



# Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

© 2011-18, publisher and licensee JDDT, This is an Open Access article which permits unrestricted non-commercial use, provided the original work is properly cited



Open  Access

Research Article

## A clinical study to evaluate the efficacy of *Patoladi Kwath (SU. CH.)* with or without *Rasnadi Pradeh (CH. SU.)* in cases of *Vatarakta (W.S.R. to Gouty Arthritis)*

Dr. Deepika Gupta<sup>\*1</sup> Dr. Kamal Sachdev<sup>2</sup> Dr. Richa Garg<sup>3</sup>

<sup>1</sup> Ph.D. Scholar, P.G. Dept. of Kayachikitsa, National Institute of Ayurveda, Jaipur, Rajasthan, India.

<sup>2</sup> MD (Ay.), Reader & HOD, P.G. Dept. of Kayachikitsa, State Ayurvedic College and Hospital, Faculty of Ayurveda, Lucknow University, Lucknow, Uttar Pradesh, India.

<sup>3</sup> MD (Ay.), Lecturer, P.G. Dept. of Kayachikitsa, State Ayurvedic College and Hospital, Faculty of Ayurveda, Lucknow University, Lucknow, Uttar Pradesh, India.

### ABSTRACT

In *Ayurveda*, health means the state of *Doshasamyā*, *Agnisamyā*, *Dhatusamyā* and *Samanya Malkriya* as well as wellness of *Atmendriya* and *Mana*<sup>1</sup>, which according to *Acharya Charak* is necessary to achieve *Dharma*, *Artha*, *Kama* & *Moksha*<sup>2</sup>, the ultimate aim of life. But it has become quite difficult due to the various health obstacles experienced by men during his routine life. The disease *Vatarakta* is one of them and the number of *Vatarakta* patient are increasing day by day. The status of *Vatarakta* is often compared with Gouty Arthritis in the allied sciences. As far as the treatment of *Vatarakta*/Gouty Arthritis is concerned various research works conducted from time to time, which had shown encouraging result, but still there are many *Ayurvedic* medicine whose effect has to be established in the management of *Vatarakta*/Gouty Arthritis based on latest scientific parameters. *Acharya Charak* has advocated the use of different *Ghrut Yog*, *Tail Yog*, *Lepa*, *Pradeha*, etc for external application in different types of *Vatarakta* for relieving pain, swelling, stiffness, burning, itching, etc. So, for this research work we selected *Patoladi Kwath* from *Susrut Chikitsa Sthana 5* and *Rasnadi Pradeh* from *Charak Sutra Sthana 3* to evaluate their efficacy in the management of *Vatarakta* (w.s.r. to Gouty Arthritis). For this research work 56 diagnosed patient of *Vatarakta* having age of 21 to 60 years were registered and sequentially randomized into two parallel groups. Leaving 6 dropout (3 from each group), 25 patients of group A were treated with 40 ml *Patoladi kwath* 2 times a day after meal for 90 days and 25 patients of group B were treated with 40 ml *Patoladi kwath* 2 times a day after meal with *Rasnadi Pradeh* for local application over affected joint in the evening for 90 days. The result of the treatment was accessed based on the improvement in terms of symptomatic relief and improvement in terms of Lab investigation i.e, decrease in Serum Uric Acid level and ESR.

**Keywords:** *Vatarakta*, Gouty Arthritis, Serum Uric Acid, ESR.

**Article Info:** Received 15 Feb 2019; Review Completed 22 March 2019; Accepted 26 March 2019; Available online 15 April 2019



### Cite this article as:

Gupta D, Sachdev K, Garg R, A clinical study to evaluate the efficacy of *Patoladi Kwath (SU. CH.)* with or without *Rasnadi Pradeh (CH. SU.)* in cases of *Vatarakta (W.S.R. to Gouty Arthritis)*, Journal of Drug Delivery and Therapeutics. 2019; 9(2-s):98-110 <http://dx.doi.org/10.22270/jddt.v9i2-s.2587>

### \*Address for Correspondence:

Dr. Deepika Gupta, Ph.D. Scholar, P.G. Dept. of Kayachikitsa, National Institute of Ayurveda, Jaipur, Rajasthan, India.

### INTRODUCTION

*Vatarakta* is a disease where both *Vata* and *Rakta* are afflicted by distinct etiological factors. According to *Acharya Charak*, when the vitiated *Vata Dosha* circulates through the *Srotus* the pre-vitiated *Rakta* forms an *Avarana* over *Vata* and further agitates *Vata Dosha*. Vitiated *Vata* and *Rakta* together lead to a complex effect on the joint and produces *Vatarakta*<sup>3</sup>. According to *Acharya Susruta*, the process of disease initiates from *Padamula* i.e. feet and sometimes from *Karamula* i.e. hand and spreads throughout the body like *Mushika vish*<sup>4</sup> (rat poison).

