncho dilators and corticosteroids.

The drug Zn5 was given to patients as per dosage. Follow-up of the patients were done on four, eight and 12 weeks of treatment. After the completion of duration of therapy the patients were assessed at 1-2 weeks intervals up to next four weeks.

3. Observations and Results

The detailed findings subjective and objective response and other observations were recorded during the study.

3.1. Age and Sex Distribution

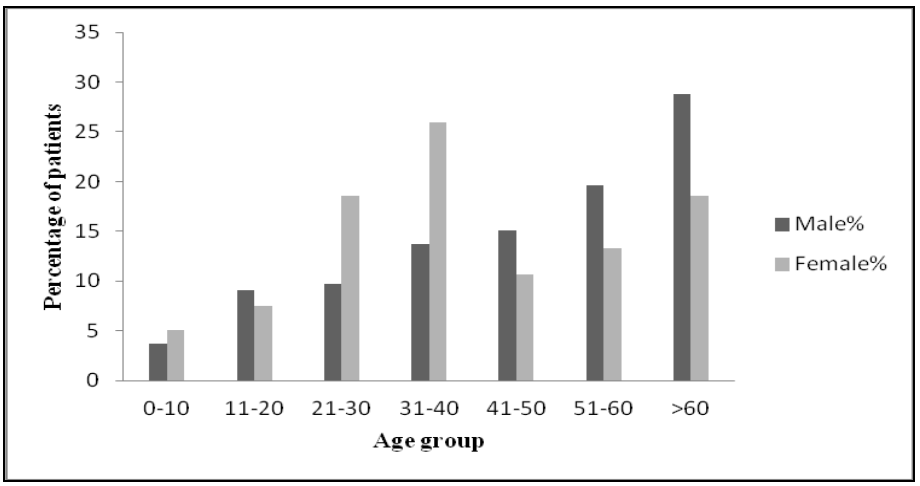

Figure 1: *Age and sex distribution of the study population*

The Figure 1 shows the incidence of *Zeequn Nafas* increasing gradually as the age advances. The highest incidence has been recorded in the age group of more than 60 years. At this juncture, we can conclude that the elderly suffer more than the youngsters. Out of the 2559 patients registered, 51.02% were male and 48.98% female, indicating that the occurrence of the disease is slightly higher among males (Figure 1).

3.2. Occupation

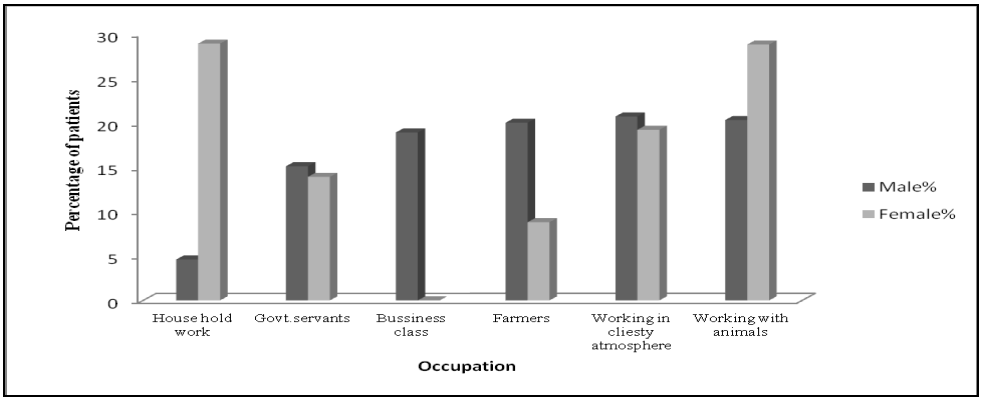

Figure 2: *Distribution of patients according to occupation*

In the study it was found that females working with animals and in household jobs are more prone to the disease in comparison to males, whereas male farmers, business class, working in cliesty atmosphere and government sector are more prone than the females (Figure 2).

3.3. Duration of Chronicity

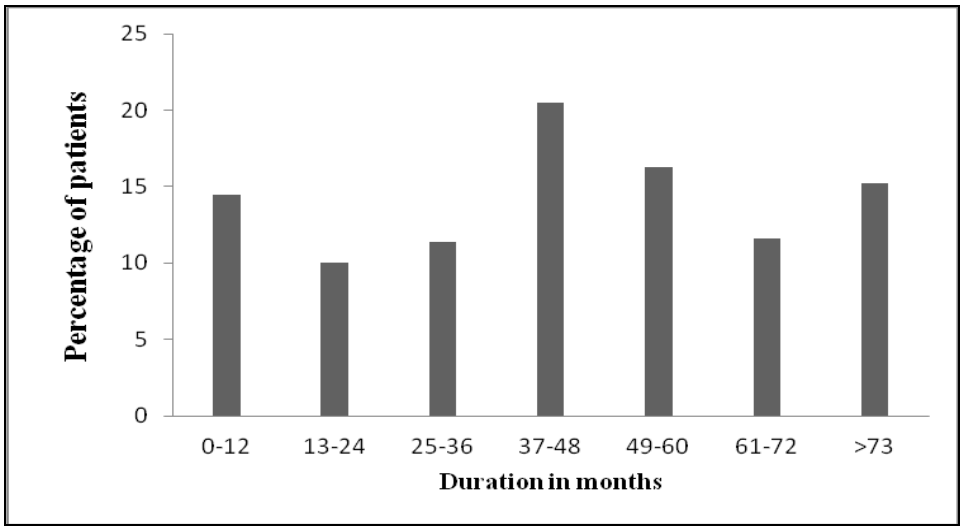

Figure 3: *Distribution of patients according to duration of chronicity*

The Figure 3 shows that all the cases were chronic bronchial asthma and none was of acute origin. Among 2559 cases 20.0% cases were having the duration of chronicity of 37 to 48 months followed by 16.3% cases having 49 to 60 months chronicity.

3.4. Safety Evaluation of Coded Unani Formulation Zn5 in *Zeequn Nafas* Patients

There was no change in pathological and biochemical markers before and after the intervene of Zn5.

3.5. State of Withdrawal of Bronchodilators and Cortisones

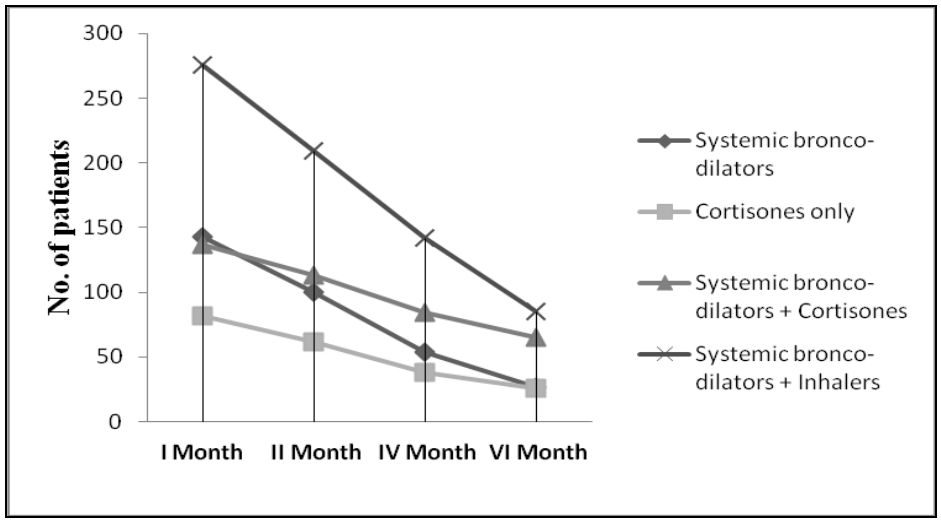

Figure 4: *Distribution of patients on status of withdrawal of bronco-dilators and corticosteroids*

Figure 4 shows that out of the 2559 patients, 1778 (69.48%) patients used Bronco-dilators and Cortisones or both at base level. After completion of protocol therapy it was found that 79.13% patients had withdrawn the use of bronchodilator and cortisones.

3.6. Sex-Wise Response of Zn5 in *Zeequn Nafas* Patients

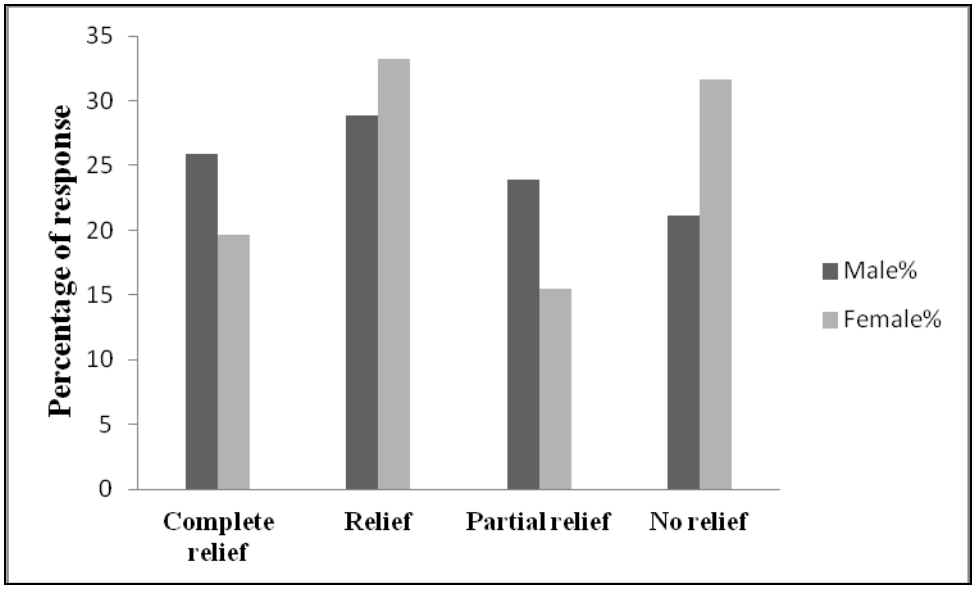

Figure 5: *Sex-wise response of Zn5 in Zeequn Nafas patients*

Out of the 2559 patients which completed the protocol therapy, 54.8% males and 52.9% females got relief, 23.9% males and 15.5% females got partial relief in their signs and symptoms, while 21.2% males and 31.6% females did not get significant relief in their sign and symptoms.

3.7. Over All Response of Zn5 in *Zeequn Nafas* Patients

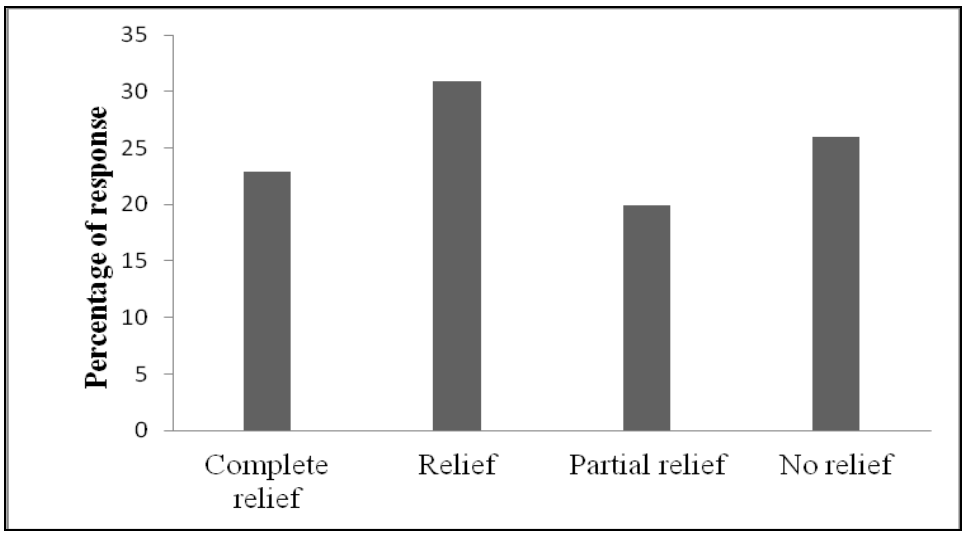

Figure 6: *Over all response of Zn5 in Zeequn Nafas patients*

In the Figure 6, it was found that 54% patients got relief, 20% patients got partial relief in their signs and symptoms, while 26% patients did not respond to the therapy.

The criteria used for the assessment of relief were as follows:

1. Relief = 100-70% regression in symptoms
2. Partial Relief = 71-40% regression in symptoms
3. No Relief = < 40% regression in symptoms

4. Discussion and Conclusion

2559 patients were registered, out of which 1778 (69.48%) patients used bronco-dilators and cortisones. After completion of protocol therapy, it was found that 1407 (79.13%) patients had withdrawn the use of bronchodilator and cortisones. The ingredients of this coded Unani drug are *Munaffis-e-balgham* (Expectorant), *Mukhrij-e-balgham* (Phlegmagogue), *Daf-e-Sual*, *Daf-e-Humma*, *Muhallil-e-Auram*. The drugs having these properties are said to be effective in the management of *Zeequn Nafas* (Ghani, 1998; Nabi 1932; Lubhaya, 1977). Zn5 significantly reduces the use of bronchodilator and cortisones after completion of therapy. No adverse effects have been observed except gastric irritation in some cases.

In light of the above observation and discussion, it may be concluded that the coded Unani formulation Zn5 successfully reduces the symptoms and signs of the disease and helped in withdrawal of cortisones and bronchodilators. It may also be concluded that the Unani formulation Zn5 acts as *Munaffis-e-Balgham* (expectorant) possibly *Mufatteh Urooq-e-Khashna* (Broncho-dilator) and antihistaminic.

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Research Article | Open Access

Preliminary Analysis of Siddha Antidiabetic Herbal Formulation (*Ilavankaathy ilekiyam*)

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Abstract 'Ilavankaathy ilekiyam' a siddha herbal confection which literarily recommended for the treatment of diabetes mellitus (Mathumegam) in the authentic Siddha text book "Therayar yamaga venba". The herbal preparation consist clove, Bee's honey, ghee, milk and sugar as ingredients. There are no standards for this antidiabetic herbal preparation. Standardization of the individual ingredients helps to prepare a quality test drug which responsible for the desired pharmacological effect. So the present study has been performed to standardize individual ingredients and the herbal formulation 'Ilavankaathy ilekiyam' as a preliminary study by using three groups of test drug samples. The parameters used to standardize the preparation are organoleptic characters, physicochemical properties and thin layer chromatography. The organoleptic characters such as color, taste, odor, smell and consistency of the ingredients and the test drug were evaluated. Physico-chemical parameters were determined as per WHO guidelines and reported as total ash, acid insoluble ash, water soluble extractive, ethanol soluble extractive, total sugar, reducing sugar content, fat content and loss on drying. Thin layer chromatography developed for different solvent system and detection of TLC finger print profiles were carried out under UV light at the wavelength of 366nm and also viewed after spraying with anisaldehyde sulfuric acid spray reagent. Colors and R_f Values of major spots were noted. The procedures developed in the present study will serve as parameters for Ilavankaathy ilekiyam analysis and further studies are warranted to ensure the effective herbal drug standardization by a regulatory standard guide for the future research endeavors in more focused manner.
Keywords *Ilavankaathy Ilekiyam; Antidiabetic; Standardization; TLC*

1. Introduction

Siddha medicine being an ancient medical science reported to have surfaced more than 10,000 years ago. *Siddha* formulations are used to treat a wide variety of diseases including *Madhumegam.* The ancient traditional *Siddha* medical system was formulated on the scientific parameters available at those times. So there is a need of standardizing herbal formulations to minimizes batch to batch variation; assure safety, efficacy, quality and acceptability of the polyherbal formulations for the desired therapeutic effect.

'*Ilavankaathy ilekiyam'* a siddha herbal formulation recommended in the authentic *Siddha* textbook 'Therayar *Yamaha venba*' for the treatment of *Madhumegam* [1]. It consists of clove, honey, ghee, milk and sugar as ingredients. The efficacy of the treatment apart from other parameters depends upon the efficacy of the drugs used. The complexity of chronic diabetes leads to sudden onset of diabetes poses a significant risk of occurrence of ketoacidosis and diabetic coma, if untreated/unnoticed respectively. As diabetes mellitus need a long term treatment providing an effective side effect less standard herbal remedy will be beneficial to the improve of the disease as well as the quality of the patients life.

2. Materials and Methods

The drug "*Ilavangaathy Ilekiyam"* was selected from "*Therayar Yamaha venba"*, an authentic *siddha* text book reveals that this herbal preparation could be used for *Madhumegam*. Three groups of test drug prepared for evaluation.

2.1. Organoleptic Evaluation

Organoleptic evaluation refers to evaluation of individual drugs and formulations by color, odor, taste, texture, etc. [2]. The organoleptic characters of the samples were carried out based on the method as described by Wallis [3].

2.2. Physico Chemical Evaluation

Physicochemical parameters such as Total ash, Acid insoluble ash, Water soluble extractive Alcohol soluble extractive, Loss on drying at 105c [4]. Fat content, Reducing sugar, Total sugar And Sucrose content [5] was evaluated.

2.3. Development of TLC Fingerprints of 'Ilavankaathy Ilekiyam' [6]

Two types of test solution prepared such as dicloromethane extract and Methanol extract.

Test solutions of test group samples were spotted by capillary tube on a pre-coated TLC plate. The plate was developed in the solvent system for a distance of 6cm.The Adsorbent Silica gel 60 F_{254}, and Solvent_system_was Toluene: Ethyl acetate (4.65:0.35).It was detected before spraying by Under UV light (at 366nm) and there after anisaldehyde sulphuric acid was sprayed to the TLC plate and heated at 105°C for 5 min. It was used to detect the heated chemical constituents.

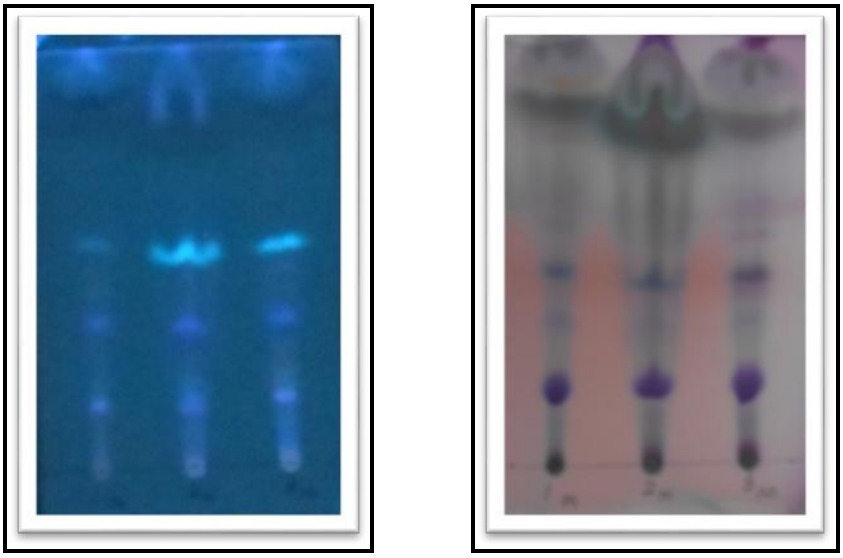
A clear different was not observed in the chemical constituents of the test drug group as evident from the TLC finger prints developed in the above mentioned solvent system. Therefore, polarity of the solvent system was changed (a-c) to detect any different chemical profiles for dichloromethane extract.

a) Hexane: dichloromethane (2:1)
b) Toluene: Ethyl acetate (4.65:0.35)
c) Toluene: Ethyl acetate(3.5:1.5)

3. Results

Table 1: *Organoleptic and Physico Chemical Parameters of Three Groups of Test Drug Sample*

No	Tests	Results (n=3, Mean ± Std deviation)		
		Sample 01	**Sample 2**	**Sample 3**
	Organoleptic character a) Taste b) Color c) Odour d) Texture	 Pungent Dark brown Smell of clove Sticky mass	 Pungent Dark brown Smell of clove Sticky mass	 Pungent Dark brown Smell of clove Sticky mass
	Total ash% (w/w)	2.03 ± 0.10	2.27 ± 0.36	2.04 ± 0.08
	Acid insoluble ash% (w/w)	0.06 ± 0.0251	0.03 ± 0.0057	0.04 ± 0.02
	Water soluble extractive % (w/w)	61.76 ± 1.01	61.38 ± 1.13	61.71 ± 1.12
	Alcohol soluble extractive % (w/w)	26.64 ± 0.93	26.15 ± 0.52	25.28 ± 0.39
	Loss on drying at 105c % (w/w)	13.37 ± 1.97	12.36 ± 1.52	13.32 ± 1.84
	Solid % (w/w)	86.83 ± 1.97	57.64 ± 1.52	86.68 ± 1.84
	Fat content% (w/w)	14.46 ± 0.23	14.46 ± 0.23	14.46 ± 0.23
	Reducing sugar % (w/w)	23.94 ± 0.46	24.18 ± 0.58	26.02 ± 2.70
	Total sugar% (w/w)	63.35 ± 1.56	63.74 ± 1.11	63.04 ± 1.21
	Sucrose content% (w/w)	39.41 ± 1.44	38.55 ± 0.54	37.02 ± 1.84



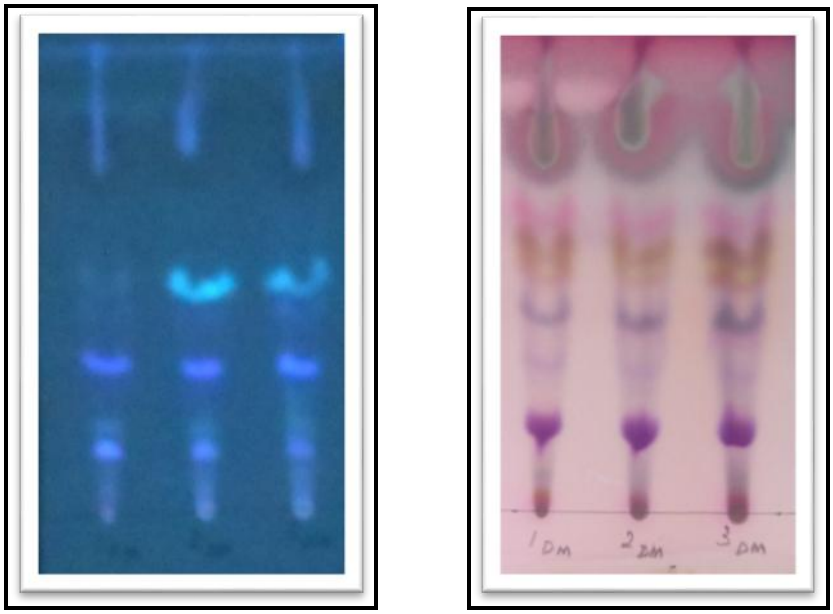
(A) (B)