*Vatarakta* is one of the burning health problems of the present era as the number of *Vatarakta* patient are increasing day by day. The dramatic increase is presumably due to lifestyle and food habits. Now a day lifestyle is

becoming more & more luxurious. People do not take proper diet and do not follow proper dietary rules as described in *Ayurveda* under *Dincharya*, *Ritucharya*, etc. Improper dietary habits such as *Adhyashana*, *Virudhashana*, *Ahitashana*, etc and use of meat of aquatic and marshy animals, more consumption of fast food, junk food, high protein diet, less tendency to exercise, more vehicle riding, long term vehicle riding over damaged road have increased the number of *Vatarakta* patient.

The disease *Vatarakta* has been described in *Garunpura*, *Agnipurana* and in almost all *Ayurvedic* classics such as *Brihatrayi*, *Laghutrayi*, *Vangsenā*, *Chakradutta* and *Bhaisajya Ratnavali*, etc, which shows that this disease was prevalent widely in early era too.

The status of *Vatarakta* is often compared with Gout/Gouty Arthritis in the allied sciences due to the outstanding similarities and also because in previous research works hyperuricaemia has been observed as a common feature in patients of *Vatarakta*. Gout is a clinical syndrome and is a type of metabolic disease in which clinical manifestations are associated with tissue deposition of crystals of Monosodium Urate Monohydrate (MSUM) from hyperuricemic body fluids. Acute Gout affects mainly joints, synovial membrane, articular cartilages, tendon sheaths and bursae but the local aggregation of Monosodium Urate Monohydrate crystals may also occur in non-articular cartilage. Acute Gouty attack mostly initiates from great toe but it may sometime initiate from ankle, knee, wrist, finger, elbow, etc. and is characterized by rapid onset of pain, swelling, redness, tenderness, itching and burning sensation and discoloration of skin over affected joint. Over the span of years, the progressive accumulation of urate crystal and recurrent attack of inflammation leads to chronic destructive arthritis leading to different kind of deformities.

The *Vatarakta* has attracted the attention of world's scientists working on the problem, not only due to the problem faced by patient during acute attack but due to its remote complications and sequels. If the chronic condition is not treated properly, the deformity of joints and cartilages cripples a person throughout his life.

Gout is more common in men than in women and more prevalent in black races than white. A number of factors have been found to influence rates of gout, including age, sex, race, and the season of the year. Gout is seen in only one-tenth of the patients of hyperuricaemia. The incidence of gout varies in population from 0.2 to 3.5 per 1000, with an overall prevalence of 2 to 26 per 1000. The prevalence of Gout has increased in recent years. It is rare in children and premenopausal females and the peak age of onset in male is between 40 years and 60 years. The chances of having gout raises with age in men, with a peak around 50 while in women, gout attacks usually occur after menopause.

For the treatment of *Vatarakta*/Gouty Arthritis, along with different drugs for internal use, Acharya Charak has advocated the use of different ghrith yog, tail yog, lepa, pradeha, etc for external application in different types of *Vatarakta* for relieving pain, swelling, stiffness, burning, itching, etc. so for this research work we selected two medicines mentioned in Ayurvedic classics-

1. Patoladi Kwath (Susrut Chikitsa -5/13)
2. Rasnadi Pradeh (Charak Sutra -3/22)

### Aims and Objectives

1. To establish an effective herbal formulation for *Vatarakta*/Gouty arthritis.
2. To establish the efficacy of *Patoladi Kwath* & *Rasnadi Pradeh* in cases of *Vatarakta*/Gouty arthritis.
3. To observe clinical improvement of the disease during the follow up period.
4. To study any adverse effects of the trial drug.

## MATERIALS AND METHODS

### Protocol of Research

1. **I.E.C. Approval-** Approving of synopsis for human trial was obtained from Institutional Ethical Committee of S.A.C. & Hospital, Lucknow, U.P.
2. **Consent-** Written and informed consent of study subjects was taken before inclusion in the trial.

3. **Proforma-** Proforma incorporating detailed profile of study subjects with complaining history, signs and symptoms and assessment was prepared.

### Selection of Patients

For purpose of this clinical trial, patients of *Vatarakta* (Gouty Arthritis) were selected regardless of sex, religion, occupation and socio-economic conditions, with the age group of 21-60 year from O.P.D. & I.P.D. of State Ayurvedic College & Hospital, Lucknow and the referred cases which fulfill criteria of our clinical proforma were also included.

After careful clinical history, examination & laboratory investigations as per proforma, patients were selected and screened for their suitability of getting enrolled in this clinical trial as per specific inclusion and exclusion criteria.

### Inclusion Criteria

1. The patients of *Vatarakta* having serum uric acid >7 mg/dl in males & >5.7 mg/dl in females and at least 3 of the 4 essential symptoms with or without nonessential symptomatology.
2. Sex : Both male & female.
3. Socioeconomic status : All
4. Age : 21-60 years
5. Patient willing to sign the consent.

### Exclusion Criteria of the Patient

1. Patients below 21 year and above 60 years of age.
2. Complicated cases of *Vatarakta* by other chronic systemic disorders like RA, OA, SLE, Diabetes, Tuberculosis, Renal disease, Hepatic diseases.
3. Complicated cases of *Vatarakta* by its *Updravas* like *Hikka*, *Moorchha*, *Moha*, *Visarpa*, *Mansa-Koth*, *Angulivakrata* etc.
4. Complicated cases of gout with Chronic joint deformity, marked dysfunction, discharging tophi, etc.
5. Pregnancy and lactation.
6. Patients not willing to sign the consent.

### Criteria for Withdrawal

1. Personal matters
2. Aggravation of complaints
3. Inter current illness
4. Any other difficulties
5. Will of the patient

### Symptoms <sup>5</sup>

#### Essential Symptoms-

1. Sandhishu Ruk (pain in the affected joint)
2. Sandhishu Rag (redness in the affected joint)
3. Sandhishu Swathu (swelling in the affected joint)
4. Sparsh-asahatvam (tenderness in affected area)

#### Nonessential Symptoms-

1. Sandhishu Kathinya (Stiffness / decreased / restricted movements of joint)
2. Sandhishu Twagbahaya Tamra (Discoloration of skin of affected area)

3. Sandhishu Kandu (Itching in affected joint)
4. Sandhishu Daha (Burning sensation over joint)

#### Investigations-

- **Blood-** TLC , DLC , Hb% , ESR
- **Urine-** Routine (R) and Microscopic (M)
- **Serum Uric Acid**
- **R.A. Factor**
- **Liver Function Test-** Sr. Bilirubin, SGOT, SGPT, Sr. Alkaline Phosphatase
- **Renal Function Test-** Blood Urea, Sr. Creatinine
- **Blood Sugar -** F/PP
- **X-ray of involved joint** (if possible)- AP view and Lateral view
- **Synovial Fluid Analysis** (if possible)

#### Contents of Formulations-

1. **Patoladi Kwath**<sup>6</sup>- it contains *Patol Patra, Trifla (Haritaki, Vibhitaki, Amalki), Satavari, Guduchi & Katuka*.
2. **Rasnadi Pradeh**<sup>7</sup>- it contains *Rasna Patra, Guduchi, Yastimadhu, Bala, Atibala, Vidari Kanda, Godugdha, Goghrita and Madhuchhista* (bee-wax).

#### Preparation and Packing of the Trial Drugs

All the drugs mentioned above was taken from the central drug store of State Ayurvedic College & Hospital, Lucknow and from nearby market. All the ingredients were then authenticated by the Department of Dravyaguna State Ayurvedic College & Hospital, Lucknow.

The drugs, *Patoladi Kwath* and *Rasnadi Pradeh* were then prepared according to the classical drug preparation method described in the text by the department of Rasashastra & Bhaisajyakalpana State Ayurvedic College & Hospital, Lucknow.

#### Patoladi Kwath

##### Preparation and packing-

Dried contents were taken in equal ratio. *Yavkut* was done & packed in 600 gm packs for 15 days. Patients were advised to make *Kwath* at home by classical method as told by *Acharya Sharangadhara*<sup>8</sup>.

#### Rasnadi Pradeh

In this *Yog*, instead of *Jeevak* and *Risbhak*, *Vidari Kand* was taken, as these two drugs are not available in present time and according to *Acharya Bhav Prakash*<sup>9</sup> due to similar properties (*Gudaistat-tulyam*) *Jeevak* and *Risbhak* can be substituted by *Vidari*. So instead of one part *Jeevak* and one part *Risbhak*, two parts of *Vidari Kand* was taken.

#### Ratio of Ingredients-

- |                  |   |         |
|------------------|---|---------|
| 1. Rasna         | → | 1 part  |
| 2. Guruchi       | → | 1 part  |
| 3. Yastimadhu    | → | 1 part  |
| 4. Bala          | → | 1 part  |
| 5. Atibala       | → | 1 part  |
| 6. Vidari kand   | → | 2 part  |
| 7. Goghrit       | → | 8 part  |
| 8. Godugdha      | → | 32 part |
| 9. Jala          | → | 32 part |
| 10. Madhuchhista | → | 1 part  |

#### Preparation and packing -

The *Pradeh (Ghrit Yog)* was prepared according to the classical method given by the *Acharya Sharangdhar*<sup>10</sup> and then bee wax was added in ratio equal to one of the ingredient of *Kalka Dravya*. After *Samyak Paka* it was drained and decanted into a container through a filter and the final product "*Rasnadi Pradeh*" was packed in well for 15 day in 100 ml container.