Figure 1: *The TLC Fingerprints of Methanolic Extract of the Test Drug Samples under (A) UV at 366nm and (B) after Spray with anisaldehyde Sulfuric Acid*

M1-Methanolic extract of test drug sample 1
M2-Methanolic extract of test drug sample 2
M3-Methanolic extract of test drug sample 3

Table 2: *R_f Values of the Major Colour Spots of Methanolic Extract of the Test Drug Sample after Spraying with anisaldehyde Sulfuric Acid*

R_f Values	Major Colour Spots of Methanolic Extract
o.17	Purple
0.33	Purple
0.40	Pink
0.54	Pink



(A) (B)

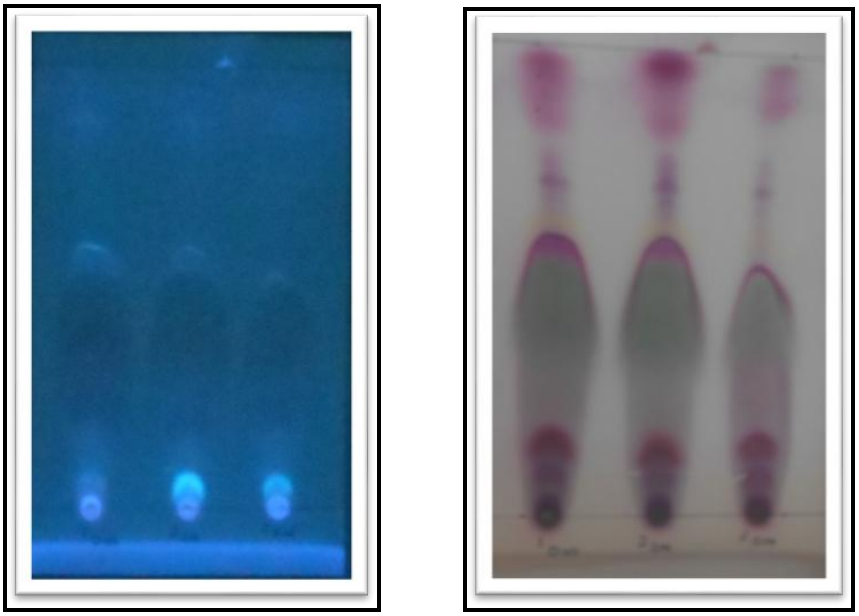
Figure 2: *The TLC Fingerprints of Dicloromethanic Extract of the Test Drug Samples under (A) UV at 366nm and (B) After Spray with anisaldehyde Sulfuric Acid.*

DM1- dicloromethanic extract of test drug sample 1
DM2- dicloromethanic extract of s test drug ample 2
DM3- dicloromethanic extract of test drug sample3

Table 3: *R_f Values of the Major Colour Spots of Dicloromethanic Extract of the Test Drug Sample after Spraying with anisaldehyde Sulfuric Acid*

R_f Values	Major Colour Spots of Dicloromethanic Extract
0.07	Black
0.19	Purple
0.36	Pink
0.49	Pink
0.51	yellow
0.6	Brown
0.62	Pink
0.72	Green

Figure 3 and 4 illustrate the TLC profiles of test drug samples by changing the polarity of the solvent system and the Table no 4 and 5 shows the major color spots of TLC fingerprints after spraying with anisaldehyde sulfuric acid.

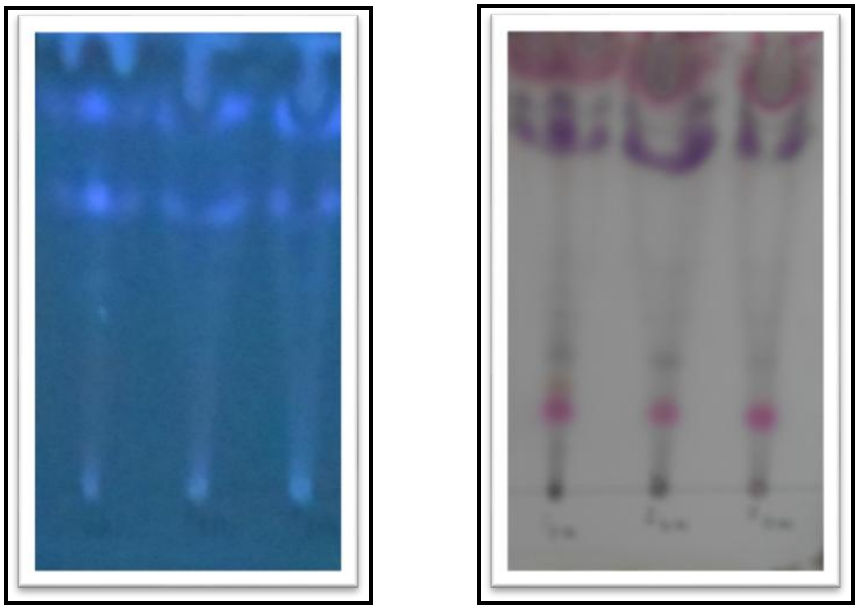


(A) (B)

Figure 3: *The TLC Fingerprints of Dicloromethanic Extract of the Test Drug Samples under (A) UV at 366nm and (B) After Spray with anisaldehyde Sulfuric Acid. Eluent: Hexane: Dicchloromethane (2:1)*

Table 4: R_f *Values of the Major Colour Spots of Dicloromethanic Extract of the Test Drug Sample After Spraying With anisaldehyde Sulfuric Acid, Eluent: Hexane: Dicchloromethane (2:1)*

R_f Values	Major Colour Spots of Dicloromethanic Extract
0.1	Blue
0.2	Pink
0.26	Yellow
0.31	Blue
0.79	Dark purple
0.89	Brown



(A) (B)

Figure 4: *The TLC Fingerprints of Dicloromethanic Extract of the Test Drug Samples under (A) UV at 366nm and (B) After Spray with anisaldehyde Sulfuric Acid.*

Eluent: Toluene: ethyl acetate (3.5:1.5)

Table 5: *R_f Values of the Major Colour Spots of Dicloromethanic Extract of the Test Drug Sample After Spraying With anisaldehyde Sulfuric Acid, Eluent: Toluene: ethyl Acetate (3.5:1.5)*

R_f value	Major Colour Spots of Dicloromethanic Extract
0.07	Purple
0.16	Brown
0.18	Green
0.57	Reddish pink
0.61	Yellow
0.97	Pink

4. Discussion

The key factors that limit commercial utility of herbal drug are standardization. Analysis natural drug development is necessary to ascertain quality, safety and reproducibility. Standardizing anti diabetic herbal formulation is beneficial and the quality product depends on the quality of the ingredients along with the herbal formulation.

The physico- chemical analysis of plant drug is an important parameter in detecting adulteration or improper handling of drugs. The total ash is particularly important in the evaluation of purity and quality of drugs. A high ash value is indicative of contamination, substitution, adulteration or carelessness in preparing the crude drug for marketing (Mukherjee, 2002). Acid insoluable ash indicates contamination with silicious materials and variation of the natural ash of the drug.

Extractive values are representative of the presence of polar and non-polar compounds in a plant material. The water soluble extractive value can be used to indicate poor quality, adulteration with any unwanted material or incorrect processing of the crude drug during the process of drying; storage etc (Mukherjee, 2002). Moisture is an inevitable component of crude drugs, which must be eliminated as far as practicable. Insufficient drying favours spoilage by molds and bacteria and makes possible the enzymatic destruction of active principles (WHO, 1998; Mukherjee, 2002)

In this study clove is the only raw material for the preparation of the drug and three samples of clove analysed to comply the standards recommended [7]. the original sample of the clove which collected from Mavanella during July consist more yield than other two market samples. The past researches proved eugenol, an active component of clove responsible for the anti-diabetic activity (Kuroda M. et al., 2012)

Bee's honey available in the market may adulterate with added sugar. The sugar level of the sample analyzed in terms of total sugar, reducing sugar and sucrose content. As this herbal formulation recommended for diabetes the honey should comply the standards to produce the desired effect.

In this study TLC fingerprints of the test drug developed for methanol and dichloromethane extract. No significant variation in the major colour spots after spayed with anisaldehyde sulfuric acid. TLC fingerprints also developed by changing the polarity by using different solvent system. The results reveal the similarities in chemical profiles of the three test group samples in terms of TLC finger prints. This study is limited to quantify the chemical composition mainly the eugenol which has been already proved for the anti-diabetic activity due to the unavailability of marker sample of eugenol and densitometer.

In conclusion, the procedures developed in the present study will serve as a protocol for the herbal preparation for certain extend which minimizes batch to batch variation, assure safety, efficacy, quality and acceptability of the formulations as a herbal anti diabetic agent. Further studies are warranted to ensure the effective herbal drug standardization methodology by a regulatory standard guide for the future research endeavors in more focused manner.

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Research Article | Open Access

A Comparative Clinical Study of Vajigandhadi Taila Basti and Agnikarma in the Management of Sciatica

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Abstract The study was undertaken to evaluate the clinical efficacy of Vajigandhadi Taila Basti & Agnikarma in the management of Sciatica. Vajigandhadi Taila contains Ashwagandha (Withania Somnifera) (Balya, Rasayan), Dashamoola Kwatha Vataghna) Bala (Sida Cordifolia) (Balya, Vatashama), Bilva (Aegle Marmelos) (Vatghna, Astringent) & Eranda Taila (Ricinus Communis) (Vatashamak, Anulomaka). Both these remedies proves extremely beneficial as it can be performed on the OPD & IPD basis, gives significant relief in the symptoms e.g. radiating pain, stiffness, twitching sensation. The subjective parameters like Pain, SLR, VAD, VDS etc., were used to score clinical outcome. The average clinical improvement was calculated by proper statistical treatment. Our experience with this modality has been encouraging as the response pattern is good in considerably short duration of treatment. The patient improves gradually after 4 weeks of treatment. The pain relief provided by Agnikarma & sustained improvement with Basti presents a window of opportunity in the clinical management of Sciatica. Ideally this technique should be practically taught to the physicians and should be evaluated scientifically using principles of biophysics and nerve conduction studies.
Keywords *Agnikarma; Sciatica; Vajigandhadi Taila Basti*

1. Introduction

Sciatica is characterized by radiating pain in an area of the leg typically served by one nerve root in the lumbar or sacral spine [20]. The most common cause of sciatica is herniated disc. The estimated annual incidence of sciatica in western countries is 5 cases per 1000 adults [22]. Lumbar spine disorders rank 5th among disease categories in the cost of hospital care & account for highest costs resulting from absenteeism from work & disability than any other category.

1.1. Aims & Objectives

1) To clinically evaluate the efficacy of Vajigandhadi Taila Kala Basti on the basis of scientific Ayurvedic principles in reversing or halting the process of Sciatica.
2) To clinically evaluate the efficacy of on the basis of Agnikarma Scientific Ayurvedic principles in reversing or halting the process of Sciatica [1].
3) To study the untoward effect of Agnikarma if any in the patients of Sciatica.
4) To compare the effect of 'Vajigandhadi Taila Kala Basti & Agnikarma' in the management of Sciatica w.r.t pain on the basis of time period required for treatment, their efficacy in giving instant relief.

2. Materials and Methods

2.1. Source of Materials

Raw materials were collected from the department of Rasashastra and Bhaishajya Kalpana, Dr. D.Y. Patil College of Ayurved & Hospital & Research Institute, Nerul, Navi Mumbai, and medicines were prepared classically in the Pharmacy of Rasashastra and Bhaishajya Kalpana.

2.2. Research Place

1) A clinical survey of subjects attending OPD and IPD of Department of Kaya Chikitsa, Dr. D.Y. Patil College of Ayurveda & Hospital & Research Institute, Nerul, Navi Mumbai Mahavidyalaya were included and subjects fulfilling the criteria of diagnosis as per the Performa have been selected for the study.
2) Informed consent of all the subjects registered was duly taken before starting the interventions in each group. Ethical clearance was taken from IEC for this study.
3) The data, which was obtained by the clinical trial was statistically analyzed by applying Student't' test [21].
4) Ethical clearance for this study was taken from IEC.

Inclusion Criteria

1) Irrespective of age, sex, race & religion
2) Patient's with positive S.L.R Test
3) Radiologically Confirmed Disc Herniation [3]
4) Lumbo-sacral radicular syndrome lasted for 6-12 weeks

Exclusion Criteria

1) Patient's with infectious disease e.g. HIV positive, HbsAg positive, Koch's
2) Patients suffering from Pott's disease, cauda equina syndrome, muscle paralysis
3) Patients with Metabolic disorders like Diabetes Mellitus etc. [7]
4) Previous spine surgeries, Bony stenosis Spondylolisthesis, Pregnancy [22]
5) Patient with skin diseases [8]

Table 1: *Methodology used in Group A & B*

Details of Procedure	Vajigandhadi Taila Kala Basti (Gadanigraha Vatarogadhikar 19/178)	Agnikarma
No of Patient	20	20
Ingredients	Vajigandha, Bala, Bilva Kalka:- [11] 240 gm Eranda Taila:-960 ml Dashmool Kwatha:-3840 ml for each patient	Rajat yukta Shalaka Agnisadhana
Vidhi a) Purvakarma	1) Abhyanga [2] 2) Swedan 3) Bhojana 4) Chankraman	1) Written Consent [19] 2) Pichhil Annasevan 3) Dhavan-Triphala kashaya
b) Pradhankarma	1) Vam Parshwa Avastha Shayan [15] 2) Bastipranidhan 3) Sphika Tadana	1) Identification of site 2) Agnidagdha site:- 4 fingers [18] above or below Janu sandhi (lateral aspect)
c) Paschyatkarma	1) Bastipratygaman & observation of Yog- Atiyog Lakshan 2) Pathyapathya 3) Observation of Sneha Vyapada if any & their treatment [13]	1)Application of Mahatiktak Ghrita + Gairik + Yashtimadhu [16] 2) Observation of Dagdha Vrana 3) Watch for any complication if any
Dose	60 ml/day	One or two Bindu
Kala	Bhuktakala	After Pichhil Annasevan [14]
Type of Basti/ Agnikarma	Matra Bastivat	Binduvata [6]
Route of Administration	Bastivata	Bahya
Duration	16 days	After every 7 days for 4 weeks

3. Drug Specifications

3.1. Contents of Vajigandhadi Taila

Table 2: *Properties of Ingredients of Vajigandhadi Taila*

No	Dravya	Rasa	Virya	Vipaka	Guna	Karya
			Kalka dravya			
1	Ashwagandha [10]	Madhur Kashaya Tikta	Ushna	Madhur	Laghu, Snigdha	Vata Kaphahar Balya, Shukrala Rasayana
2	Bala	Madhur	Shita	Madhur	Guru, Snigdha	Balya Vatahar, grahi Vrishya, Tridoshahar
3	Bilva	Kashaya Tikta	Ushna	Katu	Laghu, Ruksha	Grahi, Vatakaphahar Pachana Balya
			Kwatha dravya			
4	Bilva	Kashaya Tikta	Ushna	Katu	Laghu, Ruksha	Grahi, Vatakaphahar Pachana Balya
5	Gambhari	Madhur Tikta Kashaya	Ushna	Madhur	Laghu, Ruksha	Kaphavatahar, Shothahar
6	Agnimantha	Tikta Kashaya Katu Madhur	Ushna	Katu	Laghu, Ruksha	Trodoshahar Shothahar
7	Patala	Tikta Kashaya	Anushna	Katu	Laghu, Ruksha	Dipana, Grahi, Tridoshahar
			Kwatha dravya			
8	Shyonak	Tikta Kashaya	Shita	Katu	Guru, Snigdha	Tridoshahar
9	Shaliparni	Madhur Tikta	Ushna	Madhur	Laghu, Snigdha	Tridoshahar
			Kwatha dravya			
10	Prushniparni	Madhur Tikta	Ushna	Madhur	Laghu, Snigdha	Tridoshahar
11	Gokshura	Madhur	Shita	Madhur	Guru, Snigdha	Balya, Vatahar, Bastishodhan, Vrushya
12	Brihati	Tikta Katu	Ushna	Katu	Laghu, Ruksha Tikshna	Grahi, Pachana, Hridya, Malanashana,
13	Kantakari	Katu Tikta	Ushna	Katu	Laghu, Ruksha	Dipana, Pachana, Vatakapahahar
			Sneha dravya			
14	Eranda taila	Madhur Katu Kashaya	Ushna	Madhur	Snigdha, Guru	Adhobhagahar Vrushya, Vatahar, Srotovishodhan

3.2. Rasa Panchaka of Vajigandhadi Taila

Table 3: *Gunapradhanata of Vajigandhadi Taila*

Panchak	Property	Kalka	Kwatha	Taila	Percentage
Rasa	Madhur	2	120	6	24.24
	Kashaya	2	120	6	24.24
	Tikta	2	192	-	36.74
	Katu	-	72	6	4.78
Virya	Ushna	2	168	6	70.68
	Shita	1	48	-	19.68
	Anushna	-	24	-	9.54
Vipaka	Katu	1	144	-	58.23
	Madhur	2	96	6	41.77
Guna	Laghu	2	192	192	37.60
	Snigdha	2	96	96	20.15
	Guru	1	48	48	9.50
	Ruksha	1	144	144	32.75
	Tikshna	-	-	-	-
Karma	Vatahara	3	240	240	52.53
	Kaphahar	3	216	216	47.47

3.3. Parameter of Assessment

Clinical assessment was done under these basic subjects.

1) **Assessment of Efficacy**

A) Subjective improvement B) objective improvement

2) **Assessment of Tolerability and other procedure**

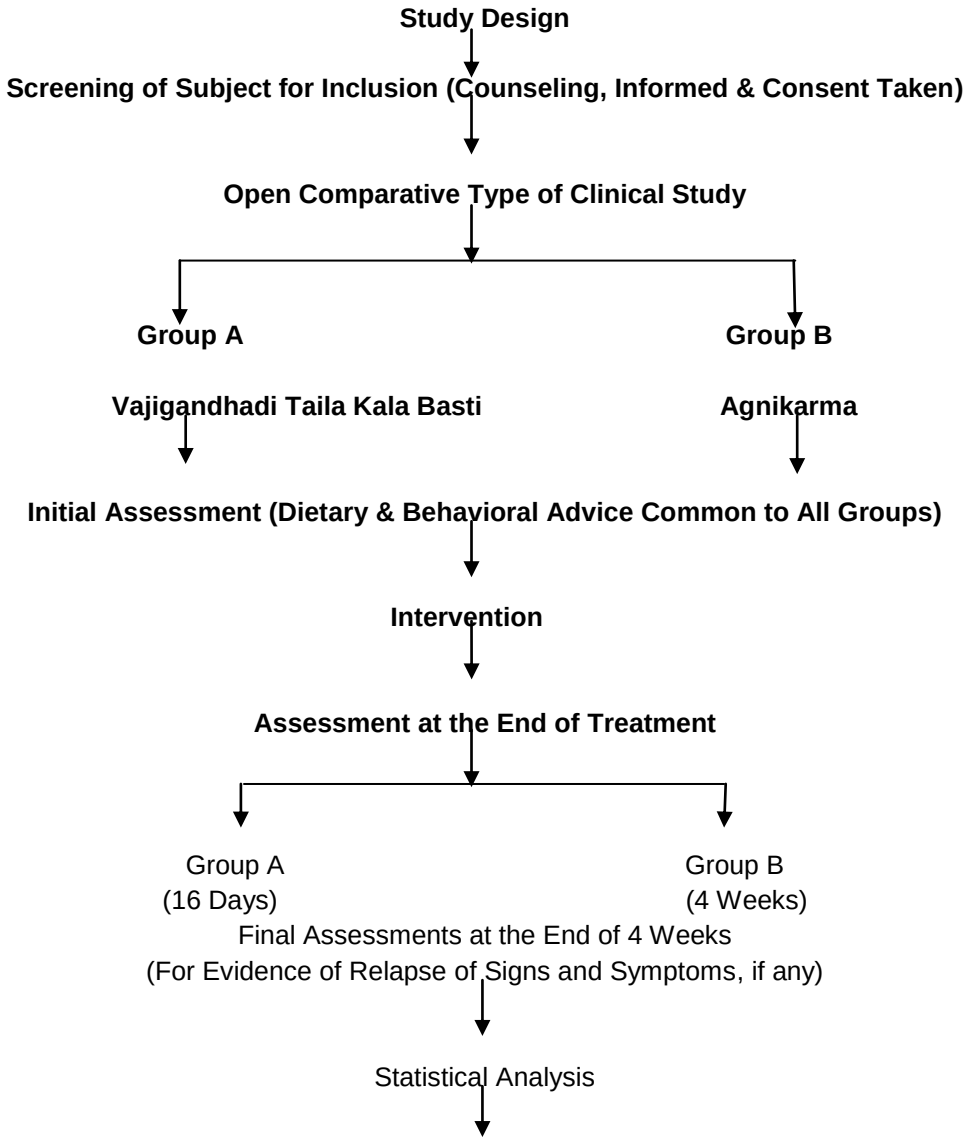
e.g. premature discontinuation-incomplete case-unsatisfactory or cured case

1) **Assessment of Efficacy**

Patients were weekly assessed under these guidelines:-

A) Subjective Assessment

Assessment of signs & symptoms were done in every week for 4 weeks. The specific criteria adopted for gradation of pain & tenderness. To assess the improvement in clinical symptoms of Sciatica patients were arbitrarily graded into four grades (0 to 3) on the basis of severity–duration-stage.