**Type of Study:** Phase-2, Rational, Randomized (sequential pattern) Parallel group study.

**Period OF Study:** Total duration of clinical trial is of 90 days.

**Sample Size:** Total 56 patients were registered including 6 dropouts.

**Grouping of the Patients and Drug Administration-** All the selected patients registered for the clinical trial were divided in two groups-

**1) Group A:** In group-A patients were kept on-

*i. Patoladi Kwath-* 40 ml *Kwath* 2 times a day after meal.

**Duration-** 90 days

**Follow up-** At every fortnight from day of registration till day 90

**2) Group B :** In group B-25 patients were kept on-

*i. Patoladi Kwath-* 40 ml *Kwath* 2 times a day after meal.

*ii. Rasnadi Pradeh-* about 2 mm thick *Pradeh* was applied over the affected joint in the evening.

**Duration -** 90 days

**Follow up -** At every fortnight from day of registration till day 90.

The assessment of subjective and objective parameters for each patient was done on 0<sup>th</sup>, 15<sup>th</sup>, 30<sup>th</sup>, 45<sup>th</sup>, 60<sup>th</sup>, 75<sup>th</sup> and 90<sup>th</sup> day.

#### Parameter for Assessment of Clinical Symptomatology:

##### (A). Subjective Parameters:

All the subjective parameters were graded 0, 1, 2, 3 (nil, mild, moderate & severe) on the basis of its intensity & severity given by patients on history taking & confirmed by clinical examination before starting the trial drugs.

##### B). Objective Criteria:

The quantitative analysis of the values of the **Serum Uric Acid** and **ESR** were done before & after the treatment and during the follow up to compare the inflammatory condition of the affected joints.

#### Criteria for assessment of result:

The results of the treatment were accessed on the basis of improvement in terms of:

1. Symptomatic Relief
2. Improvement in terms of Lab investigation i.e, decrease in Serum Uric Acid level and ESR value.

#### RESULT

The results of the present clinical trial were grouped as follows:

##### 1) Relieved:

- 1) Patients having > 75% relief in terms of symptoms.

ii) Normal range of pathological findings.

## 2) Improved:

i) Patients having improvement between 40-75% in clinical symptoms

**a) Mild Improvement-** Improvement between 40- <57.5% in clinical symptoms

**b) Moderate Improvement-** Improvement between 57.5-75% in clinical symptoms

ii) Pathological findings are improved but not within normal limit and may be up to higher side.

## 3) Unchanged:

i) Patients having improvement less than 40% in terms of clinical symptoms.

ii) Pathological findings remain same as before trial.

iii) Disease may reoccur.

## 4) Worsened:

i) Patients having no improvement in terms of clinical symptoms.

ii) Pathological findings gets disturbed (serum uric acid level may get increased).

iii) Disease may get worsen or symptoms may increased.

## Statistical tools:

The information gathered based on observation made about various parameters were subjected to statistical analysis in terms of **Mean (X)** and **Standard Deviation (SD)**.

For intragroup comparison **Wilcoxon signed rank test** and **Paired t-test** were used while for **intergroup** comparison **Mann Whitney test** and **Unpaired t-test** were used. The results calculated were interpret as below-

- Not significant :  $P > 0.05$
- Significant :  $P < 0.05$
- Very significant :  $P < 0.01$
- Extremely significant :  $P < 0.001$

## Observations

### (a) Demographic observations-

For the trial total 56 patients were registered. The demographic data was assessed for all the patients-

Patients were selected from age group of 21 to 60 years. It was found that the age group of 41 to 50 years comprises the maximum number of patients 21 (37.5%) followed by 20 (35.7%) from the age group 31 to 40 years and 11 (19.6%) from the age group 51 to 60 years while 21 to 30 years of age group have least number of patients 4 (7.1%). According to sex, 33 (58.9%) patients were male and 23 (41.1%) patients were female. Considering the relationship of the disease with the religion 44 (78.6%) patients were Hindu and 12 (21.4%) were Muslims and out of 56 patients 53 (94.60%) were married.

Occupation, educational status, economic status, residential & environmental condition plays a very important role in the causation of disease. 17 (30.405) were from service class, 18 (32.10%) from business class, 18 (32.10%) were housewives & only 3 (5.45) were students. Out of total 94.60% (53) patients were literate. High-income group were 34 (60.70%), medium class were 19 (34.0%) & only 3 (5.3%) were poor.

Most of the patients 53 (94.60%) were from urban area which strongly supports that *Vatarakta* is a disease of affluent people which supports its synonym '*Adhayavata*' of *Acharya Charak*.

Considering the diet and addiction habits of the patients, it was observed that 19 (33.90%) patients were vegetarian and 37 (66.10%) were having mixed diet pattern of diet. Out of 56 patients, 23 patients were having no addiction, 24 patients were addicted to tea/coffee, 9 were addicted to smoking, 8 were alcoholic and only 2 patients were addicted to tobacco chewing.

Considering the *Deha Prakriti* of the patients 26 (46.40%) were *Vata-Pittaj*, 19 (33.90%) patients were *Pitta-Kaphaj* and 11 (19.70%) patients were of *Vata-Kaphaj Prakriti*.

State of *Agni* and *Kostha Prakriti* when assessed before the trial, 34 (60.70%) patients were having *Vishmaggni*, 11 (19.60%) had *Mandagni*, 7 (12.50%) patient had *Samagni* and only 4 (7.2%) had *Tikshnagni*. Out of 56 patients, 39 (69.70%) had *Madhyama Kostha*, 11 (19.60%) had *Mridu Kostha* and 6 (10.70%) had *Krura Kostha*. Among these patients 23 (41.10%) had irregular bowel habit, 19 (33.90%) had regular bowel habit, 8 (14.70%) patient had tendency to pass hard stool while 6 (10.70%) passes loose stool.

Considering nature of work predominantly performed by patients and pattern of exercise they execute, working pattern of 21 (37.50%) were of standing nature, sitting in 18 (32.10%), walking in 13 (23.20%) and travelling type of work in only 4 (7.20%) patients. Among these patients 29 (51.80%) do not perform exercise, 20 (35.70%) perform exercise irregularly while only 7 (12.50%) patients were performing regular exercise.

Considering the associated illness and past history, maximum patients 39 (69.60%) had no associated illness, only 7 (12.50%) patient had hypertension and 7 (12.50%) had associated back pain & only 3 (5.4%) had hypothyroidism. 37 (66.0%) patient had no history of past illness, 11 (19.60%) patient had past history of Gout attack, 3 (5.40%) had history of UTI, 2 (3.60%) had renal stone in past, 2 (3.60%) had history of trauma and only 1 (1.8%) patient had history of cholelithiasis.

Considering the family history of disease, 15 (26.8%) patient had no family history of any disease but family history of gout in 14 (25.0%), osteoarthritis in 9 (16.0%), diabetes in 3 (5.4%), rheumatoid arthritis in 1 (1.8%) and diabetes in 1 (1.8%) patient as family history.

Considering the nature of onset & pattern of involvement of joints, 31 (55.40%) patients were having sudden onset and 25 (44.60%) were having insidious onset of disease. Ankle joint was the most common site of origin of disease, it was present in 22(46.8%) patients. 35 (62.50%) patients were having asymmetrical involvement of joint while 21 (37.50%) were having symmetrical involvement of joint.

Considering the initial joint involvement, in 20 (35.7%) patients metatarsophalangeal joint (great toe) was first joint to get involved, knee joint in 12 (21.4%), ankle joint in 11 (19.7%), other phalangeal joints in 7 (12.5%) and wrist joint in 6 (10.7%) patient was first joint to get involved.

### (b) Clinical observations-

Clinical Observation was done on 50 patients who completed the trial out of 56 patients selected and registered according to predetermined "Criteria of Selection".



**Table 1: Showing prevalence of sign and symptoms in 50 cases of Vatarakta before the use of trial drug**

| S. No. | Sign & Symptoms                                                            | No. of Patients |                | Total (n=50) | Percentage |
|--------|----------------------------------------------------------------------------|-----------------|----------------|--------------|------------|
|        |                                                                            | Group-A (n=25)  | Group-B (n=25) |              |            |
| 1      | <i>Sandhishu Ruk</i><br>(Pain in the affected joint)                       | 25              | 25             | 50           | 100%       |
| 2      | <i>Sandhishu Rag</i><br>(Redness in the affected joint)                    | 12              | 13             | 25           | 50%        |
| 3      | <i>Sandhishu Swathu</i><br>(Swelling in affected joint)                    | 25              | 25             | 50           | 100%       |
| 4      | <i>Sparsh-asahatvam</i><br>(Tenderness in affected area)                   | 25              | 25             | 50           | 100%       |
| 5      | <i>Sandhishu Kathinya</i><br>(Decreased/Restricted movements of Joints)    | 25              | 25             | 50           | 100%       |
| 6      | <i>Sandhishu Twagbahaya Tamra</i><br>(Skin discoloration of affected area) | 6               | 8              | 14           | 28%        |
| 7      | <i>Sandhishu Kandu</i><br>(Itching in the affected joint)                  | 10              | 12             | 22           | 44%        |
| 8      | <i>Sandhishu Daha</i><br>(Burning sensation in affected joint)             | 15              | 17             | 32           | 64%        |

## Result

Result calculated for 50 patients, 25 in each group who completed the trial. We observed that action of the drugs was slow, steady & progressive. The trial drugs had shown the effect in almost all the symptomatology. Effect of trial drugs over various symptoms are as follows-