3.4. Gradation of Clinical Symptoms

Table 4: *Gradation of Clinical Symptoms*

Lakshana (Clinical Symptoms)	Grade 0	Grade 1	Grade 2	Grade 3
(Pain)	No pain	Mild (+) pain complained by patient when asked	Moderate (++) patient frequently complains of pain & has painful look	Severe (+++) excruciating pain associated with painful cries & agonizing look
(Tenderness)	No Tenderness	Mild (+) patient winces after digital pressure	Moderate (++) patient winces & withdrawals' the affected part	Severe (+++) patient doesn't allow to touch the affected part

2) Signs

Table 5: *Gradation of Clinical Signs*

Sr. No.	Clinical Signs	Absent 0	Mild(+) 1	Moderate(++) 2	Severe(+++) 3
1	SLR Test [26]	SLR 90	SLR 61-80	SLR 31-60	SLR 0-30 degree
2	Bragard's sign [25]	No pain on SLR, following hip & knee flexion	Mild pain on SLR following hip & knee flexion	Moderate pain on SLR following hip & knee flexion	Severe pain on SLR following Knee & hip flexion
3	Lasegue's sign [24]	No pain	Mild increase in pain on SLR, following foot dorsiflexion	Moderate increase in pain on SLR, following foot dorsiflexion	Severe increase in pain on SLR, following foot dorsiflexion
4	Verbal Dating Scale	No pain	Mild pain	Moderate pain	Worst possible pain
5	Visual Analogue scale [22]	No pain	0-5 scale	5-10	10-15

3) Investigations

Table 6: *Investigational Findings in Both the Groups*

C	Investigations	Before Treatment			After Treatment		
		Good	Fair	Poor	Good	Fair	Poor
1	CBC with ESR						
	Hb	13-14	10-11	>10	13-14	10-11	>10
	ESR						
2	Blood sugar fasting & postprandial	65-100	Up to 130	>130	90-130	Up to 165	> 180
3	Lipid profile						
	Total cholesterol	Up to 200	Up to 240	>260	Up to 200	Up to 240	>260
	Triglycerides	Up to 150	Up to 250	>250	Upto150	Up to 250	>250

4) X ray L.S – Before & After Treatment

Following reflexes were assessed after every week**.**

Reflexes

Table 7: *Reflexes*

Sr. No.	Reflexes	Right	Left
1	Planter		
2	Ankle		
3	Knee		

4. Observations and Results

4.1. Effect of Vajigandhadi Taila Kala Basti in Symptoms of Sciatica (Group A)

Table 8: *Effect of Vajigandhadi Taila in Symptoms of Sciatica*

Sr. No.	Cardinal Symptoms	Mean Score		Mean	SD±	S E±	't'	P	%
		B.T	A.T						
1	Pain	2.15	0.25	1.9	0.640	0.143	13.26	<0.0001	88.37
2	Tenderness	1.8	0.95	0.85	0.366	0.0819	10.37	<0.0001	47.22

4.2. Effect of Agnikarma in Cardinal Signs of Sciatica

Table 9: *Effect of Vajigandhadi Taila in Symptoms of Sciatica*

Sr. No.	Cardinal signs	Mean Score		Mean	SD±	S E±	't'	P	%
		B.T	A.T						
1	SLR Test	1.8	0.95	0.85	0.366	0.0819	10.376	<0.0001	47.22
2	Bragard's sign	1.8	0.95	0.85	0.366	0.0819	10.376	<0.0001	47.22
3	Lasegue's sign	1.8	0.95	0.85	0.366	0.0819	10.376	<0.0001	47.22
4	Verbal Dating Scale	2.15	0.25	1.9	0.640	0.143	13.262	<0.0001	88.37
5	Visual Analogue Scale (VAS)	2.15	0.25	1.9	0.640	0.143	13.262	<0.0001	88.37

Table 10: *Effect of Vajigandhadi Taila in Investigations in Patients of Sciatica*

Sr. No.	Investigations	Mean Score		SD±	S E±	't'	p	%
		B.T	A.T					
1	CBC							
	Hb	13.16	13.17	1.193	0.2667	0.0168	0.9867	-0.075
	ESR	17.85	14.10	7.297	1.632	2.298	0.0331	21
2	Blood sugar							
	fasting &	86.10	83.32	28.85	6.45	0.4494	0.6582	3.22
	Postprandial	99.75	100.55	33.05	7.39	0.1082	0.9149	-1.002
3	Lipid profile							
	Total cholesterol	184.9	176.95	11.19	2.50	3.177	0.005	4.29
	Sr. triglycerides.	191.3	187.35	10.55	2.35	1.674	0.1104	2.06

4.3. Effect of Agni karma in Cardinal Symptoms of Sciatica (Group B)

Table 11: *Effect of Agnikarma in Symptoms of Sciatica*

Sr. No.	Cardinal Symptoms	Mean Score		Mean	SD±	S E±	't'	p	%
		B.T	A.T						
1	Pain	2.35	0.30	2.05	0.510	0.114	17.96	<0.0001	87.23
2	Tenderness	1.85	0.55	1.3	0.571	0.127	10.177	<0.0001	70.27

Effect of Agnikarma in Cardinal Signs of Sciatica

Table 12: *Effect of Agnikarma in Symptoms of Sciatica*

Sr. No.	Cardinal Signs	Mean Score		Mean	SD±	S E±	't'	p	%
		B.T	A.T						
1	SLR Test	1.8	0.55	1.25	0.55	0.123	10.162	<0.001	69.44
2	Bragard's sign	1.8	0.55	1.25	0.55	0.123	10.162	<0.001	69.44
3	Lasegue's sign	1.8	0.55	1.25	0.55	0.123	10.162	<0.001	69.44
4	Verbal Dating Scale	2.5	0.25	2.25	0.638	0.142	15.75	<0.0001	90
5	Visual Analogue Scale (VAS)	2.5	0.25	2.25	0.638	0.142	15.75	<0.0001	90

Table 13: *Effect of Agnikarma in Investigations in Patients of Sciatica*

Sr. No.	Investigations	Mean Score		SD ±	S E ±	't'	p	%
		B.T	A.T					
1	CBC							
	Hb	12.89	12.905	0.559	0.128	0.08198	0.9356	-0.07
	ESR	19.2	13.7	8.22	1.839	2.991	0.0075	28.64
2	Blood sugar							
	fasting &	9.65	9.30	7.92	1.773	0.1974	0.8456	3.626
	Postprandial	110.5	109.15	7.67	1.716	0.8159	0.4247	0.90
3	Lipid profile							
	Total cholesterol	153	147.10	6.52	1.458	4.047	0.0007	3.85
	Sr. triglycerides.	178.15	169.3	8.85	12.44	2.78	3.181	5.15

1) **Age Wise Distribution**

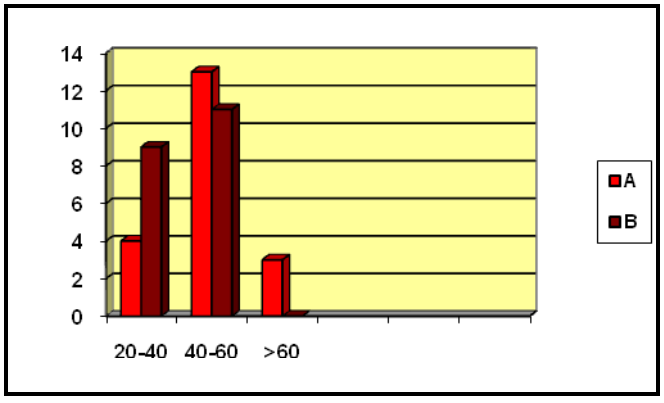


Figure 1: *Age Wise Distribution of Patients*

2) **Sex Wise Distribution**

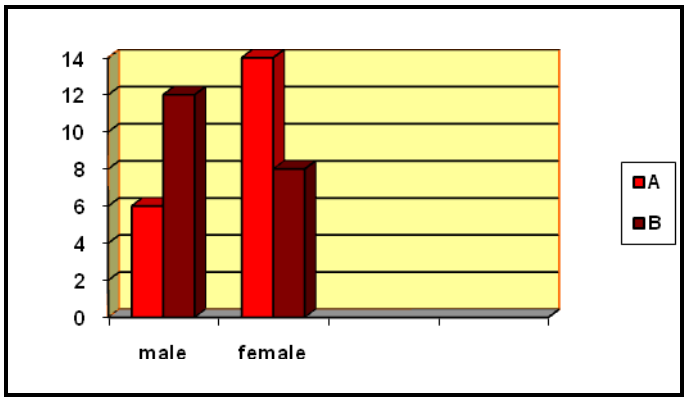


Figure 2: *Sex Wise Distribution of Patients*

3) **Religion Wise Distribution**

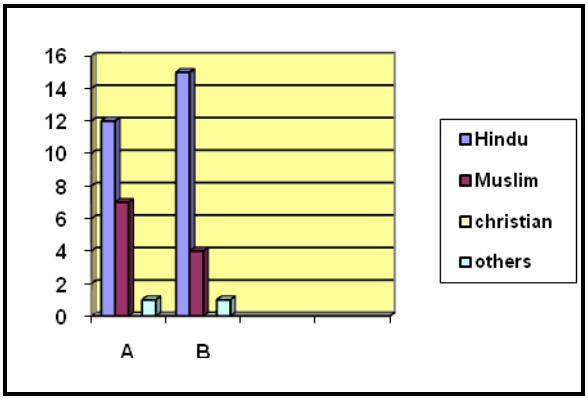


Figure 3: *Religion Wise Distribution of Patients*

4) **Socio-Economic Status**

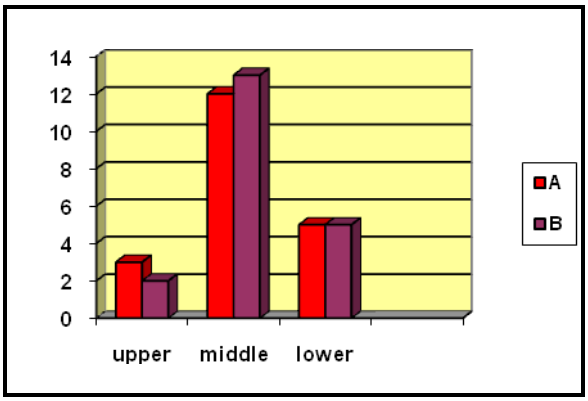


Figure 4: *Socio-economic Distribution of Patients*

5) **Occupation Wise Distribution**

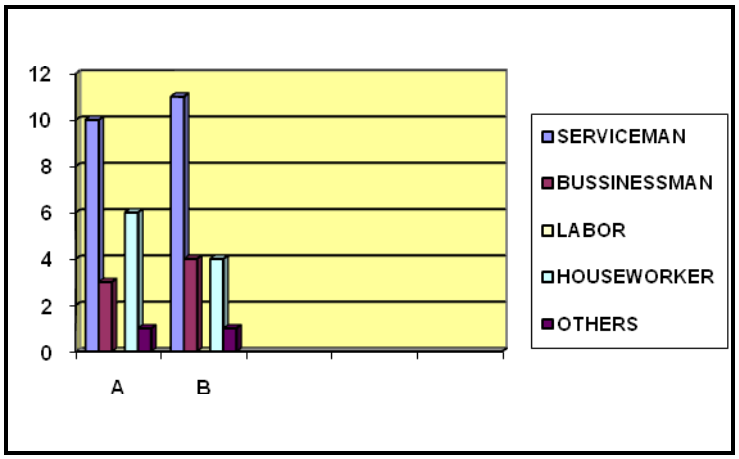


Figure 5: *Occupation Wise Distribution of Patients*

6) **Chronicity Wise Pattern**

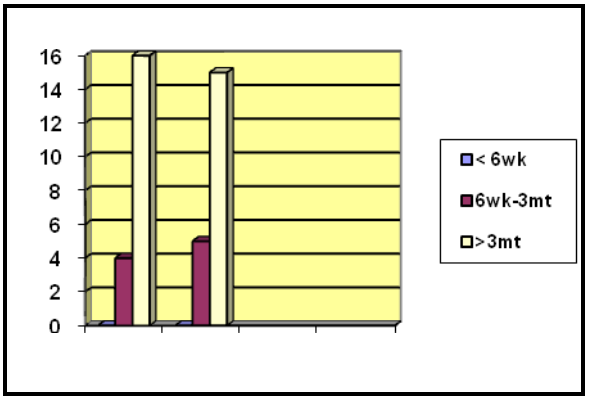


Figure 6: *Chronicity Wise Distribution of Patients*

7) **Prakriti Wise Pattern**

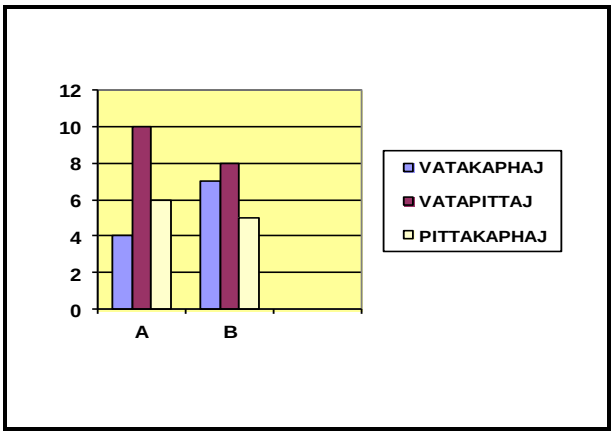


Figure 7: *Prakriti Wise Distribution of Patients*

Neurological Findings

1) **Knee Jerk**

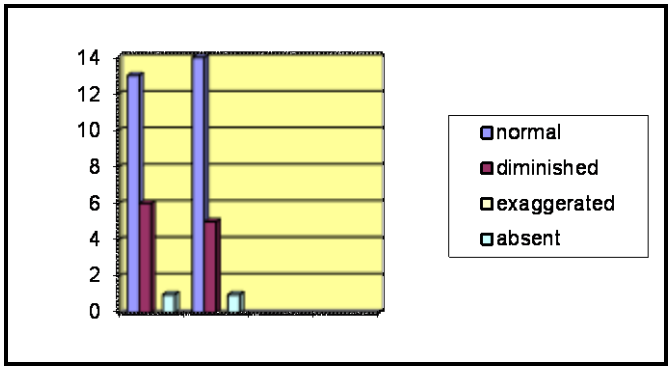


Figure 8: *Knee Jerk Findings in Both the Groups*

2) ***Ankle Jerks***

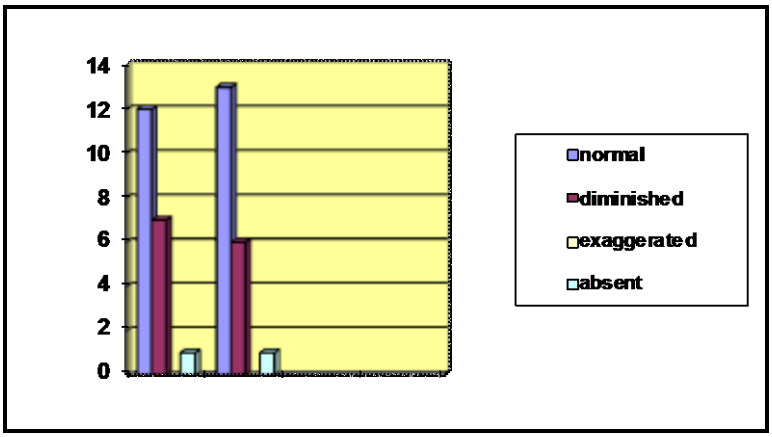


Figure 9: *Ankle Jerk Findings in Both the Groups*

Effect in Mean Grade, Scores of Investigations

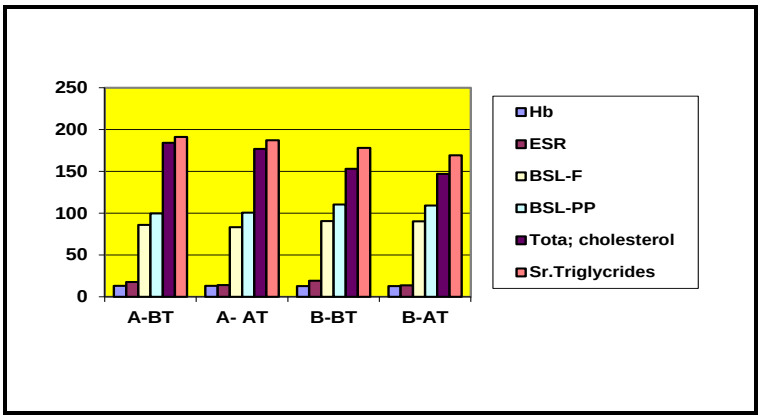


Figure 10: *Investigations in Both the Groups*

5. Discussion

The term Sciatica refers to pain beginning in the lumbar region and spreading down the back of one lower limb to the ankle or foot. There is usually little weakness or sensory loss but sometimes diminution or loss of the ankle jerk. The recurrence rate of sciatica is a major concern. Advances in science have not yielded substantial treatment option on the pain with the help of analgesics and steroidal therapy. However its role in treating the disease remains doubtful. As Ayurvedic management is believed to manage the root cause of the disease [17]. Therefore whole medical fraternities are looking towards this ancient medical science. The present study entitled aims to study and to find out the effects of Panchakarma & Anushalya procedures in Sciatica [15].

5.1. Age Groups

Age distribution was divided into three groups. (32.5%) patients were belonging to the age group of 20-40 years. (60%) patients were belonging to the age group of 40-60 years. (7.5%) were belonging to the age group of group 61 onwards. This data suggest that most of these patients fall in the age group of 40-60 years.

5.2. Sex Distribution

Out of 40 patients there were (45%) male & (55%) female.

5.3. Religion Wise Distribution

Out of 40 patients there were (72.5%) Hindu, (27.5%) Muslim, & (5%) of other religion.

5.4. Occupation Wise Distribution

There were (52.5%) Serviceman class, (17.5%) Businessman class & (25%) House worker, & (5%) of other class. This data show that Sciatica occur mostly in serviceman, & house worker who are busy in doing their strenuous work.

5.5. Chronicity Wise Distribution

There were (22.5%) patients of 6 weeks to 3 months chronicity & (77.5%) patients of chronicity more than 3 months.

5.6. Prakruti Wise Distribution

There were (27.5%) patients of Vatakaphaj prakruti, (45%) Vata Kaphaj & (27.5%) of Pittaj Kaphaj

5.7. Neurological Findings

Knee Jerks

There were shows normal knee jerk (67.5 %), (27.5%) diminished knee jerk & (5%) of absent knee jerk.

Ankle Jerks

There were (62.5%) normal jerk, (32.5%) diminished jerk and (5%) of absent ankle jerk.

Blood & X ray- L.S. Investigation in Patients of Sciatica

There were no significant changes seen in patients Sciatica of before and after treatment. Detail values in both groups before and after treatment

An objective assessment by blood investigation & X ray -L.S shows. No significant change in both the groups. No untoward effects have been observed in any of the patients in either treatment group.

6. Conclusion

1) In group a highly significant results were found than group B.
2) The pain relief provided by Agnikarma and sustained improvement with Vajigandhadi Taila Basti presents a window of opportunity in the clinical management of Sciatica.
3) There were no significant changes seen in blood & radiological investigation in patients of Sciatica before and after treatment.

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Case Report | Open Access

Ayurvedic Management for *Gridhrasi* with Special Reference to Sciatica- A Case Report

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Abstract *Gridhrasi* (sciatica) is one among *Vata-vyadhi* caused by aggravated *Vata Doshas*. It is characterized by burning, stinging or numbing pain that is felt in the buttock, thigh, leg or foot. It may or may not be associated with low back pain. Purpose of the study was to ameliorate the clinical manifestation of *Gridhrasi*. In this case report patient who suffered from *Gridhrasi* of the left leg since one year was treated with combined Ayurvedic regimen. *Patrapinda Swedana* for 21 days and *Erandmuladi Niruhabasti* as *Karma Basti* schedule were used as *Panchakarma* procedure. *Ekangaveera Rasa* 250mg B.D., *Dasmoola Kwatha* 40ml B.D., *Ashwagandha Churna* 3g B.D. and *Triyodashanga Guggulu* 2 Tablets B.D., were given for 1 month as oral medicine. Walking distance and SLR test were taken for assessment parameter, VAS score was adopted for pain. Before treatment patient was not able to walk even 4 to 5 steps due to severe pain and his SLR were 30^0 of left side. After one month treatment he can walk up to 500 meters without any difficulty, SLR was changed to 90^0 and patient had got 75% relief in pain. This case report showed that combined Ayurvedic regimen is potent and safe in the treatment of *Gridhrasi*.
Keywords *Gridhrasi;* Sciatica; Ayurvedic Management

1. Introduction

Gridhrasi (Sciatica) is a disorder in which low back pain is found, that spreads through the hip, to the back of the thigh and down the inside of the leg. There are many causes for low back pain, however true sciatica is a symptom of inflammation or compression of the sciatica nerve. The sciatica nerve carries impulses between nerve roots in the lower back and the muscles and nerve of the buttocks, thighs and lower legs. Compression of a nerve root often occurs as a result of damage to one of the discs between the vertebrae. In some cases, sciatic pain radiate from other nerves in the body. This is called referred pain. Pain associated with sciatica often is severe, sharp and shooting. It may be accompanied by other symptom, such as numbness, tingling, weakness and sensitivity to touch.

Although low back pain is a common condition that affects as many as 80-90% of people during their lifetime, true sciatica occurs in about 5% of cases. Sciatica is more common between 30 and 50 years of age [1].

Pain in sciatica is very severe, which makes the patient difficult to walk; hampering the daily routine of the individual. No satisfactory treatment available in modern medical science, patients depends on pain killers which has temporary action.