### Effect of therapy on SANDHISHU RUK (Pain in the affected joint)

**Table 2: Comparison of change in Sandhishu Ruk before and after the trial**

| Time interval | Group A (n=25)                 |       | Group B (n=25)                 |       | Inter Group          |                      |
|---------------|--------------------------------|-------|--------------------------------|-------|----------------------|----------------------|
|               | Mean                           | ±SD   | Mean                           | ±SD   | z-value <sup>1</sup> | p-value <sup>1</sup> |
| Day 0         | 2.23                           | ±0.48 | 2.36                           | ±0.49 | -0.23                | 0.82                 |
| Day 90        | 0.72                           | ±0.61 | 0.48                           | ±0.59 | 1.26                 | 0.21                 |
| Mean Change   | 1.51±0.58                      |       | 1.88±0.44                      |       |                      |                      |
| % of relief   | 68.96%                         |       | 79.66%                         |       |                      |                      |
| Intra Group   | p-value <sup>2</sup> < 0.0001* |       | p-value <sup>2</sup> < 0.0001* |       |                      |                      |

<sup>1</sup>Mann-Whitney U test, <sup>2</sup>Wilcoxon signed rank test, \*Significant

### Effect of therapy on SANDHISHU RAG (redness in the affected joint)

**Table 3: Comparison of change in Sandhishu Rag before and after the trial**

| Time interval | Group A (n=12)                |       | Group B (n=13)                 |       | Inter Group          |                      |
|---------------|-------------------------------|-------|--------------------------------|-------|----------------------|----------------------|
|               | Mean                          | ±SD   | Mean                           | ±SD   | z-value <sup>1</sup> | p-value <sup>1</sup> |
| Day 0         | 2.00                          | ±0.85 | 2.08                           | ±0.64 | 0.19                 | 0.85                 |
| Day 90        | 0.42                          | ±0.51 | 0.23                           | ±0.44 | -0.76                | 0.45                 |
| Mean Change   | 1.58±0.79                     |       | 1.85±0.55                      |       |                      |                      |
| % of relief   | 79.00%                        |       | 88.94%                         |       |                      |                      |
| Intra Group   | p-value <sup>2</sup> = 0.001* |       | p-value <sup>2</sup> = 0.0002* |       |                      |                      |

<sup>1</sup>Mann-Whitney U test, <sup>2</sup>Wilcoxon signed rank test, \*Significant

### Effect of therapy on SANDHISHU SWATHU (Swelling in the affected joint)

**Table 4: Comparison of change in Sandhishu Swathu before and after the trial**

| Time interval | Group A (n=25)                 |       | Group B (n=25)                 |       | Inter Group          |                      |
|---------------|--------------------------------|-------|--------------------------------|-------|----------------------|----------------------|
|               | Mean                           | ±SD   | Mean                           | ±SD   | z-value <sup>1</sup> | p-value <sup>1</sup> |
| Day 0         | 1.56                           | ±0.58 | 1.68                           | ±0.69 | -0.47                | 0.63                 |
| Day 90        | 0.32                           | ±0.48 | 0.20                           | ±0.41 | 0.72                 | 0.47                 |
| Mean Change   | 1.24±0.44                      |       | 1.48±0.51                      |       |                      |                      |
| % of relief   | 79.50%                         |       | 88.10%                         |       |                      |                      |
| Intra Group   | p-value <sup>2</sup> < 0.0001* |       | p-value <sup>2</sup> < 0.0001* |       |                      |                      |

<sup>1</sup>Mann-Whitney U test, <sup>2</sup>Wilcoxon signed rank test, \*Significant

## Effect of therapy on SPARSH-ASHAHATVAM (Tenderness in the affected joint)

Table 5: Comparison of change in Sparsh-asahatvam before and after the trial

| Time interval | Group A (n=25)                 |       | Group B (n=25)                 |       | Inter Group          |                      |
|---------------|--------------------------------|-------|--------------------------------|-------|----------------------|----------------------|
|               | Mean                           | ±SD   | Mean                           | ±SD   | z-value <sup>1</sup> | p-value <sup>1</sup> |
| Day 0         | 1.88                           | ±0.73 | 2.12                           | ±0.60 | -1.12                | 0.26                 |
| Day 90        | 0.56                           | ±0.51 | 0.32                           | ±0.56 | 1.55                 | 0.12                 |
| Mean Change   | 1.32±0.63                      |       | 1.80±0.50                      |       |                      |                      |
| % of relief   | 70.20%                         |       | 84.90%                         |       |                      |                      |
| Intra Group   | p-value <sup>2</sup> < 0.0001* |       | p-value <sup>2</sup> < 0.0001* |       |                      |                      |

<sup>1</sup>Mann-Whitney U test, <sup>2</sup>Wilcoxon signed rank test, \*Significant