2. Case Report

A male patient with average built of age 49 yrs was admitted in IPD male ward, Department of *Panchakarma*, National Institute of Ayurveda, Jaipur with chief complaints of pain in low back region radiating to left lower limb since one year. Patient also had complaints of tingling sensation and numbness in his left lower limb since 10 months. Last six months patient also suffered with poor appetite. For this he took treatment from different Govt. Allopathic Hospitals, but got no relief. Then he approached National Institute of Ayurveda in Panchakarma Dept. for better treatment. On examination- general condition of the patient was found antalgic gait. He was not able to walk and stand for more than one minute due to severe pain. SLR was 30^0 of left side. Lumbar scoliosis was also present. Blood pressure was 120/70 mmHg, Pulse rate was 86/minute, Weight-70 kg and Height -5.11".

Investigation was done at the time of admission. It revealed Hb. 11.5 g%, TLC 8400 th/ul, ESR 09 mm/hr, Neutrophill 60%, Lymphocytes 34%, Eosinophill 2%, Monocytes 2%, Basophill 0%, RBS 90.4mg/dl. All the investigation for hormonal assay was normal. HIV, HBsAg, VDRL were negative. MRI findings confirming the presence of severe thecal sac compression and mild narrowing of both neural foramina at L4-L5 due to diffuse circumferential bilging and posteriorly extruding disc.

After the examination this patient was diagnosed to suffering from *Gridhrasi* (sciatica) and a composite *Ayurvedic* treatment was given. *Patrapinda Swedana* for 21 days and *Erandmuladi Niruhabasti* as *Karma Basti* schedule were used as *Panchakarma* procedure. *Ekangaveera Rasa* 250mg B.D., *Dasmoola Kwatha* 40ml B.D., *Ashwagandha Churna* 3g B.D. and *Triyodashanga Guggulu* 2 Tablets B.D. were given for 1 month as oral medicine. Satisfactory results were found after one month of treatment. All haematological investigation that were done after one month were also normal

3. Discussion

Gridhrasi is a *Shoolapradhana Nanatmaja Vata-vyadhi*, intervening with the functional ability of low back & lower limbs. In this disease onset of *Ruk* (pain), *Toda* (numbing pain) and *Stambha* (stiffness) is initially in *Kati (lumbosacral region)* and radiates distal to *Pristha, Janu, Jangha* till *Paada* [2]. Arundutta in his commentary defined clearly that due to *Vata* in *Kandara* (tendon) the pain is produced at the time of raising leg straight and it restricts the movement of thigh [3]. This is an important clinical test for the diagnosis of sciatica known as SLR. In Madhava Nidana, *Dehasyapi Pravakrata* (Lumbar scoliosis) is considered in *Vataja* type of *Gridhrasi* [4].

A similar condition in modern parlance is sciatica. It is the distribution of pain along the course of the sciatic nerve or its component nerve roots is characteristic. Radiating deep seated cramping pain in buttocks followed with numbness and paresthesia in lower extremities favors the diagnosis. Restricted SLR test consolidates the diagnosis clinically and even the illness can be confirmed by imaging techniques. Prolapse of intervertebral disc, external mechanical pressure and degenerative changes of the lumbar spine are the commonest cause for sciatica.

In Charaka Samhita*, Gridhrasi* is counted as a *Swedana Sadhya Vyadhi* [5] and *Basti Karma* also indicated in *Gridhrasi Roga* [6]. Taking consideration of above fact a composite treatment plan was adopted. *Patrapinda Swedana* [7] for 21 days and *Erandmuladi Niruha Basti* [8] as *Karma Basti* schedule were used as *Panchakarma* procedure. From the *Shamana* point of view various medications that soothe the severity of pain and improve functional ability are adopted in *Gridhrasi* as *Ekangaveera Rasa* [9] 250mg B.D., *Dasmoola Kwatha* [10] 40ml B.D., *Ashwagandha Churna* [11] 3g B.D. and *Triyodashangaguggulu* [12] were also given for 1 month as oral medicine.

Before treatment patient was not able to walk even 4 to 5 steps due to severe pain and his SLR were 30^0 of left side. After one month treatment he can walk up to 500 meters without any pain and his SLR was changed to 90^0 after treatment and patient had got 75% relief in pain.

Patrapinda Swedana is a form of *Sankara Swedana.* The word *Sankara* as it suggests the mixture of different medications or drugs when used in form of *Pinda* or *Pottali,* it is called as *Pinda Swedana.* The probable mode of action of *Patrapinda Swedana* can be explained as- Thermal effect, Drug effect, Procedural effect.

Basti is the best treatment modality in the management of *Vata-vyadhi* [13]. Mixture of *Madhu, Saindhava Lavana, Sneha, Kalka, Kashaya* and *Avapa Dravya* are administered in the form of *Niruha Basti*. *Erandmuladi Niruha Basti* Which contains 34 drugs among them maximum number *Dravyas* to *Ushna Veerya*, which is indicated in *Shoola* of *Jangha, Uru, Paada and Pristha* region and it is indicated in *Kapha-avruta* conditions also.

The *Shamana* like therapy generally employed to restore *Agni* and pacify the excited *Dosha*. When we consider *Samprapti* of *Gridhrasi* due to *Apatarpana* or *Abhighata* where *Vata Prakopa* takes place due to *Rikitata* of *Srotas* or damage of vital points. Here along with *Deepana Pachana* properties, the drugs having *Rasayana* and *Balya* property, that replace the damage nerve tissue and *Vata Shamaka* property were used i.e. *Triyodasanga Guggulu, Ashwagandha Churna, Ekangaveera Rasa* and *Dasmoola Kwatha*.

In this Ayurvedic Management satisfactory relief was found in signs & symptoms of *Gridhrasi* and it may be adopted for other cases of *Gridhrasi* or sciatica & for further research in the management of *Gridhrasi* (sciatica).

4. Conclusion

This case report showed that combined Ayurvedic regimen is potent and safe and effective in the treatment of *Gridhrasi*. There were no adverse effects found in combined Ayurvedic regimen.

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Review Article | Open Access

Diagnosis and Management of Dysmenorrhea in Unani (Greeko-Arab) System of Medicine

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Abstract Dysmenorrhea is the most common gynecologic disorder among the female adolescents that affects more than half of women of 18-25 years and is one of the leading cause of their recurrent short-term absenteeism in schools and workplaces. Dysmenorrhea refers to painful menstruation and the painful cramps in the lower abdomen is associated with one or more symptoms like sweating, lower backache, fatigue, diarrhea, headache, nausea, vomiting, dizziness and in severe cases syncope etc. Pain is often not completely relieved by conventional medicines and the medicine has also its own side effects on the human body therefore, it is need of time to understand the traditionally documented therapeutic options, which has no adverse effect on the human body. Unani physicians have described the various causes and management of dysmenorrhea under the heading of waje rehm / dard rehm/ usre tams in the unani literatures. They have also mentioned some herbal drugs and unani compound formulations in unani classical literatures for treatment of usre tams (dysmenorrhea). The review article focuses on the unani concept about dysmenorrhea, its diagnosis and management in unani system of medicine. It also highlights some of the herbal drugs and unani compound formulations used in the management of dysmenorrhea.
Keywords *Dysmenorrhea; Unani Systems of Medicine; Usre Tams; Herbal Drugs*

1. Introduction

Dysmenorrhea is a common gynecological problem in women of reproductive age; in general, it begins with the first ovulation cycle and occurs about two years after menarche and most of the severe episodes occurs before 25 years of age [1]. Dysmenorrhea word is derived from Greek words ‘dys’ meaning ‘difficult, painful or abnormal’; ‘meno’ meaning ‘month’ and ‘rrhoea’ meaning ‘flow’ that means “Painful menstrual flow [2]. The affected women experience sharp, intermittent spasm of pain usually concentrated in the suprapubic area but pain may also radiate to the back and along the thighs [3, 4]. The painful cramping sensation in the lower abdomen is often accompanied by some other symptoms including sweating, lower backache, fatigue, diarrhea, headache, nausea, vomiting,

dizziness and in severe cases syncope etc. [5, 6]. It affects more than 50% of menstruating women in age group 18-25 years [7] and 10% of these women suffer severely enough to render them incapacitated for one to three days in each menstrual cycle [8]. It is one of the leading cause of recurrent short-term absenteeism of young women in schools and workplaces, affecting their performances, social and sports activities [9]. This situation has not only significant impact on personal health but also have a global economic impact [10].

Unani physicians have discussed the various causes and management of dysmenorrhea under the headings of waje rehm / dard rehm/ usre tams uterine pain [4, 11]. They worked on the theory of temperament and succeeded in locating the relationship between disease, various humours and disturbance of the temperament. Therapy in unani system of medicine is based on the understanding that a particular illness in the patient has developed due to disharmony in her/his temperament, which has deviated from its equilibrium status therefore; the objective of treatment is rectification of the disturbance of temperament. According to Unani physicians, it is the altered temperament (sue mijaz) that causes obstruction in flow of menstruation fluid that results difficult menstruation [12]. Treatment is therefore, aimed directly at restoring balance to patient's temperament or humours.

The conventional medicines prescribed for treatment of dysmenorrhea are NSAID and OCPs (prostaglandin inhibitors) that have notable side effects like nausea, stomach irritation, gastrointestinal ulcers and renal blood flow etc.[13] therefore, herbs and unani drugs formulations, which have least or no side effect on human body, have received special attention to get relief from menstrual pain..

In this review article, an effort has been made to focus on the various causes of dysmenorrhea; diagnosis and management of dysmenorrhea by unani system of medicine. Some herbs and unani compound formulations used in treatment of usre tams (dysmenorrhea) have also been highlighted.

2. Historical Background

The word "dysmenorrhoea" makes its appearance in the English language in about 1810 [14]. Amenorrhea and dysmenorrhea were known to Egyptian practitioners as abnormal conditions. Dysmenorrhea was also known to Greek philosopher Hippocrates, whose opinion was that usre-tams [dysmenorrhea] occurs due to cessation of flowing of menstrual blood secondary to cervical obstruction, which causes painful menstrual cycle but it does not occur when the menstrual flow is regular and adequate in quantity [15, 16]. According to Hippocrates, delaying of motherhood may be one cause of uterus disorder and difficult blood flow therefore women suffering with disease were urged to marry and conceive as quickly as possible to get relief from menstrual pain [17]. Both, Hippocrates and Aristotle have advocated for breathing exercises to relieve the pain [18]. Dysmenorrhoea and other menstrual disorders were treated by the Roman Physicians by using the herbs, specifically asparagus root. Ibne Sina has mentioned in the treatise 'Canon of Medicine' that obstruction in the menstruation flow due to change of temperament results difficult menstruation [12]. Zakarya Razi has described the dysmenorrhea as pain of uterus [darde rehm] in his manuscripts 'Al HawiFilTib' and has recommended some unnai drugs for treatment of waze rehm [uterine pain]. He has also advised dry cupping and massage on lower abdomen and sitz bath to relieve the menstrual pain [11]. Both, Majoosi and Ibn Huba have described in their legendary texts Kamilassina and Kitab al Mukhtarat fil tibb respectively that women having scanty flow of menstruation usually suffer with painful menstruation [19, 20]. According to I. Jurjani, pain occurs in abdomen along with pain of uterus, headache and backache. After a long period pain gets lodged in the hips [21]. According to Hkm. Ajmal Khan, in usre tams either menses stops from beginning or ceases after sometimes of normal menstruation or comes in decreased amount or occurs in a little amount with gap associated with pain [22]. Hassan Qurashi has described that usre tams is characterized by difficulty and pain at

the time of menstruation, which is often exaggerated. Akber Arzani has stated that backache is present in the usre tams before and during the menstrual flow [23].

3. Classification of Usre Tams Dysmenorrhea

Usre tams is classified into five types [24, 25],

(i) Inflammatory or Warmi Usre Tams

It is due to inflammation in uterus or cervical canal and occurs after the delivery, when uterus does not return back to its anatomical position. Most of the obese women experience this type of usre tams.

(ii) Spasmodic or Tashannuji Usre Tams

It occurs due to uterine cramps, which is severe before the first or second day of the start of menstruation flow. The pains are spasmodic in nature and strongest over the lower abdomen, but they may also radiate to the back and the inner aspects of the thigh; suprapubic and umbilicus region. It usually occurs in female adolescents.

(iii) Obstructive or Suddi Usre Tams

This type of usre tams occurs due to small size of uterus, displacement of uterus or some obstructions in cervix opening. The inflammation in cervix results obstructions in cervical canal.

(iv) Membranous or Gheshae Usre Tams

It occurs due to weakness of uterus and exposure to cold. It is mostly experienced by woman with tension and anxiety.

(v) Ovarian or mubaizee Usre Tams

It occurs due to ovarian cyst or other diseases of the ovaries. Patients experience pain mostly in the left ovary.

4. Clinical Features of Usre Tam

Pain in pelvic region is common in all types of usre-tams. Ibn Sina has stated that menstrual pain is felt in suprapubic area and radiates to thigh and legs. According to Hkm. Azmal Khan and G. Jilani have described in Hazique and Mukhzanul-Ilaz that menstrual pain may be so severe that patient may become faint and unconscious.

Patients feel sharp pelvic cramps or deep / dull ache before or during the menstruation flow. It is often accompanied with associated symptoms like pain in hips, pain in lower back or thighs, big/ heavy stomach, Scanty menstrual flow, Phlegmatic swelling in uterus, backache, headache, general achiness, paleness or yellowish on face, tiredness, weakness, feeling unhappy, increased heartbeats, palpitation, vomiting, nausea, diarrhea, fever and others [4, 26, 27, 28, 29, 30].

5. Diagnosing of Usre Tams

Inflammatory or Warmi Usre Tams

Menstrual fluid becomes thick and some viscid fluids (Balghame ghaleez) stick around the cervix. Patient experiences scanty blood flow with severe pain in first day, heaviness in pelvic region and lower abdomen pain before 5-7 days of the start of menstrual flow, pain in uterus, backache, restlessness, nausea, headache and mild fever.

Spasmodic or Tashannuji Usre Tams

The cramps are most severe on the first or second day of menstruation. Pains are spasmodic in nature and strongest over the lower abdomen but they may also radiate to the back and the inner aspects of the thigh. Symptoms seldom persist for more than 2-3 days. The cramp is commonly accompanied by one or more systemic symptoms, including nausea, vomiting, fatigue, diarrhea, lower backache and headache.

Obstructive / Suddi Usre Tams

Pain is so severe that patients may become unconscious and faint. The patient complains of vertigo, giddiness, nausea and vomiting. Some patient also complaints of nasal, oral and vesicular bleedings.

Gheshae or Membranous Usre-Tams

Gheshae or Membranous usre tams is an advance stage of spasmodic usre-tams. This type of usre-tams is hereditary and often occurs after delivery. Menstrual flow decreases after 24 to 36 hours and mucous membrane discharges with menstrual fluids. After discharge of mucous membrane, menstrual flow becomes normal.

Mubaizi or Ovarian Usre Tams

In the Mubaizi / Ovarian Usre Tams, the patients feel pain just before to start of menstrual flow and complaints of pain mostly in left ovary, flatulent and frequent painful urine. Swelling may be observed after palpation [23, 24, 25, 30].

6. Etiology

Unani scholars have described the various causes of dysmenorrhea under heading of waje rehm / dard rehm/ usre tams. According to them, imbalance of humours causes obstruction in the flow of menstruation. Ibn sina has described that any obstruction in the flow of menstruation fluid may cause usre tams and it occurs, when the menstruation cycle is irregular and menstruated blood is not balanced in quality and quantity [12]. According to Hkm. Ajmal Khan, usre tams is caused by ghaleez khoon and during menstruation, rehm undergoes forceful contraction to expel the ghaleez khoon, which results pain in uterus [29].

The others etiological causes of waje rehm/dard rehm/usre tams as described in unani classical texts are Sue-mizaj (distemperament), Warme rehm (inflammation of uterus), Zofe rehm (weakness of uterus), Quroohe rehm (ulcers of uterus), Sayalan-al-rehm (whitish vaginal discharge), Sartane rehm (carcinoma of uterus), Amraze rehm sabaqe (previous disease of uterus), Sailan khoon (menorrhagia), Qillate dam (anemia), Qillate tams (oligomenorrhea), Ehtebase tams (amenorrhea),

Sozish-e-khasyatur rahm (ovarian cyst), Insidade fame rehm (cervical stenosis), Muzmin amraz (prolonged and chronic disease), Displacement of uterus, Uterine rupture, Accumulation of excess fats in Uterus, Tension and anxiety, Exposure to cold, Cold bath, Wearing wet clothes for long time, Increased black bile and phlegm in blood, Increased viscosity of blood, Consumption of ghaleez foods and Obesity [4, 11, 21, 24, 25, 27].

7. Preventive Measures

i. Regular physical exercise.
ii. Avoid smoking and alcohol consumption.
iii. Avoid foods that contain caffeine.

8. Non-Medicinal Treatments to Get Relief from Pain of Dysmenorrhea

(i) Lying on the back and supporting the knees with a pillow.
(ii) Holding a heating pad or hot water bottle on your abdomen or lower back.
(iii) Taking a warm bath
(iv) Gently massaging the abdomen
(v) Mild exercises like stretching or walking to improve blood flow and reduce pelvic pain.

9. Conventional Treatments and Its Limitation

(i) Non-Steroidal Anti Inflammatory Drugs (NSAIDs) such as Iboprufen, Cataflam, Diclofenac, Ketoprofen, Meclofenamate, Mefanamic acid, Naproxen and Aspirin etc. act as prostaglandins inhibitors to give relief from menstrual pains [13].
But, use of NSIADS for prolonged period causes gastro-intestinal bleeding and ulcers, risks of heart attack, stroke and renal dysfunction. Prolonged use of NSAIDs may have adverse effects such as Nausea, vomiting, diarrhea, constipation, decreased appetite, rash, dizziness, headache and drowsiness etc.

(ii) Oral contraceptives: OCs reduces menstrual fluid volume through suppression of endometrial tissue growth, giving rise to reduced prostaglandin levels.
But, OCs may have adverse effects such as mood-changes, nausea, fluid retention, breast tenderness, headache, nausea, anxiety, loneliness, weight gain, acne etc.

(iii) Surgical interventions – Surgery may be used to treat the dysmenorrhea but it is costly, uncomfortable and various complications may be developed after surgery.

10. General Principle of Treatment (USOOLE ILAJ)

Treatment of usre tams (dysmenorrhea) is based on 4 aspects;

(i) Ilaj bil Ghiza (Dietotherapy)
(ii) Nafseeyati (Psychotherapy)
(iii) Ilaj bil Dawa (Pharmacotherapy)
(iv) Ilaj bil Tadbeer (Regimental therapy)

10.1. Dieto-Therapy

Dieto-therapy seeks to restore the imbalances in the body due to errant lifestyles. Unani physicians have advised the patients of usre-tams to take high nutritious diets in case of general weakness; mutton ka shorba, lamb meats, murgh ka shorba, diet rich in iron like carrot, green leaf vegetable; diet rich in fibre to remove constipation; diet rich in magnesium like fish, milk and fish-oil; bottle-gourd; pulses of arhar and moong and plenty of water etc. [24, 27].

10.2. Nafseeyati (Psychotherapy)

Prompt psychological counseling should be done for psychological care of the patient because most of the patients depressed psychologically. Patients and their relatives should be assured that dysmenorrhea is a common problem in female adolescents and is curable.

10.3. Ilaj Bil Dawa (Pharmacotherapy)

Warmi Usre Tams

(i) Decoction of Abhal (Juniprus communis) and Karafs Kohi (3 gm each); Tukhme kharpaza (Cucumis melo seeds), Khare khasak (Tribulus terrestris linn.) and Bekhe kashni (Cichorium intybus) (6 gm each) prepared with 70 gms of Arq-shatra (Fumaria parviflora lam) and Arq-makoh (Solanum nigrum linn.) should be given with 20 ml of Sharbat Bazoori.

(ii) Decoction of Tarmas (white lupine), Abhal (Juniprus communis linn.), mustara maseeh (Mentha pulegium linn), majeeth (Rubiscordi folia linn), berge sodabe, podina khusk (7 gm each) prepared with 375 ml water should be given with 40 ml of Sharbat Bazoori.

(iii) Luaabe behdana (Cydonia oblonga mill) (3gm), Sheerae unnaab (Zizyphus vulgaris lau) (5 pills), Arqe-gauzeban (Borago officinalis linn.) (120 ml) should be given with 20 ml of Sharbate Nilofer. [25].

Tashannuji or Spasmodic Usre Tams

(i) Decoction of drugs Tukhme Karafs (Apium graveolens), podina (mentha arvensis) (dry) and Badiyan (Foeniculum vulgare) (5 gm each); Tukhm-Kharpaza (Cucumis melo seed) and post Amaltaas (Cassiafistula linn.) (7 gm each); Tukhme Bhang (Cannabis sativa linn.) and Ajwain Khurasani (Hyoscyamus Niger) (1 gm each) prepared with 375 gm of water should be given with 25 ml of Sharbat Bazoori Motadil.

(ii) Pills made by mixing of fine powders of Jund Baidaster and Halteet (Ferula Asafoetida) (1 gm); Tukhme Bhang (Cannabis sativa linn.), Ajwain Khurasai (Hyoscyamus Niger) and Podina nahri (Mentha Arvensis) (2 gm each); Kafoor (Cinnamomum Camphora) (3 gm) with honey should be given thrice daily [25].

Gheshae or Membranous Usre Tams

Decoction of Tukhme Qurtum (Carthamus tinctorius L.), Gauzuba badiyan (Foeniculum vulgare), Tukhme kharpaza (Cucumis melo seed), Tukhme Karafs (Apium graveolens), Bekhe Kashni (Cichorium intybus) (5 gm each) prepared with 250 ml water should be given with 25 ml of Sharbat Bazoori Motadil [25].

Suddi / Obstructive Usre Tams

(i) Surgery- To remove the obstruction in the uterus.

(ii) Dilator should be used to wide and expand the opening of narrow cervical canal.

Mubaizi or Ovarian Usre Tams

(i) Surgery – To remove the cyst in ovary

(ii) Eliminate the real cause of the ovary diseases.

- If menstruation pain is due to imbalances in humours then decoction of mixed ingredients Chirraita, Bekhe Badiyan and Bekhe Karafs (7 gm each) should be given with 50 ml Sharbat Bazoori Motadil to correct the imbalance in humour.

- If the cause is due to uterine displacement then constipation should be avoided. Habbe Tinkar (3 pills) with warm water should be given in night to treat the constipation.

- To correct the generalized weakness of the patient, Kushta Faulad (1 pill) should be given either with Dawaul Misk Motadil Jawahar wali (5 gm) or with Khamira Abresham Hakeem Arshad wala before the meal and Sharbate Faulad (3 gm). After the meal, Maul Laham Zadeed or Mul Laham Ambary 50 (gm) mixed with Sharbate Anar Siri 25 ml and Mauz zahab (5 drops) mixed together with Maul Laham Khas (50 gm) should be given [27].

10.4. Ilaj-Bil- Tadbeer (Regimental Therapy)

Ilaj-Bil-Tadbeer (Regimental therapy) is one of the four methods of treatment in the Unani system of medicine, which is used independently or in combination with other methods of treatment like Ilaj Bil Dawa (Pharmacotherapy), Ilaj Bil Ghiza (Dietotherapy) and Ilaj Bil Yad (Surgery). The different types of method used for care and general health maintenance of sick people are riyazat (exercise), dalak (massage or friction), takmeed (fomentation), zimaad wa tila (ointment and liniment), sitz bath, ishall (purgation) and hijamat (cupping) etc.

- Post-e-khaskhas (12gm) and guletesu (25 gm) boiled with two liter of water should be used as fomentation on the lower abdomen to reduce the severity of the pain.

- If obesity, overweight and cold exposure are the main cause of the disease then use purgative medicines before 2 to 4 days of the expected date of menses. This should be accompanied with sitz bath in 20 gm mustard seed powder mixed with luke warm water.

- Abzan (Sitz Bath): With decoction of drugs like Abhal, Berge suadaab, Shatur farasi, Gule babuna, Akleelul Mulk, Podina Khusk, Tokhme sabat, Marzan josh and Tukhme karafs (9 gm each) boiled with 1 liter water and added with 20 liter of hot water.

- Leeching: Leeching of upper part of the thigh.

- Zimad (paste): Tukhme sabat, Satar farasi, Murmakki, Qust talk, Measaila, Tukhme karafs, and Shahme hanzal (6 gm each) should be grinded with green Makoh and added with castor oil (12 gm) to make paste. Luke warm paste should be applied on the lower abdomen.

- Humool (pressary): Mur (6 gm), Soddaab (6 gm) and Raziana (6 gm) should be mixed and grinded to use the fine powder with honey as pressary before 3 days of the expected date of menstrual cycles.

- Hijama (dry cupping) over the umbilicus removes the blood and fluid from the site of inflammation to give relief from the menstrual pain.

- Heat Application: Apply heat to external genitalia or abdomen by burning of concoction of wine, fennel (a perennial plant of the genus Feniculum) and rose oil. Other method for applying heat on lower abdomen includes hot compress, heating pads and hot water bottles.

- Dalak (massage): Massage on lower abdomen with aromatic oil as gives relief from pain of dysmenorrhea. [11, 14, 16, 25, 27].

11. Herbal Drugs Effective in Dysmenorrhea

Abhal (Juniprus communis linn.), Asarun (Asarum Europaeum linn.), Sonf (Pimpinella anism linn.), Asgand (Withania somnifera Dunal), Amaltas (Cassia fistula linn.), Annanas (Bromeliacace), Elva (Aloe barbadensis Mill), Babuna (Matricaria chamomilla linn.), Bakain (Melia azedarach linn.), Bandal (Luffa echinata Roxb), Parshioshan (Adiantum capilus veneris linn.), Podina (Mentha arvensis linn.), Khare khask (Tribulus terretris linn), Hulba (Trigonella foenum graecum linn), Hilteet (Ferula foetida Regel), Kalonji black seed (Nigella sativa linn.), Mushtar Mashi (Menthas pulegium linn.), Neem (Azadirachata indica A. Juss), Darchini (Cinnamomum zeylanicum Blume), Qust (Saussurea lappa) and Ginger (Zingiber officinale Rose) etc.

12. Unani Pharmacopoeial Formulation Used In Management of Usre Tams

(i) Sharbat Bazoori Motadil
(ii) Qurs Kafoor
(iii) Habbe Mudire Haiz
(iv) Habbe Rewand
(v) Safoof-e-Mudire Haiz
(vi) Dawa Mudire Haiz
(vii) Dawae Ussurttams
(viiii) Dawae Mudir
(ix) Kushta Sadaf

13. Conclusion

Dysmenorrhea is a common gynecological disorder in women of reproductive age and it refers to painful menstruation. Because of the known side effects of the conventional medicines and the long history of the effectiveness of unani drugs and its compound formulations in treatment of usre tams, the unani system of medicine can be good alternative to treat the disorders such as dysmenorrhea because the unani drugs have no side effect on the human body. It is need of time to maximize and generalized this line of treatment for dysmenorrhea. The article focuses on diagnosis and management of dysmenorrhea by using herbs and unani formulations because it is devoid of any side effect on the human body.

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Research Article **Open Access**

The Clinical Study on the Management of *Sthula Madhumeha* by Herbal Drugs

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Abstract *Ayurveda* originated along with nature for the management of health and diseases of the human beings. *Ayurveda* described *Dincharya* and *Rutucharya* to maintain health, ultimately first aim of *Ayurveda*. But at present due to several causes' people does, not follow that type of lifestyle, in proper way which leads to several life threatening problems, IHD, Cardiac problems, Kidney diseases, HTN and other. *Sthula Madhumeha* (Obesity induced DM) is one of them. Now days, proportion of *Sthula Madhumeha* (Obesity induced DM) increases very rapidly with various complications which is very hazardous to human creatures and leading to death in many situations. But no satisfactory management up till now is available for *Sthula Madhumeha* (Obesity induced DM) though several research works carried out. Keeping, this view into mind, '*Apatarpana- Chikitsa'* is given to the patients under clinical study. For that *Kadar* (acacia sumo) *Sara*, *Khadir* (Acacia catechu) *Churna* and *Pugphala* (Acacia Arabica) *churna* were taken for research work, which was described by *Chakradatta*. Clinical study entitled as "The clinical study on the management of *Sthula Madhumeha* by herbal drugs". The enrollment number of the study is NU/A5/9210 on 17/03/2005. The study was done in Government Ayurved College and hospital as dissertations in department of Kayachikitsa.
Keywords *Sthula Madhumeha; Kadar, Khadir; Pugphala; Apatarpana*

1. Introduction

Ayurveda originated along with nature for the management of health and diseases of the human beings. *Ayurveda* described *Dincharya* and *Rutucharya* to maintain health, ultimately first aim of *Ayurveda*. But at present due to several causes' people does, not follow that type of lifestyle, in proper way which leads to several life threatening problems, IHD, Cardiac problems Kidney diseases, HTN and other, *Sthula Madhumeha* (~Obesity induced DM) is one of them.

Diabetes mellitus is a syndrome characterized by chronic hyperglycemia that is due to relative insulin deficiency or resistance or both [1]. The number of people with DM increase with the age of the population, ranging from an incidence of 1.5% in individuals from 20 to 39 years to 20% of individuals

>75 years. The incidence of DM is similar in men and women throughout age ranges but is slightly greater in men > 60 years [2].

Now days, proportion of *Sthula Madhumeha* (~Obesity induced DM) increases very rapidly with various complications which is very hazardous to human creatures and leading to death in many situations. But no satisfactory management up till now is available for *Sthula Madhumeha* (~Obesity induced DM) though several research works carried out. Keeping, this view into mind, '*Apatarpana-Chikitsa* [3]*'* is given to the patients under clinical study. For that *Kadar* (acacia sumo) *Sara*, *Khadir* (Acacia catechu) *Churna* and *Pugphala* (Acacia Arabica) *churna* were taken for research work, which was described by *Chakradatta* [4]. Clinical study entitled as "The clinical study on the management of *Sthula Madhumeha* by herbal drugs". The study was done in Government Ayurved hospital, as dissertations from 2005 to 2008.

1.1. Aims and Objectives

Aims and objectives of this study were pinpointed as follows.

a) To evaluate the *Dosha-Dushya Sammurchhana* of *Sthula Madhumeha* (~Obesity induced DM) with relation to *Samprapti*.
b) To evaluate the effect of '*Kadaradi* herbal compound' in *Sthula Madhumeha* (~Obesity induced DM).
c) To compare the effect of '*Kadaradi* herbal compound' with Metformin.
d) To evaluate the effect of drug on Blood sugar level and Lipid profile.
e) To evaluate the effect of drug on Physical Characters such as weight of body, Body mass index, circumference of chest, abdomen, waist, hip and hip to waist ratio.
f) To evaluate the effect of drug on urine and urine sugar.
g) To review the past and present literary work of *Madhumeha*.

2. Materials and Methods

60 patients suffering from *Sthula Madhumeha* (~Obesity induced DM) were randomly selected irrespectively to age, sex, caste, religion, socio economical and educational status. All the patients were examined on the basis of special case paper for the dissertation. Necessary investigations were performed to rule out any other pathology. In treated group '*Kadaradi* compound' were given to the patients while Metformin given to control group patients of *Sthula Madhumeha*.

2.1. Criteria of Diagnosis

a) The patients were diagnosed on the basis of signs and symptoms of *Sthula Madhumeha* (~Obesity induced DM), which are described in *Ayurvedic* text as well as the symptoms like *Mukha Madhurya* (~sweetness of mouth), *Supti* (~Numbness), *Daha* (~burning sensation), *Avil Mutrata* (~ turbid urine), *Prabhuta Mutrata* (~ frequent micturition) [5].
b) Necessary investigations were carried out like BSL Fasting- Post meal, Lipid profile and BMI for confirmation of diagnosis and in doubtful cases to rule out other systemic disease.

2.2. Criteria of Selection

The patients complaining signs and symptoms which are described earlier and fulfilling the criteria of diagnosis were selected for study.

2.3. Criteria of Rejection

The patients who had post meal blood sugar level more than 350 mg/dl and Body mass index less than 25 and who bears fatal complication were also rejected for clinical study.

2.4. Groups of Management

All the 60 patients, diagnosed with the help of criteria of diagnosis were randomly categorized into two groups. 30 patients in the treated group were given to “capsules of *Kadaradi* herbal drugs orally along with Luke warm water before meal twice in a day for 6 weeks, while in control group 500 mg Metformin BD given to the patients before meal [6].

2.5. Criteria of Assessment

Patients assessed after complete therapy in connexion to following points.

a) Effect of *Kadaradi* compound drugs and Metformin on symptoms and signs of patients of *Sthula Madhumeha* (~Obesity induced DM).
b) Effect of therapy on quantity and specific gravity of Urine and Urine Sugar.
c) Effect of therapy on fasting and post meal blood sugar level.
d) Effect of therapy on cholesterol level and lipid profiles.
e) Effect of therapy on body mass index, abdominal circumference, waist circumference, hip waist ratio.

2.6. Effect on Symptoms Score

Effect on symptoms of *Sthula Madhumeha* (~Obesity induced DM) evaluated with the help of scoring system. This scoring system was described by Thatere A. (2004) in his P.G. Thesis.

The general symptoms score system adopted for the statistical analysis was as follows –

a) Two marks were allotted each symptom present before the treatment.
b) One mark was allotted to each of the symptom, which reduced remarkably often the treatment.
c) Complete relief in the symptoms was taken zero mark.
d) No improvement in symptoms after completion of therapy considered as two marks.

The same symptoms score used for *Dosha* and *Dhatu dusti lakshanas*.

The important parameters used in this study were evaluated as follows.

[A]. Weight

Weight measure of the patient before treatment every follow-up change in weight noted then the after therapy weight measure three times successively and calculated.

[B]. Body-Mass index [7]

Body mass index calculated before and after by following formulae.

BMI = Weight in kg / (Height in meter) [2]

[C]. Circumferences Hip, Waist, Abdomen, Chest, Hip-Waist Ratio

Measurements of these parameters are as same as weight measurement method. Hip measurement was taken at the level of greater trochanter and waist measurement was taken from anterior-superior iliac spine, then Hip waist ratio calculated for *Sthulata* (~obesity) of patient. In same manner chest measurement was taken from at the nipple level and abdomen measured at navicular region.

[D]. Blood Pressure

Blood pressure measured before and after treatment. It is also measured in every follow-up by auscultatory method with sphygmomanometer.

[E]. Urine Examination

(a) Urine Quantity

The patients, twenty four hour urine collection measure in liters; before and after treatment. In between this period 24 hours urine collection from 8.00 am to 8.00 am measured at every successive follow up. Finally mean of urine quantity calculated for accuracy.

(b) Specific Gravity

Specific gravity measured with urinometer before and after treatment.

(c) Urine Sugar

Urine Sugar investigated as post meal before and after therapy by strip method.

[F]. Laboratory Investigations

Maintain record of all laboratory investigation such as Hemoglobin %, Total leucocyte count, Differential leucocyte count, erythrocyte sedimentation rate, fasting blood sugar, post prandial blood sugar, lipid profile. The changes in investigations were noted and maintain the record.

The overall effect of this therapy in both the groups was assumed according to synopsis of this study previously submitted to university for adjudication.

Total effect of therapy was assessed in terms of cured, markedly cure, improved, unchanged and LAMA i.e. left against medical advice.

a) **Cured**

Complete relief in the signs and symptoms along with certain physical and laboratory parameter and maintained the same condition for about long duration without medicine was considered as cured.

b) **Markedly Improved**

The signs and symptoms of *Sthula Madhumeha* (~Obesity induced DM) relived in between 50% to 75% along with improved physical and biochemical change was considered as markedly improve.

c) **Improved**

Signs and symptoms of Sthula *Madhumeha* (~Obesity induced DM) relived between, 25% to 50% was considered as improved.

d) **Unchanged**

The signs and symptoms of *Sthula Madhumeha* (~Obesity induced DM) relieved below 25% and proved by laboratorial investigations was considered in unchanged category.

e) **LAMA**

The patient of *Sthula Madhumeha* (~Obesity induced DM) who left the treatment in between without consultation or against medical advice due to some unavoidable circumstances was included in this group. They termed as leave against Medical advice.

3. Observation and Results

Table 1: *Showing Incidence of Clinical Features in 60 Patients of Sthula Madhumeha*

S.N.	Clinical Features	Total No. of Patients	Percentage of
1	*Mukha Madhurya*(~sweetness in mouth)	56	93.33%
2	*Supti*(~numbness)	49	81.67%
3	*Daha*(~burning sensation)	55	91.67%
4	*Trishnadhikya*(~polydipsia)	57	95%
5	*Alasya*(~laziness)	57	95%
6	*Maladhikya*	42	70%
7	*Nidradhikya*(~excessive sleep)	58	96.67%
8	*Tandra*	51	85%
9	*Mutradhikya*(polyuria)	60	100%
10	*Avil-mutrata*	60	100%
11	*Kshudhadhikya*(polypepsia)	60	100%
12	*Medadhikya*(excessive fat)	59	96.67%
13	*Anutsaha*	50	83.33%
14	*Sakashta-Maithuna*(~difficulty in intercourse)	34	56.67%
15	*Durbalata*(~weakness)	51	85%
16	*Durgandhirharir*(~bad odour)	50	53.33%
17	*Svedadhikya*(~excessive sweat)	57	95%

Table 2: *Showing Effect of Herbal Drug on Symptom Score in 60 Patients of Sthula Madhumeha*

S.N.	Symptom	Groups	Symptoms Score			Percentage
			B.T.	A.T.	Diff.	
1	*Mukha Madhurya*(~sweetness in mouth) *Supti*(~numbness)	Treated Group	56	14	42	75%
		Controled Group	39	13	26	66.66%
2	*Daha*(~burning sensation) *Trishnadhikya*(~polydipsia)	Treated Group	54	09	45	83.33%
		Controled Group	35	10	25	71.42%
3	*Alasya*(~laziness) *Maladhikya*	Treated Group	34	10	44	81.48%
		Controled Group	40	10	30	75%
4	*Nidradhikya*(~excessive sleep) *Tandra*	Treated Group	58	20	38	65.51%
		Controled Group	46	19	27	58.69%
5	*Mutradhikya*(polyuria) *Avil-mutrata*	Treated Group	51	11	40	78.43%
		Controled Group	44	17	27	61.36%
6	*Kshudhadhikya*(polypepsia) *Medadhikya*(excessive fat)	Treated Group	30	08	22	73.33%
		Controled Group	33	13	20	60.00%
7	*Anutsaha* *Sakashta-Maithuna*(~difficulty in intercourse)	Treated Group	48	08	40	83.33%
		Controled Group	40	12	28	70%
8	*Durbalata*(~weakness) *Durgandhirharir*(~bad odour)	Treated Group	47	09	38	80.85%
		Controled Group	39	11	28	71.79%
9	*Svedadhikya*(~excessive sweat) *Mukha Madhurya*(~sweetness in mouth)	Treated Group	59	20	39	66.10%
		Controled Group	41	12	29	70.73%
10	*Supti*(~numbness) *Daha*(~burning sensation)	Treated Group	60	16	44	73.33%
		Controled Group	44	15	29	65.90%
11	*Trishnadhikya*(~polydipsia) *Alasya*(~laziness)	Treated Group	55	17	38	69.09%
		Controled Group	41	10	31	75.60%
12	*Maladhikya* *Nidradhikya*(~excessive sleep)	Treated Group	54	13	41	75.92%
		Controled Group	43	13	30	69.76%
13	*Tandra* *Mutradhikya*(polyuria)	Treated Group	47	12	35	74.46%
		Controled Group	32	06	26	81.25%
14	*Avil-mutrata* *Kshudhadhikya*(polypepsia)	Treated Group	05	02	03	60%
		Controled Group	07	05	02	71.14%
15	*Medadhikya*(excessive fat) *Anutsaha*	Treated Group	51	15	36	70.58%
		Controled Group	32	12	20	62.5%
16	*Sakashta-Maithuna*(~difficulty in intercourse) *Durbalata*(~weakness)	Treated Group	51	12	39	76.49%
		Controled Group	33	09	24	72.72%
17	*Durgandhirharir*(~bad odour)	Treated Group	55	16	39	70.90%
		Controled Group	36	09	27	75%

Table 3: *Showing Effect of Therapy on Certain Parameters of 60 Patients of Sthula Madhumeha*

S.N	Parameters	Group	Mean ± SD		Diff. of Mean ± SD	SEd	T	p
			BT	AT				
1.	Weight in Kg.	T.C.	77.17 ± 14.67	73.7±14.66	3.47±1.7	0.31	11.19	<0.001
		C.G.	69.2±10.91	66.4±10.50	2.8±0.96	0.176	5.45	<0.001
2.	B.M.I. in Kg/m2	T.C.	28.17±3.15	26.70±3.05	1.47±1.11	0.20	7.15	<0.001
		C.G.	28.744±2.54	27.54±2.45	1.204±0.418	0.076	15.76	<0.001
3.	Hip Circumference in cm	T.C.	99.3±6.44	96.97±5.94	2.33±1.30	0.24	9.71	<0.001
		C.G.	97.17±1.95	95.7±2.12	1.47±0.504	0.92	15.57	<0.001
4.	Waist. Circumference in Cm	T.C.	96.33±6.01	95.56±5.99	0.77±0.95	0.173	10.57	<0.001
		C.G.	96.1±1.94	95.06±2.21	1.04±0.96	0.175	5.88	<0.001
5.	Abdominal Circumference in Cm	T.C.	96.7±7.071	95.33±6.87	1.33±0.844	0.154	8.63	<0.001
		C.G.	95.03±2.89	94.43±2.47	0.6±0.72	0.132	4.54	<0.001
6.	Chest Circumference	T.C.	87.23±5.34	86.97±5.03	0.26±0.45	0.082	3.17	<0.001

	in Cm	C.G.	86.43±2.76	86.17±2.72	0.26±0.149	0.082	3.24	<0.001
7.	Hip to waist ratio	T.C.	0.019±0.018	1.01±0.016	0.09±0.014	0.0026	5	<0.001
		C.G.	1.010±0.0098	1.006±0.0084	0.004±000766	0.00141	5.43	<0.001
8.	Systolic B.P. in mm/Hg.	T.C.	143.33±10.93	134.67±12.24	8.66±6.83	1.25	7.52	<0.001
		C.G.	140±8.70	133±7.02	7±6.51	1.190	5.88	<0.001
9.	Diastolic B.P. mm/Hg	T.C.	87.67±10.40	80.66±8.27	7.01±7.59	1.39	6.47	<0.001
		C.G.	92.67+6.91	83±7.94	9.67±8.50	1.55	6.23	<0.001

Table 4: *Showing Effect of Therapy on Lipid Profiles of 60 Patients of Sthula Madhumeha by Paired't' Test*

S.N	Parameters	Group	Mean ± SD		Diff. of Mean ± SD	SEd	t	P
			BT	AT				
1.	Total Cholesterol in Units Mg/dl	Treated	187.5 ± 49.77	158.23±41.05	29.27±38.51	7.040	4.78	<0.001
		Control	195.10±64.16	156.09±31.03	39.01±61.14	11.17	4.53	<0.001
2.	High density Lipoprotein in mg/dl	Treated	46.44±12	43.80±12.24	2.64±18.04	3.298	0.998	>0.1
		Control	40.75±8.97	41.14±9.57	-0.39±12.75	2.33	0.33	>0.1
3.	Low density Lipoproteins	Treated	118.83±51.55	88.47±31.06	30.36±40.17	7.34	5.21	<0.001
		Control	121.6+60.44	94.95+29.44	26.65+54.31	9.92	4.39	<0.001
4.	Serum Triglycerides mg/dl	Treated	194.4+252.42	150.86+141.66	43.54+153.87	28.13	2.32	<0.02
		Control	148.87+67.37	131.30+50.54	17.57+53.81	9.83	3.82	<0.001

Table 5: *Showing Effect of Therapy on Urine Examination of 60 Patients of Sthula Madhumeha, by Paired't' Test*

S.N	Parameters	Group	Mean ± SD		Diff. of Mean ± SD	SEd	t	p
			BT	AT				
1.	Quantity in Ltrs	Treated	2.13 ± 0.307	1.65±0.247	0.48±0.224	0.0409	11.49	<0.001
		Control	2.03±0.215	16.3±0.269	0.4±0.237	0.0434	9.21	<0.001
2.	Specific gravity	Treated	1.026± 0.004412	1.02±0.0331	0.001± 0.00322	0.00588	11.105	<0.001
		Control	1.019±0.002395	1.015± 0.00188	0.004± 0.00237	0.000433	9.37	<0.001

Table 6: *Showing Effect of Therapy on Blood Sugar Level In 60 Patients of Sthula Madhumeha, by Paired't' Test*

S.N	Blood Sugar Level	Group	Mean ± SD		Diff. of Mean ± SD	SEd	t	P
			BT	AT				
1.	Fasting blood sugar level in mg/dl	Treated	168.5 ± 20.78	131.56±33.90	36.34±24.38	4.46	8.90	<0.001
		Control	142.61±12.73	103.57±10.55	39.04±13.94	25.48	1.613	>0.1
2.	Post meal blood sugar level in mg/dl	Treated	221.46± 42.40	180.4±25.53	41.06± 48.66	8.89	4.91	<0.001
		Control	236.02±52.91	164.11± 16.40	71.91± 52.95	9.68	7.42	<0.001

Table 7: *Showing Total Effect of Therapy on 60 Patients of Sthula Madhumeha*

S.N.	Total Effect of Therapy	Group of Treatment	Total No. of Patients	Percentage
1	Cured	Treated	00	00
		Control	00	00
2	Markedly improved	Treated	26	86.66%
		Control	24	80%
3	Improved	Treated	04	13.33%
		Control	06	20%
4	Unchanged	Treated	00	00
		Control	00	00
5	LAMA	Treated	00	00
		Control	00	00

4. Discussion

The effect of Therapy was assessed mainly on clinical features. Randomly selected 60 patients of *Sthula Madhumeha* (~Obesity induced DM) including both groups analyzed statistically in the following manner.