## Effect of therapy on SANDHISHU KATHINYA (Decreased/ Restricted movements of the affected joint)

Table 6: Comparison of change in Sandhishu Kathinya before and after the trial

| Time interval | Group A (n=25)                 |       | Group B (n=25)                 |       | Inter Group          |                      |
|---------------|--------------------------------|-------|--------------------------------|-------|----------------------|----------------------|
|               | Mean                           | ±SD   | Mean                           | ±SD   | z-value <sup>1</sup> | p-value <sup>1</sup> |
| Day 0         | 1.80                           | ±0.41 | 1.96                           | ±0.54 | -0.81                | 0.41                 |
| Day 90        | 0.52                           | ±0.59 | 0.36                           | ±0.59 | 0.92                 | 0.36                 |
| Mean Change   | 1.28±0.61                      |       | 1.64±0.58                      |       |                      |                      |
| % of relief   | 71.10%                         |       | 81.63%                         |       |                      |                      |
| Intra Group   | p-value <sup>2</sup> < 0.0001* |       | p-value <sup>2</sup> < 0.0001* |       |                      |                      |

<sup>1</sup>Mann-Whitney U test, <sup>2</sup>Wilcoxon signed rank test, \*Significant

## Effect of therapy on SANDHISHU TWAGBAHAYA TAMRA (Skin discoloration of affected area)

Table 7: Comparison of change in Sandhishu Twagbahaya Tamra before and after the trial

| Time interval | Group A (n=6)               |       | Group B (n=8)                  |       | Inter Group          |                      |
|---------------|-----------------------------|-------|--------------------------------|-------|----------------------|----------------------|
|               | Mean                        | ±SD   | Mean                           | ±SD   | z-value <sup>1</sup> | p-value <sup>1</sup> |
| Day 0         | 1.67                        | ±0.52 | 1.88                           | ±0.35 | 1.36                 | 0.17                 |
| Day 90        | 1.17                        | ±0.41 | 0.88                           | ±0.64 | -0.71                | 0.48                 |
| Mean Change   | 0.50±0.54                   |       | 1.0±0.53                       |       |                      |                      |
| % of relief   | 29.94%                      |       | 53.20%                         |       |                      |                      |
| Intra Group   | p-value <sup>2</sup> = 0.25 |       | p-value <sup>2</sup> = 0.0156* |       |                      |                      |

<sup>1</sup>Mann-Whitney U test, <sup>2</sup>Wilcoxon signed rank test, \*Significant

## Effect of therapy on SANDHISHU KANDU (Itching in the affected joint)

Table 8: Comparison of change in Sandhishu Kandu before and after the trial

| Time interval | Group A (n=10)                 |       | Group B (n=12)                 |       | Inter Group          |                      |
|---------------|--------------------------------|-------|--------------------------------|-------|----------------------|----------------------|
|               | Mean                           | ±SD   | Mean                           | ±SD   | z-value <sup>1</sup> | p-value <sup>1</sup> |
| Day 0         | 1.30                           | ±0.48 | 1.75                           | ±0.62 | 1.51                 | 0.13                 |
| Day 90        | 0.40                           | ±0.52 | 0.33                           | ±0.49 | -0.23                | 0.81                 |
| Mean Change   | 0.90±0.32                      |       | 1.42±0.51                      |       |                      |                      |
| % of relief   | 69.23%                         |       | 81.14%                         |       |                      |                      |
| Intra Group   | p-value <sup>2</sup> = 0.0039* |       | p-value <sup>2</sup> = 0.0005* |       |                      |                      |

<sup>1</sup>Mann-Whitney U test, <sup>2</sup>Wilcoxon signed rank test, \*Significant

## Showing effect of therapy on SANDHISHU DAHA (Burning sensation in the affected joint)

Table 9: Comparison of change in Sandhishu Daha before and after the trial

| Time interval | Group A (n=15)                 |       | Group B (n=17)                 |       | Inter Group          |                      |
|---------------|--------------------------------|-------|--------------------------------|-------|----------------------|----------------------|
|               | Mean                           | ±SD   | Mean                           | ±SD   | z-value <sup>1</sup> | p-value <sup>1</sup> |
| Day 0         | 1.53                           | ±0.64 | 1.59                           | ±0.71 | 0.11                 | 0.91                 |
| Day 90        | 0.40                           | ±0.51 | 0.24                           | ±0.44 | -0.77                | 0.44                 |
| Mean Change   | 1.13±0.74                      |       | 1.35±0.49                      |       |                      |                      |
| % of relief   | 73.85%                         |       | 84.94%                         |       |                      |                      |
| Intra Group   | p-value <sup>2</sup> = 0.0002* |       | p-value <sup>2</sup> < 0.0001* |       |                      |                      |

<sup>1</sup>Mann-Whitney U test, <sup>2</sup>Wilcoxon signed rank test, \*Significant