4.1. Effect of Therapy

Observing the Table (1) to (5) it was conclude that *Kadaradi* compound drug has very positive result on *Medadhatu*. Statistical analysis also showed that significant reduction in weight, hip to waist ratio. (Table 3) Total cholesterol, Low density lipoprotein and Serum Triglycerides were also reduced significantly – (Table 4)

4.2. Total Effect of Therapy

Table (7) show more patients markedly improved in treated group than control group. While more patients improved in control group than treated group.

5. Conclusion

[A]. The Statistical study shows reduction in Meda Dhatu, which indicated important role in the manifestation of *Sthula Madhumeha* (~Obesity induced DM).
[B]. Significant reduction shows in Weight, Hip-Waist ratio and circumference of Abdomen, Hip and Waist.
[C]. Reduction found in total cholesterol, Serum Triglycerides, Low density lipoproteins were also observed.
[D]. Maximum *Kapha Vridhi Lakshanas* reduced while positive effect on *Rasa Dushti, Majja Dusti*, and *Meda Dhatu dusti* also observed.
[E]. More patients markedly improved in treated group rather than control group, which indicates efficacy of *Kadaradi* compound drugs in *Sthula Madhumeha* (~Obesity induced DM).

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Efficacy of an Unani Formulation in Reducing Post Inflammatory Acne Hyperpigmentation Marks- A Clinical Study

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Abstract There is no single malady which causes supplementary psychic disturbance and more general insecurity and feeling of inferiority than acne vulgaris with post inflammatory acne pigmentation marks does. It is strongly associated with depression and anxiety. In addition to individuals with little objective evidence acne with post inflammatory acne hyperpigmentation marks may endure severe subjective impairment, greatly affecting their health related quality of life. Unani System of Medicine contains treatise of basic and compound formulations that can be administered orally and locally in improving post inflammatory acne hyperpigmentation marks. To evaluate the efficacy of a poly herbal Unani formulation in improving post inflammatory acne hyperpigmentation marks. The study was observational self-comparison before and after treatment on 32 female patients. The separate powders of drugs; *Shūnīz*, *Būra Armanī*, *Naushādar* sieved and mixed with *Sirka* (vinegar) and prepared a Unani formulation and were applied topically. All the patients were assessed for change in pigmentation marks of face by using "Visual arbitrary scale for acne hyperpigmentation marks". In present study out of 32 acne patients 20 (62.5%) reported decrease in acne hyperpigmentation marks. The effect of drug was significant ($p<0.01$) statistically and clinically both. In the present study it was concluded that the used Unani formulation was much effective in improving post inflammatory acne hyperpigmentation marks.
Keywords *Post Inflammatory Acne Hyperpigmentation Marks; Unani System of Medicine; ShūNīz; Būra Armanī; Naushādar; Unani formulation*

1. Introduction

In acne vulgaris, without therapeutic intrusion, small papules and pustules, even with mild squeezing and picking generally heal within 1-2 weeks [1]. But inflammatory lesions like large papules, pustules and cysts that have been traumatized often heal with altered pigmentation, while remaining scarring may not develop [1, 2]. Post inflammatory hypopigmentation and hyperpigmentation [3] are more apparent in those with brown or swarthy skin, and without therapy take months to one year to resolve [1].

Shūnīz (Nigella sativa), *Būra Armanī* and *Naushādar* all have *jāli* (detergent) effect due to which they resolve post inflammatory acne hyperpigmentation marks [4, 5, 6]. *Sirka* due to its volatility possess quickly infusible property, so it is mixed with *ḍimad* (paste), face pack and massage oil [7, 8].

2. Methods

This study was observational self-comparison before and after treatment, conducted in OPD of hospital of the National Institute of Unani Medicine, Bangalore. Duration of this study was one year. 32 female acne patients with post inflammatory acne hyperpigmentation marks, of age group 15-26 were included in this study. The drugs *Shūnīz* (Nigella sativa), *Būra Armanī, Naushādar* (ammonium chloride) in equal amount were pulverized and sieved through 80 number filter and mixed with sirka (vinegar) to make a Unani formulation, were applied topically for one month, on whole face, daily at night for initial 15 days then on every second day for another 15 days, paste was kept overnight and then washed with luke warm water in morning. Patients were advised to avoid application of paste on eyes, ears, nostrils etc. Patients were assessed on a four point "Visual arbitrary scale for acne hyperpigmentation marks", which consists of grades 6, 4, 2, 0 (Table 1). All the subjects were assessed fortnightly.

Table 1: *Visual Arbitrary Scale for Acne Hyperpigmentation Marks*

Severity	Grade Description
0	Few small pigmentation marks, scattered and lighter in appearance
2	10-12 pigmentation marks, scattered and darker than grade 0
4	Between grade 2 and 6, marks are darker and more in diameter, worthy of treatment
6	Loaded with pigmentation marks on whole face, diameter is between 1-2 cm. and can be easily recognized by 2.5 meter distance

3. Results

In the present study out of 32 patients 20(62.5%) reported improvement in acne hyperpigmentation marks and 12(37.5%) did not (Table 2). ANOVA repeated measure was applied for statistical analysis and the significance was seen at ($p<0.01$). The effect of Unani formulation was significant clinically and statistically.

Table 2: *Distribution of Patients according to Change in Hyperpigmentation Marks Post Treatment*

Pigmentation Marks	No. of Patients (n=32)	Percentage (%)
Reduced	20	62.5
No effect	12	37.5
Total	**32**	**100**

In the present study on 0th day 6 patients were in grade 6; 15 patients were in grade 4; 11 patients were in grade 2.

On 15th day 2 patients were in grade 6; 9 patients were in grade 4; 18 patients were in grade 2 and 3 patients were in grade 0.

On 30th day 2 patients were in grade 6; 5 patients were in grade 4; 15 patients were in grade 2 and 10 patients were in grade 0 (Table 3).

Table 3: *Effect of Unani Formulation According to Grades of Visual Arbitrary Scale for Acne Hyperpigmentation Marks*

Grades	Visual Arbitrary Scale for Acne Marks					
	0th day		15th day		30th day	
	No. of patients	Percentage (%)	No. of patients	Percentage (%)	No. of patients	Percentage (%)
6	6	18.75	2	6.25	2	6.25
4	15	46.8	9	28	5	15.6
2	11	34.3	18	56.2	15	46.8
0	0	0	3	9.3	10	31,25
Total	**32**	**100**	**32**	**100**	**32**	**100**

4. Discussion

In the present study 20(62.5%) patients reported improvement in post inflammatory acne hyperpigmentation marks ($p<0.01$) (Table 1). In other study Humyra et al.; by using *ḍimād muhāsa* reported improvement in postinflammatory hyperpigmentation ($P<0.001$) [9]. This is due to the *jāli* effect of *Shūnīz*, *Būra Armanī*, *Naushādar* and *Sirka*. *Najmul Ghani* mentioned that locally *Būra Armanī* reduces blue spot; it also eliminates *ghalīẓ khilṭ* (viscous humors) [7]. According to Kabīruddin, *Būra Armanī* produces a strong detergent effect [6]. According to *Ibne Baitar*, *Naushādar* removes *mādda* (matter) from deep part of skin, so it provides *jilā* to skin [5]. According to *Jālīnūs*, *Shūnīz* is very beneficial where *jilā* (cleaning) is required [4]. *Najmul Ghani* mentioned *sirka* sorts out *ghalīẓ khilṭ* [7].

5. Conclusion

The present Unani formulation has both clinically and statistically significant effect in reducing post inflammatory acne hyperpigmentation marks. To enhance precision level large sample size study should be conducted.

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Research Article | Open Access

Trends of Cerebral Palsy in Rajasthan, India

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Abstract The aim of this study was to determine the incidence of etiological factor and clinical features of children with cerebral palsy (CP) in Rajasthan. Five dissertations done in the Post Graduate Department of Pediatrics Ay., National Institute of Ayurveda, Jaipur with diagnosed case of spastic CP, from year 2010 to 2014 were included in the study. Age, sex, etiological factors, clinical classifications, and epidemiological characteristics as well as the problems associated with CP were analysed in all children. Of the total of 240 children male: female prevalence comes out to be 2.3:1. The most common etiologic risk factors were birth asphyxia and low birth weight in perinatal period; HIE, Respiratory distress syndrome and neonatal convulsions in the postnatal period. In clinical classification it was seen that maximum subjects 52.92% were found to be Diplegic followed by 27.50% cases were Quadriplegic in nature, 12.50% cases were found to have Hemiplegic pattern. Drooling of saliva was the most common associated problem. Study has found perinatal asphyxia as major cause of cerebral palsy and Diplegia as major presentation of CP in Rajasthan. The studies can help in further planning for reduction in incidence of CP in Rajasthan.
Keywords *Cerebral Palsy Rajasthan; Jaipur; India*

1. Introduction

Cerebral palsy (CP) describes a group of permanent disorder of the development of movement and Posture causing activity limitation that are attributed to non-progressive disturbances that occurring in the developing foetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, perception, cognition, communication, behaviour, epilepsy, and secondary musculoskeletal problems [1]. Different studies have shown different incidence of spastic cerebral palsy. Having knowledge about epidemiologic characteristics of the disease, will be beneficial in terms of both treatment and prevention. The present study is selected to in order to review the trends of cerebral palsy present in Rajasthan state of India and its association with various etiological factors.

1.1. Need of Study

CP worldwide incidence is 2 to 2.5 per 1000 live births while in India it is 2-4 per 1000 live birth [2]. Cerebral palsy is still one of the major challenge with no complete management so far. In the recent years with the advent of more advanced neonatal resuscitation, increased maternal age etc. have

caused an increase in the incidence of cerebral palsy and its major etiological factors and incidence of associated problems varies in different part of the world hence study need to be done to evaluate incidences of CP area wise to understand the exact trend of CP at different part of world.

1.2. Aim and Objectives

Following study is done to review trends of cerebral palsy in Rajasthan state of India in order to establish the major etiological factors and risk factors prevalent in the state causing cerebral palsy.

2. Materials and Methods

All the children with Spastic cerebral palsy who attended OPD and IPD of PG Department of Pediatrics Ay., National Institute of Ayurveda, from 2010 to 2014, have been enrolled under departmental dissertation each year, all the incidence and prevalence were recorded in the dissertation strictly following the norms of the Institute. For the present study five research works [3-7] have been selected in order to analyze all the children of spastic cerebral palsy since 2010 to 2014 who attended institutes OPD and IPD. As children attending NIA OPD and IPD are equally from all over Rajasthan hence the study is limited to the state. The study was done to evaluate the trends of cerebral palsy prevalent in Rajasthan.

3. Results

Etiological factors have been evaluated for all children and properly recorded. The factors studied are sex, consanguinity, mother's age of conception, antenatal care of mother, birth order of child, mode of delivery, place of delivery, status of fetus presentation, Birth maturity of newborn, Birth weight, History of birth asphyxia have been evaluated (Table 1).

Table 1: *Showing Trends of Etiological Factors of Cerebral Palsy among 240 Children Screened in the Study during Year 2010 To 2014*

S. No.	Etiological Factors		Prevalence (n=240)
1.	Sex	Male	165 (68.75%)
		Female	75 (31.25%)
2.	Consanguinity	Present	212 (88.33%)
		Absent	28 (11.67%)
3.	Mothers Age of Conception	Appropriate age (20 to 35 years)	197 (82.08%)
		Late age (>35 years)	23 (9.58%)
		Early age (<20 years)	20 (8.33%)
4.	ANC Checkup	Proper	190 (79.16%)
		Improper	50 (20.84%)
5.	Birth Order	1st Child	139 (57.91%)
		2nd Child	72 (30.00%)
		3rd and above	29 (12.09%)
6.	Mode of delivery	Normal (SVD)	199 (82.91%)
		LSCS	23 (9.58%)
		Instrument aided	8 (3.33%)
7.	Place of delivery	Hospital	194 (80.83%)
		Home	43 (17.91%)
		Other	3 (1.25%)
8.	Fetal presentation	Vertex	208 (86.67%)
		Breech	20 (8.33%)
		Unknown	12 (5.00%)

9.	Birth maturity	Full-term	165 (68.75%)
		Pre-term	70 (29.17%)
		Post-term	5 (2.08%)
10.	Birth Weight	Normal	120 (50.00%)
		LBW	75 (31.25%)
		VLBW	20 (8.33%)
		ELBW	3 (1.25%)
		Over weight	9 (3.75%)
		Not known	13 (5.42%)
11.	Birth Asphyxia	Present	127 (52.91%)
		Absent	68 (28.33%)
		Not known	45 (18.75%)

Abv: ANC: Ante Natal Care; SVD: Spontaneous Vaginal Delivery; LSCS: Lower Segment Cesarean Section; LBW: Low Birth Weight; VLBW: Very Low Birth Weight; ELBW: Extremely Low Birth Weight

Apart from these major etiological factors were studied after categorizing them as antenatal factor, Perinatal Factors and postnatal factors (Table 2).

Table 2: *List of Various Etiological Factors Causing Cerebral Palsy (CP) and their Incidence among Children Evaluated Under Study*

Etiological Factors	Total Number of Cases	Percentage n=240
Antenatal Factors		
Hyperemesis	4	1.67%
Eclampsia	8	3.33%
Twins	9	3.75%
Hypothyroidism	5	2.08%
APH	4	1.67%
UTI	4	1.67%
HTN	5	2.08%
Placenta Previa	2	0.83%
Jaundice	6	2.50%
TORCH Infection	17	7.08%
Diabetes	8	3.33%
Fever	6	2.50%
Cervical Incompetence	3	1.25%
Other	5	2.08%
Perinatal Factors		
Prolonged 2nd Stage	57	23.75%
Meconium Stained Liquor	34	14.16%
Cord Prolapse	13	5.42%
Fetal Distress	77	32.08%
L.S.C.S.	23	9.58%
Pre Maturity	70	29.17%
Post Maturity	5	2%
L.B.W.	98	40.83%
Instrumental Delivery	8	3.33%
Breech	20	8.33%
Birth Asphyxia	127	52.91%
Postnatal Factors		
Sepsis	30	12.50%
HIE	87	36.25%
Seizures	45	18.75%
Hyper Bilirubinemia	37	15.42%

N.E.C.	8	3.33%
R.D.S	59	24.58%
Intracranial Hemorrhage	12	5.00%

Abv: APH: Antepartum hemorrhage; UTI: Urinary Tract Infection; HTN: Hypertension; TORCH: Toxoplasma Others Rubella Cytomegalovirus Herpes; LSCS: Lower Segment Cesarean Section; LBW: Low Birth Weight; HIE: Hypoxic Ischemic Encephalopathy; NEC: Necrotizing Enterocolitis; RDS: Respiratory Distress Syndrome

Major associated problems with CP have been evaluated; in the study maximum children were found to have drooling of saliva as major associated complaint followed by many other problems enlisted in table (Table 3).

Table 3: *List of Major Associated Problems with Cerebral Palsy*

Symptoms	Number of Cases	Percentage n=240
Speech	112	46.67%
Hearing	12	5.00%
Drooling	129	53.75%
Eye problems	94	39.17%
Feeding	109	45.42%
Mental Retardation	86	35.83%
Contractures	57	23.75%
Teething problem	82	34.17%
Constipation	66	27.50%
Malnutrition	72	30.00%
Sleep disturbance	87	36.25%
Seizure	46	19.17%

4. Topographical Incidence of Spastic CP

Of the total registered cases of Spastic C.P. (n=240) the maximum number of children i.e. 127 (52.92%) were found to be Diplegic followed by 66 (27.50%) children Quadriplegic in nature, 30 (12.50%) cases were found to have Hemiplegic pattern, 14 (5.83%) cases were monoplegic and 4 (1.67%) cases were having double hemiplegia.

5. Discussion

In the present study the sex wise prevalence comes out to be 2.3:1. Latest data also shows that, the incidence is higher in males than in females. Consistent with these results, Johnson et al. (2002) reported [8] boy/girl ratio as 1.33 in Europe and Laisram et al. (1992) reported [9] as 1.9 in India. Thus showing male predominance of CP. Consanguineous marriage was absent in maximum cases. This may be due to the fact that maximum cases in the study were of non-Muslim community (there is a widely recognized culture of consanguinity within Muslim communities) [10]; however consanguineous marriage is now supposed to be one of the factors of congenital cerebral palsy. A study conducted in Saudi Arabia reported 2.5 fold increase in the occurrence of CP in consanguineous families [11]. Mother's age of Conception was appropriate in maximum cases. Fletcher N.A. et al. (1993) [12] reported low paternal age and extremes of maternal age to be significantly associated with CP. But such condition was not found in this study. Mothers of maximum children with C.P. were found to have proper ANC check-up. Signifying the increased awareness toward proper ANC checkup; a positive output of Government advertisement for promoting proper care during pregnancy.

Maximum number of incidence of CP was found in 1st Birth order. Another study also indicated first pregnancy was associated more with incidence of CP [13]. The incidence of prolonged labour and other perinatal complications are associated with first pregnancy.

Maximum numbers of children with CP were delivered normally, followed by LSCS. In India still maximum deliveries are occurring normally in spite of the availability of LSCS due to cost factor in LSCS and lack of proper facility in remote areas and less awareness of merits of LSCS in complicated delivery among majority of people. An Indian data by Singhi P. et al. (2002) shows [14] that out of the studied children 85% were of normal delivery, 9.95% were with caesarean delivery while 3.7% were with instrumental delivery.

Maximum numbers of Children were delivered at hospital followed by delivery at home. Though if we compare the percentage of delivery in hospital to home delivery the rate of occurrence of CP will be seen more in home deliveries. In a study Home birth were significantly more common in the mother of children with Cerebral Palsy. Delivery in a non-hospital setting places the infant at a risk of some of the suspected associations of CP such as birth asphyxia [15]. Maximum number of cases had vertex presentation. The above findings may be due to the fact that vertex is most common presentation in pregnancy however abnormal foetal presentation have strong connection with CP [16].

Maximum numbers of cases i.e. (68.75%) were born as full term, while (29.17%) Preterm babies were recorded. Nearly 40% of cases were having low birth weight (Including VLBW, ELBW). In Indian society lack of awareness about balanced diet and health supplements is the major culprit for high incidence of low birth weight babies. Low birth weight is associated with higher rates of cerebral palsy. Maximum number of cases had a positive history of birth asphyxia and many others were found with no clear history present of birth asphyxia which can be added on either side thus showing high incidence of birth asphyxia in present study. According to WHO, between four and nine million new-born develop birth asphyxia each year; of these, an estimated 1.2 million die and at least the same number develop severe consequences such as epilepsy, cerebral palsy and developmental delay [17]. But many other research have given antenatal cause as major etiology for developing cerebral Palsy and perinatal asphyxia accounts for between 6% and 8% of cerebral palsy [18]. Overly inclusive definitions were associated with high rates of attribution of CP to birth asphyxia. This explains the high incidence of Birth asphyxia in study. For determining the exact asphyxia etiology to CP, cases with known or probable non asphyxia etiologies such as brain malformations, death of a co-twin, or metabolic or neuromuscular disease should be excluded, and a generalized definition need to be laid for considering a particular case to be included as exclusive birth asphyxia or not.

Among antenatal causes all causes were having equal incidence thus no one disease can be attributed to its major antenatal cause. Though incidence of TORCH was found maximum with 7.08% incidence which may be considered as comparatively important disease causing CP, laying importance of spreading awareness for its prenatal screening to avoid this cause of CP.

Clinical classification categorizes CP as spastic (quadriparesic, diplegic, hemiplegic), hypotonic/ataxic, dyskinetic and mixt-type CP. The most common types are the spastic types in worldwide. However, the distribution of the clinical subtypes of spastic CP cases differed from the results of western countries. In our study, 52.92% of cases were spastic Diplegic and 27.50% were spastic quadriparesic. In another study Eriman et al. [19] evaluated 202 children with CP and they reported that 34% was spastic Diplegic and 32% was spastic quadriplegic. Though the incidence in India is different. In an analysis of 1000 cases of CP from India, it was found that spastic quadriplegia constituted 61% of cases followed by Diplegia 22% [20]. Whereas, in European countries spastic

Diplegia is seen in significantly higher rates. Studies reported the ratio of spastic quadriparetic CP as 18% - 20.8% and spastic Diplegic CP as 40.9% - 54.9% in European countries [21-22].

6. Conclusion

To conclude, it was observed that birth asphyxia was the leading risk factors in CP etiology. Though it may occur secondary to other perinatal etiology hence perinatal cause cannot be neglected either and the most common CP prevalent in Rajasthan is Diplegic CP. The studies can help in further planning for reduction in incidence of CP in Rajasthan.

- *What is already known and what this study adds:*

Available studies on cerebral palsy provide findings regarding the causative factors and presentation of the disease. Present study adds some new findings and supports the previous one so that these findings will help in future research related to Cerebral Palsy.

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Research Article | Open Access

Antioxidant Evaluation of *Romasanjanana Lepa*- A Compound Formulation for *Indralupta*

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Abstract Alopecia Areata (AA) is the common form of hair loss affecting the quality of life of many patients. In Ayurved, loss of hair is coined as '*Indralupta*' described in *Kshudra Rogas. Vata Pitta Kapha Dosha* along with the vitiation of *Rakta* is responsible for pathophysiology of *Indralupta* whereas, according to modern science, Alopecia areata is a tissue-restricted autoimmune disease. Therefore it is important to evaluate the role of antioxidant in the treatment. Ayurveda has advocated *Lepa* in *Indralupta*. Therefore a compound formulation consisting of leaf of *Karanja*, fruit of *Kapittha*, *Kasisa* and *Hastidant Mashi* was formulated following standard guideline. To evaluate the antioxidant activity in the compound formulation, it was subjected to Total phenolic content by Folin's reagent, Antioxidant by DPPH(1,1-diphenyl-2-picrylhydrazyl), Antioxidant by FRAP (ferric reducing antioxidant power), total flavonoid content, and assessment of phenolic compound by HPLC method on distilled water, methanolic and ethanolic extract of the formulation. Result of the study showed maximum Total phenolic content in distilled water extract, whereas total flavonoid was maximum in methanolic extract, Antioxidant by DPPH was maximum (85.24±0.30) in distilled water extract. Whereas by FRAP method, it was maximum (0.017±0.02) in methanolic extract. Total phenolic content was highest in ethanolic extract.
Keywords *Antioxidant; Indralupta; Romasanjanan Lepa*

1. Introduction

Alopecia is a chronic dermatological disorder in which people lose some or all of the hair on their head and sometimes on their body as well. It is a chronic inflammatory disease that affects the hair follicles. In Ayurvedic approach, loss of hair is coined out as in term of '*Indralupta*' under the broad heading of *Kshudra Rogas* [1]. Overdose of salt also cause *Indralupta* [2]. *Vata Pitta Doshas* vitiate the hair follicles and is followed by obstruction of the hair follicles with *Sleshma* and *Shonitha*, which restrict their re-growth [1]. Alopecia Areata (AA) is the common form of hair loss affecting the quality of life of many patients. Alopecia has many significant deleterious effects like social anxiety, increased self-consciousness, low – self-esteem embarrassment and depression impairing psychological well-

being thus affecting mental and social status of person [3]. The risk of allopathic treatment outweighs their benefits. The pathophysiology of AA has not been clearly defined; however, it appears as a tissue-restricted autoimmune disease mediated by T lymphocytes [4]. Therefore it is important to evaluate the role of antioxidant in the treatment of AA.

In Ayurveda, '*lepa*' (local application of medicine) has been advocated in *Indralupta'* (Alopecia) [5]. A compound formulation '*Romasanjana Lepa'* was formulated which consists of leaf of *Karanja*, fruit of *Kapittha*, *Kasisa* and *Hastidant Mashi*. Phytochemicals such as phenolics, terpenoids, anthocyanins and other flavonoids contributes antioxidant activities in plants. *Therefore, Romasanjana Lepa* was subjected to evaluate total phenolic content, total flavonoid content, Antioxidant by DPPH (1, 1-diphenyl-2-picrylhydrazyl), Antioxidant by FRAP (ferric reducing antioxidant power) and assessment of phenolic compound by HPLC method.

2. Materials and Methods

Compound formulation '*Romasanjana Lepa'* consists of leaf of *Karanja*, fruit of *Kapittha*, *Kasisa*, *Hastidant Mashi*. Tender leaves of *Bhringaraja* (*Eclipta alba* Linn. - Compositae) required for *Kasisa* (Ferrous Sulphate; $FeSO_4*7H_2O$) *Shodhana* (purification) and leaves of *Karanja* (*Pongamia glabra* Vent*;* Leguminaceae) were collected from the Dr. D.Y. Patil Ayurvedic Herbal Garden. *Kapittha* fruit *(Feronia elephantum* Linn*;* Rutaceae) and *Kasisa* (Ferrous Sulphate, $FeSO_4*7H_2O$) was purchased from the local herbal market. *Hastidanta Mashi* (Burnt *Mashi* of Ivory) was purchased from Dindayal Pharmacy. *Romasanjanan Lepa* was prepared following standard procedure of *Lepa* described in classical text of Ayurveda. First *Kasia* was purified with *Bhringaraja*. Equal quantity of *Shuddha Kasisa and Karanja Patra* was triturated in till *Kalka* (homogeneous mixture) formed. Then *Swarasa* (Fruit pulp juice) of ripen '*Kapittha'* was added to above *Kalka* and triturated well till it dried completely. *Hastidanta Mashi* was added to this dried powder. This powder was then stored in air tight container and named as '*Romasanjanana Lepa'*.

2.1. Extraction of Sample

Ten grams of each sample were suspended in 60 ml of different solvent systems viz; distilled water, methanol, and ethanol and kept overnight [6]. Then the extracts were filtered through muslin cloth and concentrated using rotary evaporator at 56˚C. Total phenolic content, Antioxidant by DPPH, Antioxidant by FRAP, total flavonoid content, and assessment of phenolic compound by HPLC method were carried out on compound formulation *Romasanjana Lepa*

2.2. Total Phenolic Content by Folin's Reagent

Folin-Ciocalteu reagent was used for the determination of total phenolic content (TPC) as per. 0.2 ml of the extract was mixed with 0.5 ml of Folin-Ciocalteu reagent and 2ml of 20% aqueous sodium carbonate. The mixtures were incubated for 15 min at room temperature. The absorbance was taken at 650 nm. Total phenolic values were expressed as mg/ml using tannic acid standard which is a common reference compound [7] [8].

2.3. DPPH (1, 1-diphenyl-2-picrylhydrazyl) Antioxidant Assay

The free radical scavenging activity was estimated using DPPH [9]. A solution of 0.3 mM DPPH in methanol was prepared and 2 ml of this solution was mixed with 1.9 ml of distilled water and 100µl of sample dissolved in methanol, ethanol and acetone respectively. The reaction mixture was incubated in dark at room temperature for 30min. The absorbance of the mixture was measured using

spectrophotometrically at 517nm. Readings were repeated in triplicates. The ability to scavenge DPPH radical was calculated using following formulae:

$$\% \text{ Inhibition} = \frac{\text{Absorbance of the Control – Absorbance of Sample}}{\text{Absorbance of Control}} \times 100$$

2.4. FRAP (Ferric Reducing Antioxidant Power) Antioxidant Assay

FRAP assay was carried out according to the method of Benzie and Strain (1996) [10]. FRAP reagent was prepared using acetate buffer (1.6 g sodium acetate and 8 ml acetic acid make up to 100ml) (pH 3.6), 10 mM TPTZ solution in 40 mM HCL and 20 mM iron (III) chloride solution in proportion of 10:1:1 (v/v) respectively. The FRAP reagent was prepared fresh daily and was warmed to 37ºC in oven prior to use. A total of 100µl samples extract were added to 3 ml of the FRAP reagent and mixed well. The absorbance was measured at 593 nm using spectrophotometer at 0 mins and after 4 mins. Samples were measured in three replicates. Standard curve of Ascorbic acid was prepared. FRAP reagent was used as a blank both for standard and samples.

FRAP value of sample was obtained using the formula

$$\% \text{ Inhibition} = \frac{\text{Change in Absorbance of Sample from 0 to 4 mins}}{\text{Change in Absorbance of Standard from 0 to 4 mins}} * 1000u$$

2.5. Total Flavonoids Content

Flavonoids were estimated using aluminium chloride solution in methanol. (Zhishen et al., 1999; Zou et al., 2004). The total flavonoids content was determined using a 2% aluminum chloride in methanol solution. The dealcoholized samples were diluted with distilled water in the ratio 1:5. 1.5 ml of diluted samples was taken to which 1.5 ml of $AlCl_3$ in methanol was added. The samples were then incubated for 10 minutes after which the absorbance was recorded at 368 nm using quercetin as standard. All readings were carried out in triplicates.

2.6. RP-HPLC (Reversed-Phase High Performance Liquid Chromatography) Methodology

Analysis of individual phenolic compound present in the different solvent extracts were performed on a Waters HPLC (Model 2487), using a hypersil C18 reversed phase column 15cm with 5µ particle size. A constant rate of 0.75ml/min was used with two mobile phases: (A) 25% methanol in 1% Acetic acid and solvent (B) 75% methanol in 1% Acetic acid. The elution gradient was linear starting with (A) and ending with (B) over 60 min, using an UV detector set at wavelength 280 nm. Phenolic compound from each sample were identified by comparing their relative retention time with the standards of mixture chromatogram. Standard phenolic compounds were obtained from Sigma (USA). The concentration of an individual compound was calculated on the basis of peak area measurements and then converted to ppm. All the chemicals and solvents used were HPLC spectral grade [11] [7].

3. Observation and Results

Table 1: *Estimation of Total Phenolic Content and Antioxidant Activity in Formulated Sample*

Sr. No.	Solvent	Readings (mg/ml)
1.	**Distill water**	**21.66±0.32**
2.	**Ethanol**	4.80±1.60
3.	**Methanol**	16.05±1.09

Total Phenolic Content was maximum in distilled water extract of formulation.

Table 2: *Estimation of Antioxidant Activity in Formulated Sample by using* ***DPPH*** *Assay (Mean + SD)*

Sr. No.	Solvent	Readings (mg/ml)
1.	**Distill water**	85.24±0.30
2.	**Ethanol**	70.89±0.05
3.	**Methanol**	81.11±0.21

Antioxidant activity in Formulated sample by using DPPH assay was maximum in distilled water extract.

Table 3: *Estimation of* ***Antioxidant Activity in*** *Formulated Sample by using* ***FRAP*** *Assay (Mean +SD)*

Sr. No.	Solvent	Readings (mg/ml)
1.	**Distill water**	0.011±0.01
2.	**Ethanol**	0.015±0.013
3.	**Methanol**	0.017±0.02

Antioxidant activity in formulated sample by using FRAP assay was maximum in methanolic extract.

Table 4: *Estimation of* ***Total Flavonoid*** *in the Formulated Sample (Mean+SD)*

Sr. No.	Solvent	Readings (mg/ml)
1.	**Distill water**	0.58±0.02
2.	**Ethanol**	0.51±0.02
3.	**Methanol**	0.72±0.02

Total flavonoid was highest in methanolic extract of formulation.

Table 5: *Quantification of Various Phenolic Compounds using RP-HPLC*

Solvent	Gallic Acid (ppm)	Cathechol (ppm)	Caeffic Acid (ppm)	Vanillin (ppm)	p-coumaric acid (ppm)	Ferullic Acid (ppm)
Distill Water	……	2.471	0.883	0.337	……	3.562
Ethanol	……	50.701	1.923	0.760	……..	……
Methanol	…….	……	8.066	0.605	…….	……..

4. Discussion

Plants produce various antioxidant compounds to combat reactive oxygen species posing an oxidative stress. Antioxidant activity is strongly dependent on the solvent due to the different antioxidant potentials of phytochemical compounds with distinct polarities and extractability. Antioxidant properties of single compounds within a group can vary remarkably, so that the same levels of phenolics do not necessarily correspond to the same antioxidant responses. Lipid peroxidation is caused due to reactive oxygen species (ROS) which is responsible for the deterioration of food by leading the formation of potential toxic compounds. The concentration of peroxide decreases with the increase in the antioxidant activity, while the absorbance values are much smaller with higher antioxidant activities of the samples. The TBA assay is not specific for malondialdehyde (MDA) which is one of the breakdown products of lipid peroxidation. The non-specificity probably results from the acid eating step of the TBA assay that causes the formation of

artificial TBA/MDA-like derivatives. The DPPH scavenging activity was found to be in agreement with the % protection activity of the extracts. Correlation analysis clearly determine that assay such as total phenol content, DPPH radical scavenging activity and lipid peroxidation correlates with each other. But total flavonoid content has negative correlation with total phenols and lipid peroxidation [9] [12]. (Table 1)

4.1. Total Phenolic Content

The maximum concentration of the total phenolic was found to be in distilled water 21.66±0.32 mg/ml whereas the minimum concentration was observed in ethanol 4.80±1.60 mg/ml. Distilled water formulation is the better solvent for phenolic content estimation because water molecules can retain the phenolic compounds for a longer period of time [13]. (Table 2)

4.2. DPPH Assay (Antioxidant Activity)

The highest antioxidant capacity of formulation was observed in the distilled water 85.24±0.30 mg/ml and the lowest activity was observed in ethanol 70.89±0.05 mg/ml. Thus the phenolic and polyphenolic compounds are natural antioxidants which enhance the free radical scavenging activity [14]. (Table 3)

4.3. FRAP Assay (Antioxidant Activity)

Ferric reducing antioxidant power was found maximum in methanol 0.017±0.02 mg/ml and minimum in distilled water 0.011±0.01 mg/ml. (Table 3)

4.4. Flavonoids Estimation

Flavonoid content was observed maximum in methanol content 0.72±0.02 mg/ml and minimum in ethanol content 0.51±0.02 mg/ml. (Table 4)

4.5. RP-HPLC

The RP-HPLC results was observed maximum in ethanol formulation were cathechol was observed to be 50.701 ppm and caeffic acid 1.923 ppm. Caeffic acid and vanillin in methanol formulation was observed to be 8.066 and 0.605 respectively. (Table 5)

5. Conclusion

Total phenolic content was maximum (21.66±0.32) in distilled water extract, whereas total flavonoid was maximum in (0.72±0.02) methanolic extract, Antioxidant by DPPH was maximum (85.24±0.30) in distilled water extract. Whereas by FRAP method, it was maximum (0.017±0.02) in methanolic extract. In the assessment of Total phenolic content, Catechol (50.701 ppm) and Vanillin (0.760) was maximum in ethanolic extract, whereas caeffic acid was maximum 8.066 ppm in methanolic extract. Result of present study showed that A compound formulation *Romasanjanana Lepa* consisting leaf of *Karanja*, fruit of *Kapittha*, *Kasisa* and *Hastidant Mashi* posses antioxidant activity.

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The Dual Action of Varunadi Kwath in Renal Calculi as well as Uterine Fibroid- A Case Study

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Abstract Mutrashmari (Renal Calculi) is very common disorder. This distressing urinary disorder affects around 5-7 million people in India [11]. The chances of recurrence are always high and the surgery having disadvantage of high cost. The available treatment in modern science is only conservative and surgical in this present study an effort was made to evaluate the role of Varunadi Kwath in Mutrashmari. The main aim of this particular study was inclined towards the disintegration, dissolution, dislodgement and expulsion of renal calculi. The contents of Varunadi Kwath are easily available, economical and are easy to administer, which are having Anti-inflammatory, Diuretic and Antilithic properties. A case of renal calculi with uterine fibroid was diagnosed and the treatment was given for a period of 9 months. The size of the calculus was studied by periodic ultrasonography; the symptoms Mutrakruchrata (Dysuria), Shula (Pain in abdomen), Sadaha Mutrata (Burning micturition) are significantly reduced within less than 45 days and total expulsion of calculi in less than 180 days.
Keywords *Mutrashmari; Varunadi Kwath; Renal Calculi; Uterine Fibroid*

1. Introduction

Renal calculi are the third most common disorders of the urinary tract [5]. An alarming rise in the incidence of renal calculi in recent years has provoked to explore a treatment of significant effect without any adverse side effect. As much as 10% of men and 3% of women have calculi at least once in their lifetime. At least 1/1000 of Indian population needs hospitalization due to urinary calculi. The highest incidence of calculi occurs between the ages of 30 to 50 years [7] [8].

In Ayurveda, Mutrashmari is a Mutraavrodhajanya vikara and is considered as one of the ‘Astamaha gadas’. Formation of Mutrashmari, according to Sushrut, is due to Srotovaigunya resulting from dushita Kapha localized in Basti in conjunction with pradushita vata and pitta [10].

Mutrashmari (Renal Calculi) is associated with symptoms like excruciating pain during micturition, sudden stoppage of urine flow, blood stained urine, twisting and slitting of urine, aggravation of pain during running, jolting etc., go on in accordance with symptoms of modern science [11] [5].

1.1. Need of Study

In Renal calculi patient experiences so much Pain, Ureteric colic, Haematuria, Recurrent UTI which disturb his daily routine work. Many modern surgical procedures like are available which are expensive and disadvantages of high expenditure and disease recurrence. Despite advancement in modern techniques, the recurrence rate of calculi is approximately 50% within 5 to 7 years [8]. Disease recurrence may cause acute renal injury and a decrease in renal function. This is unwanted effect.

So there is need to find such medicine which is an inexpensive, economical, effective and easily available which has no adverse effects. The aim of treatment is not only elimination or to remove the disease but also meanwhile avoid the recurrence by prakriti-vighatana chikitsa. The ingredients of Varunadi kwath are minimum expensive and easily available which is very economical for the society.

2. Aim and Objective of the Study

To evaluate the role of Varunadi Kwath in renal calculi by assessing the symptomatic relief, reduction/expulsion of Renal calculi.

Case History

A case detail of 26 year old female married patient diagnosed with Renal calculi with uterine fibroid.

C/o-

Pain in abdomen, Painful, Dribbling and Burning Micturition Intermittent since 15 days.
Flatulence since 1 month.
No H/o DM/HTN/any other major illness/any operative procedure.

H/o past illness-

One day patient suddenly noticed severe pain in the abdomen. The patient consulted nearby physician and got temporary relief. Later she developed same symptoms with burning and painful micturition after 7 days. So the patient was advised to undergo USG (Abdomen + Pelvis) which showed Left kidney having calculus of 13 mm in lower calyx. Uterus shows a lower posterior echogenic fibroid of 13 mm (dated 29/04/2013).

F/H/O not significant

Diet history reveals that her food intake was irregular in terms of quality and quantity due to her stressful work as a housewife.

O/E-
Pulse- 80/min B.P – 140/90 mm of Hg
Bowel- Constipation
Urine- sadaha mutrata (Burning Micturition), mutradhara sanga (Interrupted flow of urine), saruja mutrapravrutti (Painful Micturition), Udara pradeshi vedana (Pain in abdomen).

Tongue – Saam (Coated) Touch- Anushna (Afebrile)
Eyes-No pallor Built – Madhyam (Moderate)

S/E-

RS- AEBE clear
CVS- S1S2 NAD
CNS- Conscious oriented

Menstrual H/O: 3-4 days — Regular
28-30 days — Moderate
Painless

P/A- No organomegaly
Tenderness elicited in the left side of the lumbar region and left side of renal angle.

As advised, Patient underwent Ultrasonography of the abdomen pelvis which revealed left kidney showing a calculus of 13 mm in lower calyx. Uterus shows a lower posterior echogenic fibroid of 13 mm with normal features
Dushta Srotas Parikshan-
Mutravaha- sadaha and saruja mutrapravrutti, sanga, Udara pradeshi vedana.
Artavaha- Uterine Fibroid
Vyadhi Vyavacched-
Mutrakruchra
Mutraghata
Shoola

Vyadhi Vinischya- Mutraashmari (Renal Calculi with Uterine Fibroid)

Intervention

Table 1: *Intervention*

Treatment Given	Dose	Duration	Follow up	Advise
Varunadi Kwath	15 ml bd with equal quantity of water	9 months (180 days)	Every 15 days after administration of medicine till 45 days then every month upto 9 months of treatment.	2-3 litres of water per day

3. Observations and Results

The patient treated with Varunadi Kwath has shown good effect on calculi. All the symptoms like Pain in abdomen, Burning and Dribbling Micturition were reduced markedly within 15 days. In next follow up i.e. 30 days, Dribbling micturition had totally disappeared. Burning micturition and Pain in abdomen also were reduced significantly. In next 45 days, USG (Abdomen + Pelvis) was done which showed size of calculi was reduced by 2 mm and fibroid was reduced by 1 mm which was shown in previous report. The treatment was continued for complete expulsion of calculi. So again USG was repeated after 9 months of treatment. The USG showed no e/o renal calculi or uterine fibroid (dated 31/01/14). This shows Varunadi Kwath had significant result on renal calculi of above 10 mm as well as in uterine fibroid.

Results in USG

Table 2: *Results in USG*

Scanning Date	Impression
29/04/2013	Left kidney shows calculus of 13 mm in lower calyx without complication. Uterus shows a lower posterior echogenic fibroid of 13 mm
11/06/13	Left kidney shows a calculus of 11 mm in lower calyx without complication.

	Uterus shows a fibroid of 19x12 mm in posterior cervix
31/01/14	No findings or evidence suggestive of calculi or uterine fibroid

Effect on Signs and Symptoms

Table 3: *Effect on Signs and Symptoms*

Signs and Symptoms	'0' day	1st F/U 15 days	2nd F/U 30 days	3rd F/U 45 days	3rd F/U 90 days	4Th F/U 180 days (Completion of treatment)
Pain in abdomen	+++	++	-	-	-	-
Dribbling micturition	+	+	-	-	-	-
Dysuria	++	+	-	-	-	-
Burning Micturition	+++	++	-	-	-	-

4. Discussion

4.1. Probable Mode of Action

The ingredients of Varunadi Kwatha possess properties like of Chedana, Bhedana, Lekhana, Tridoshgna, Mutrala, Mutrakrucchrahara, Anulomana, and Krimigna which helps significantly in Mutrashmari treatment. The ingredients of the formulation pacify Kapha Dosha by virtue of their Ruksha Guna, Katu Vipaka and Ushna Virya. The Vatanulomana, Shothahara and Mutrala properties helps to relieve pain and Shotha. Thus in total this formulation has the capacity to disintegrate the pathogenesis of the disease 'Ashmari'. [3] [6] [12]

Table 4: *Mode of Action*

Varuna	1) Acts as urinary antiseptic, anti - inflammatory and diuretic. 2) It is Sleshmahara shows Lekhana property due to Ushna Virya. 3) **Lupeol**, a chemical constituent of Craeteva Nurvala (Varuna) has shown antiurolithiatic activity, normalizes specific gravity, pH, ketone, blood, urobilinogen and protein in urine. It has shown to minimize the tubular damage and reduced crystal deposition in kidneys. Lupeol reduces the risk of stone formation by preventing oxalate and crystal-induced per oxidative changes in renal tissues and increase the urinary excretion of oxalate. Varuna has shown nephroprotective activity by decreasing the concentration of blood nitrogen and creatinine[1].
Gokshur	1) Diuretic. 2) It contains Potassium nitrite in rich quantity which acts as a urine alkalizer. The synergistic action is enhanced when yavakshar is combined with Gokshur and appreciating the results in disintegration of calculus. 3) Due to the prevention of urinary supersaturation, inhibition of mineralization of stone forming constituents, normalization of cellular function in renal oxidative stress, correction of crystalloid colloid balance as well as the beneficial effects such as ant inflammatory, antimicrobial, diuretic, antispasmotic, litholytic, and anticalcifying activities.
Shunthi	1) Being Madhura vipaki and Ushna virya, these properties help in shamana of vata dosha. Deepan property helps in further check of ama at jatharagni level.
Yavakshara	1) Yava Kshara is having pH 11.73. Thus it helps to neutralize the acidic media and prevent calculus formation. As yavakshara is alkaline in nature which changes the pH of urine, this helps in preventing the hyper concentration of the urine. 2) By the properties of Kshara like Rooksha, Laghu, Teekshana, Shigragami, it will reduce the chance of nidus formation as well as it reduces the growth of the stone by inhibiting the binding property of Kapha Dosha[4] [13] 3) Kshar has its specific action on fibroid to destroy uterine fibroid due to prabhava and bhedana.

According to Ayurveda the pathogenesis of uterine fibroid involves Mamsa, Meda and Rakta Dosha. The bhedan, kapha mamsa meda lekhan, Vatanuloman, Kledaghna, Deepan pachan, shothhar and Vatakapha shamak action of Varunadi Kwath has shown effect in fibroid. [6]

5. Conclusion

This study has shown highly significant result in reducing symptoms within 45 days like Shula (Pain in abdomen), Saruja mutrata (Painful micturition), Sadaha Mutrata (Burning Micturition), Mutradharasang (interrupted flow of urine) and complete expulsion of calculi within 180 days. Moreover it has acted on complete dissolution of uterine fibroid.

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Prevalence of *Viruddha Ahara* in Patients Attending Arogyashala of N.I.A and Its Effects on Health

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Abstract Nowadays, the era of urbanization has produced increased number of fast foods and restaurants. The food habits and life style has also been customized according to the profession/ career of an individual. Hence much importance for taste is given but not for health benefits. "*Viruddha*" or "*Vairodhika*" is the technical terms for incompatible or antagonistic. *Viruddha Dravyas* dislodge the various *Doshas* but do not expel them out. So they cause various disorders. As mentioned in *Samhita*, it is prime cause of many diseases like *Kushtha*, *Amavata*, *Amlapitta, Atisara, Pandu, Visarpa, Vatarakta, Grahani* etc. To survey the prevalence of *Viruddha Ahara* consumption in patients and its hazardous effects on health and to find out the presence of *Viruddha Ahara* as a causative factor in different diseases. For this purpose a survey study was planned and a total of 416 subjects were interviewed. The data shows that all (100%) patients were consuming *Viruddha Ahara* (incompatible diet) having *Mandagni* and *Avara Vyayamashakti*. *Raktavaha Srotodushthi* found in maximum number of patients. From the above results, it is concluded that *Viruddha Ahara* is an important aspect of today's improper dietary habits.
Keywords *Mandagni; Raktavaha Srotodushthi; Viruddha Ahara Consumer*

1. Introduction

Ahara, which is ingested and thus it includes in itself both diet and drugs [1]. Food is a substance which when taken in the body, is able to build up or repair tissue, protects against ill health [disease] as supply materials for the production of health and energy. Wholesome diet is responsible for the growth and development of the body, on the contrary, unwholesome diet causes several diseases [2]. *Acharya Sushruta* have emphasized that *Ahara* is responsible for the *Preenana* of the body. It produces instant strength, increases the lifespan, lustre, happiness as well as normal mental activities like memory power etc. *Ahara* plays a vital role in retrieval the lost strength during the stage of convalescence. All *Acharyas* have accepted a vital role of *Viruddha Ahara* in the manifestation of many diseases. Diet articles are inimical to the body elements tend to disagree with the body system [3]. The food, which having disclosed the morbid humours but do not eliminate them from the body are to be regarded as unwholesome [*Viruddha Ahara*] [4]. *Charaka* has mentioned 18 types of *Viruddha Ahara* which are *Viruddha to Desha* [place], *Kala* [period], *Agni* [digestive power], *Matra*

[doses], *Satmya* [habit], *Aniladibhi* [*Doshas*], *Sanskara* [mode of preparation], *Virya* [potency], *Koshtha* [state of bowel], *Avastha* [state of health], *Krama* [order of intake], *Parihara* [pro-scription], *Upachara* [prescription], *Paka* [cooking], *Samyoga* [combination], *Hrit* [palatability], *Sampada* [richness of quality] and *Vidhi* [against to rules of eating] etc.

All types of *Viruddha Ahara* not produce the disease because body elements like *Dushya* and *Deha Bala* [immunity] protect the body from the diseases.

As mentioned by our *Acharyas*, *Virudhha Ahara* [incompatible diets] is responsible for disease formation such as *Kushtha,* [5] *Amavata,* [6] *Amlapitta,* [7] *Atisara,* [8] *Pandu,* [9] *Visarpa,* [10] *Vatarakta,* [11] *Grahani* [12] etc. So *Viruddha Ahara* is one of the main potential factors for many diseases. With above point in mind and to search out cause and effect relationship between *Viruddha Ahara* [incompatible diet] and various diseases, the present study has been selected.

2. Aims and Objectives

1) To survey the prevalence of *Viruddha Ahara* consumption in patients and its effects on health.
2) To find out the presence of *Viruddha Ahara* as a causative factor in different diseases.

3. Materials and Methods

To conduct a survey study to gather the data for prevalence of *Viruddha Ahara* consumption in patients, a duly prepared proforma was made. For this survey study, total 416 patients were screened on the basis of prepared questionnaires which are mentioned in annexure 1.

4. Selection of Patients

Patients suffering from different diseases without considering age, sex, religion, marital status, socioeconomic status were selected randomly from O.P.D. & I.P.D.

5. Observation

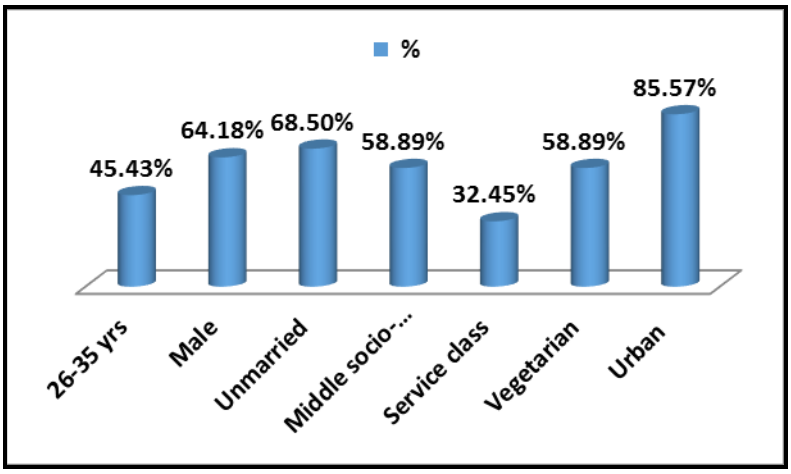

Figure 1: *Prevalence of Age, Gender, Marital Status, Socio-Economic Status, Occupation, Diet Pattern, Habitat of Total Study Patients [n=416]*

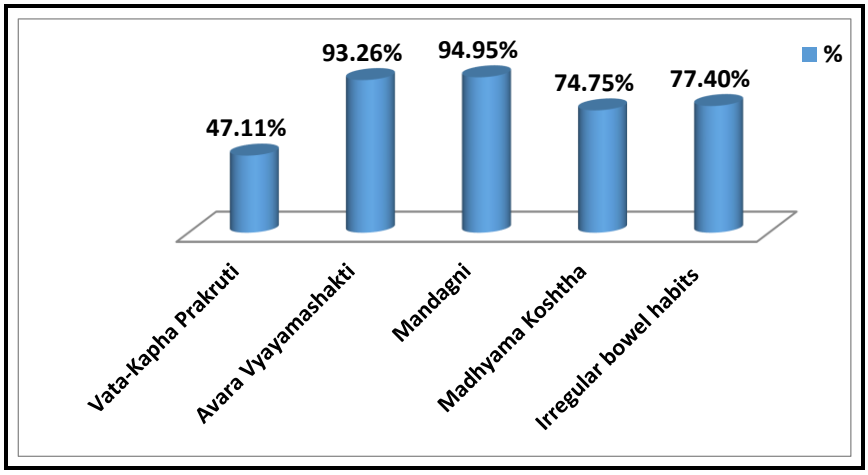

Figure 2: *Prevalence of Sharirika Prakruti, Vyayamashakti, Agni, Koshtha and Bowel Habits of Total Study Patients (n=416)*

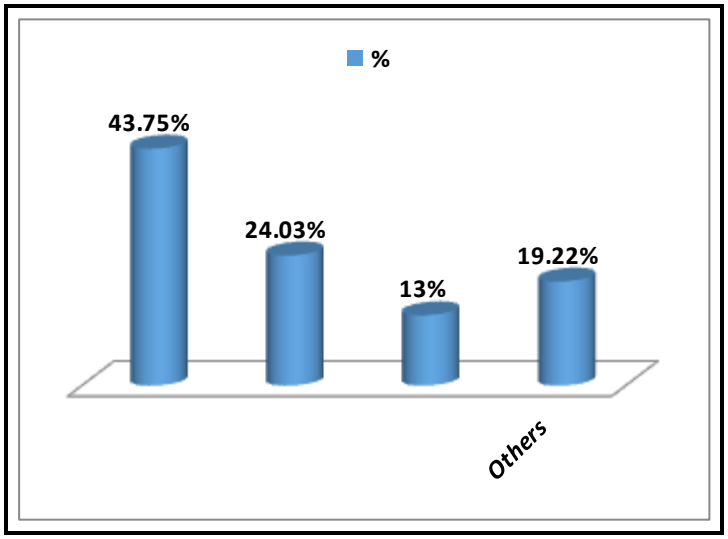

Figure 3: *Prevalence of Srotodushti of Total Study Patients (n=416)*

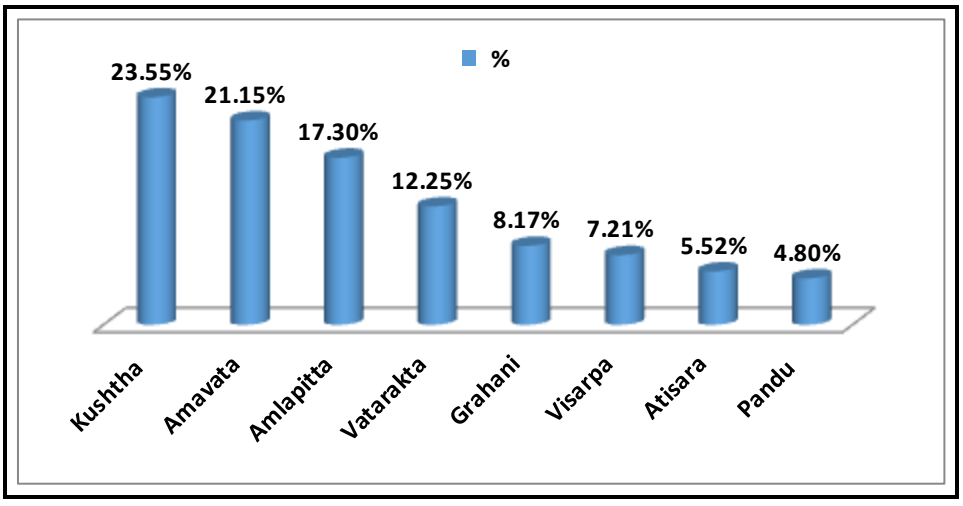

Figure 4: *Prevalence of Diseases of Total Study Patients (n=416)*

In Survey study, out of 416 patients, maximum numbers of patients (45.43%) were found in the age group of 26-35 years. 64.18% patients were male followed by 35.82% female. Maximum patients (68.50%) were unmarried. Most of the patients were from middle socio-economical class (58.89%). In case of occupation, 32.45% patients were service class, 26.44% patients were in student occupation. 58.89% patients were vegetarian and 85.57% patients were from urban population (Figure 1).

On considering the data of *Sharirika Prakruti*, maximum i.e. 47.11% patients had *Vata-Kapha Prakruti*, 34.85% had *Pitta-Kapha Prakruti*. In this study, 93.26% patients were having *Avara Vyayamashakti*. On considering the data of *Agni*, maximum i.e. 94.95% patients were having *Mandagni*, 4.56% patients were having *Vishamagni* and 2.90% were having *Tikshnagni*. On analyzing the *Koshtha* of patients, it was found that 74.75% of patients were having *Madhyama Koshtha*. Bowel habits of most of the patients were found irregular (77.40%) (Figure 2).

In case of *Srotodushti*, it was observed that vitiation of *Raktavaha Srotasa* was found in maximum number of patients who had consuming *Viruddha Ahara* (43.75%). Vitiation of *Annavaha Srotasa* and *Rasavaha Srotasa* was observed in 24.03% and 13% patients respectively (Figure 3).

Out of 416 *Viruddha Ahara* consumer patients, it was observed that maximum no. of patients i.e. 23.55% were of *Kushtha* (skin disease). 21.15% patients of *Amavata*, 17.30% patients of *Amlapitta*, 12.25% patients of *Vatarakta*, 8.17% patients of *Grahani*, 7.21% patients of *Visarpa*, 5.52% patients of *Atisara*, 4.80% patients of *Pandu* were found of *Viruddha Ahara* consumer (Figure 4).

6. Viruddha Ahara Consumer

Table 1: *Prevalence of Nidana (Cause)*

Availability of *Nidana*	No. of Patients	%
Intake of milk with *Guda* (jaggery)	416	100%
Intake of milk with Khichadi (cooked rice)	289	69.47%
Intake of milk + sour fruits	416	100%
Intake of non-vegetarian diet + curd/milk	66	15.66%
Intake of curd at night	416	100%
Milk Shake	416	100%
Fruit-salad	231	55.52%
Milk + curd + Bhata (cooked rice)	389	93.50%
Milk+Idli /Samosa/Kachodi	416	100%
Milk + Salt	356	85.57%
Intake of junk food like samosa chaat, dabheli, pani puri, dahi puri, sheva puri, bhela puri, ragada patis etc., fried foods & oily, spicy foods, bakery products and processed food (frozen, canned, packaged or wrapped)	416	100%

All patients (100%) were found of *Viruddha Ahara* consumer.

On considering data of 416 patients, all patients (100%) were taking milk with *Guda* (jaggery), milk + sour fruits, Milk+Idli /Samosa/Kachodi, curd at night, milk shake and junk food like samosa chaat, dabheli, pani puri, dahi puri, sheva puri, bhela puri, ragada patis etc., fried foods & oily, spicy foods, bakery products and processed food (frozen, canned, packaged or wrapped). 93.50% patients were consuming Milk + curd + Bhata (cooked rice), Milk + Salt were predominant in 85.57% patient. 69.47% and 55.52% patients were milk with Khichadi (cooked rice) and Fruit-salad respectively. 15.66% patients were taking non vegetarian diet + curd & milk (Table 1).

7. Discussion

The dietetics for human beings that are in changing manner due to shorter world and mostly due to human behaviour. Now-a-days it is observed that, peoples are forgotten the code and conduct of dietetics- which is also vary from region to region. In present era, due to changing life, urbanization and fascination of western culture, food habits of society are changing. Peoples mind set up with the two words- delicious & continental, means delicious dishes means continental- we are unable to think about state or even country level. Those are still present like traditional Rajasthani, Panjabi, Marwari or Bengali dish only restricted as a service in a Holiday Package. In this era the style also unnoticely entered in the kitchen room through the media specially television. Everyone, apart from sex and age try to establish herself or himself as good chemist in the production of tasty articles. But there is a big gap between tasty and healthy. If we make a balance between two then it is fine otherwise not. Unfortunately what is happening today with our dish that is nothing but a misuse of the sense of taste. So naturally today the food & food habits are changing according to changing life-style of present inhabitants. In a word the century is fast as its time, food or food habits and ultimately makes a perplex combination and that is definitely incompatible and injurious for health. And day to day the trends are gradually increasing, people are most of the time submerged with 'incompatible' either in diet or habit form which leads to most of the diseases.

It was found that 100% of the patients were habitual to *Viruddha Ahara*. At present time, younger age group (26-35yrs), due to ignorance or carelessness are take diet without considering rules and regulations of dietetics. Reported data of gender shows 64.18% patients were male, possible rationale may be that, male may be more affected by incompatible diet due to some conditions i.e. hostel, business and service schedule. Maximum patients (32.45%) were service class, 26.44% patients were in student occupation, owing to busy time and work load, they were having irregular, improper, inappropriate diet practice, and regular intake of *Viruddha Ahara*.

It was observed that, 85.57% patients were from urban population. In urban area modernized peoples are lives with hard and fast life so they more consume incompatible diet.

In case of *Sharirika Prakruti*, maximum i.e. 47.11% patients had *Vata-Kapha Prakruti*, followed by 34.85% *Pitta-Kapha Prakruti*. It support the *Ayurvedic* concept that the willing or craving to 'types of food' is totally different with their individual constituents. And it is also observed that the grammar of the maximum incompatible diets is sour, salty and spicy.

As mentioned in *Charaka Samhita*, that due to some factors dietetic incompatibility becomes neutralized viz. homologation and slight quantity of *Viruddhahara*, strong digestive power, young age, taking of unctuous elements, daily exercise etc [13]. These all improves the immunity of individual. So spreading of *Dosha* by *Viruddha Ahara* becomes neutralized. But in survey study 94.95% patients were found of *Mandagni* and 93.26% were of *Avara Vyayamashakti*. So they can't neutralise the effect of *Viruddha Ahara.*

Vitiation of *Raktavaha Srotasa* was found in maximum number of patients. *Viruddha Ahara* is direct cause of *Rakta Dushthi* [14]. *Shonita Dushthi* can affect in two ways – by producing different skin diseases and also by affecting the proper nourishment of body and its tissue.

Out of 416 *Viruddha Ahara* consumer patients, maximum no of patients (23.55%) were found of skin disease (*Kushtha*). According to most of *Ayurvedic* texts, all types of *Kushtha* have been considered as '*Rakta Pradoshaja Vikara*' and *Rakta Dushthi* can directly occur by use of *Viruddha Ahara.*

Generally, *Viruddha Ahara* leads to *Dosha* aggravation *& Dhatu* aggravation [15] because *Viruddha Ahara* are nothing but those articles of food, which dislodge the morbid humours (*Utklesha* (aggravation or excitation) of *Dosha*), but do not eliminate them from the body [16]. So continuous intake of *Viruddha Ahara* lead to vitiation of *Agni*, [17] which is root (main) cause of every disease. Because *Agni* is responsible for biotransformation of different materials. So vitiation of *Jatharagni* leads to vitiation of *Dhatvagni* and *Bhuagni*. This vitiated *Jatharagni* does not digest even the lightest of food substances, resulting in indigestion (*Ajirna*). This undigested food material turns sour and acts like a poison, which is called *Ama Visha* in *Ayurvedic* terminology. '*Ama Visha'* (undigested poisonous food) leads eventually to the breakdown of immune system. *Tridosha* gets provocated by this type of ingestion [18]. Intake of incompatible Diet vitiates *Srotasa* as mentioned that general food substances and activities (*Vihara*) which are similar in quality to body humours and deleterious to the body elements vitiate the body channels [19] and Therefore *Srotovarodha* or *Sanga* or obstruction in channels is occurs which leads to several diseases of acute to severe nature.

Thus by *Viruddhahara*, all responsible factors of disease get vitiated, due to which body becomes vulnerable to diseases.

8. Conclusion

Study shows that all (100%) patients were consuming *Viruddha Ahara* (incompatible diet) having *Mandagni* and *Avara Vyayamashakti*. *Raktavaha Srotodushthi* found in maximum no. of patients. So it is concluded that *Viruddha Ahara* is an important aspect of today's improper dietary habits. This can lead to several hazardous diseases most commonly skin diseases. Majority of people are not aware about these incompatible diets. If people avoid these faulty dietary intakes, then production of most of the diseases will be controlled up to some extent.

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