## Showing effect of therapy on SERUM URIC ACID (mg/dl)

Table 10: Comparison of change in Serum Uric Acid (mg/dl) before and after the trial

| Time interval | Group A (n=25)                                                |       | Group B (n=25)                                                 |       | Inter Group p-value <sup>1</sup> |
|---------------|---------------------------------------------------------------|-------|----------------------------------------------------------------|-------|----------------------------------|
|               | Mean                                                          | ±SD   | Mean                                                           | ±SD   |                                  |
| Day 0         | 8.43                                                          | ±1.65 | 8.22                                                           | ±1.47 | 0.64                             |
| Day 90        | 6.68                                                          | ±1.41 | 6.45                                                           | ±1.13 | 0.53                             |
| Mean Change   | 1.75±1.00                                                     |       | 1.78±0.77                                                      |       |                                  |
| % of Relief   | 20.76%                                                        |       | 21.53%                                                         |       |                                  |
| Intra Group   | t-value <sup>2</sup> = 8.72<br>p-value <sup>2</sup> < 0.0001* |       | t-value <sup>2</sup> = 11.45<br>p-value <sup>2</sup> < 0.0001* |       |                                  |

<sup>1</sup>Unpaired t test, <sup>2</sup>Paired t test \*SignificantShowing effect of therapy on ESR (mm/1<sup>st</sup> hrs. by Westerngreen Method)

Table 11: Comparison of change in ESR before and after the trial

| Time interval | Group A (n=25)                 |       | Group B (n=25)                 |       | Inter Group p-value <sup>1</sup> |
|---------------|--------------------------------|-------|--------------------------------|-------|----------------------------------|
|               | Mean                           | ±SD   | Mean                           | ±SD   |                                  |
| 0 Day         | 27.60                          | ±4.43 | 28.40                          | ±5.13 | 0.59                             |
| 90 Day        | 20.64                          | ±4.15 | 21.36                          | ±4.39 | 0.596                            |
| Mean Change   | 6.69±2.71                      |       | 7.04±2.83                      |       |                                  |
| % of Relief   | 25.22%                         |       | 24.79%                         |       |                                  |
| Intra Group   | p-value <sup>2</sup> < 0.0001* |       | p-value <sup>2</sup> < 0.0001* |       |                                  |

<sup>1</sup>Unpaired <sup>2</sup>Paired t-test \*Significant

## Showing effect of therapy on biochemical parameters

Table N12: Comparison of change in biochemical parameters before and after the trial

| Hb (gm/dl)                   |                                                     |          |                                                     |          |                                  |
|------------------------------|-----------------------------------------------------|----------|-----------------------------------------------------|----------|----------------------------------|
| Time interval                | Group A (n=25)                                      |          | Group B (n=25)                                      |          | Inter Group p-value <sup>1</sup> |
|                              | Mean                                                | ±SD      | Mean                                                | ±SD      |                                  |
| BT                           | 11.46                                               | ±0.90    | 11.40                                               | ±0.97    | 0.24                             |
| AT                           | 11.80                                               | ±0.82    | 11.68                                               | ±0.87    | 0.56                             |
| Intra Group                  | M.C. = -0.34±0.22<br>p-value <sup>2</sup> < 0.0001* |          | M.C. = -0.28±0.28<br>p-value <sup>2</sup> <0.0001*  |          |                                  |
| ESR (mm/hr.)                 |                                                     |          |                                                     |          |                                  |
| Time interval                | Group A (n=25)                                      |          | Group B (n=25)                                      |          | Inter Group p-value <sup>1</sup> |
|                              | Mean                                                | ±SD      | Mean                                                | ±SD      |                                  |
| BT                           | 27.60                                               | ±4.43    | 28.40                                               | ±5.13    | 0.59                             |
| AT                           | 20.64                                               | ±4.15    | 21.36                                               | ±4.39    | 0.596                            |
| Intra Group                  | M.C. = 6.96±2.71<br>p-value <sup>2</sup> < 0.0001*  |          | M.C. = 7.04±2.83<br>p-value <sup>2</sup> < 0.0001*  |          |                                  |
| TLC (cells/mm <sup>3</sup> ) |                                                     |          |                                                     |          |                                  |
| Time interval                | Group A (n=25)                                      |          | Group B (n=25)                                      |          | Inter Group p-value <sup>1</sup> |
|                              | Mean                                                | ±SD      | Mean                                                | ±SD      |                                  |
| BT                           | 10770                                               | ±1264.95 | 11070                                               | ±1105.59 | 0.56                             |
| AT                           | 10020                                               | ±824.35  | 10280                                               | ±1074.76 | 0.61                             |
| Intra Group                  | M.C. = 750±501.66<br>p-value <sup>2</sup> = 0.0011* |          | M.C. = 790±430.63<br>p-value <sup>2</sup> = 0.0003* |          |                                  |

<sup>1</sup>Unpaired t-test <sup>2</sup>Paired t-test \*Significant, M.C.= Mean Change

## Showing effect of therapy on DLC (Differential Leucocyte Count)

Table 13: Comparison of change in DLC before and after the trial

| NEUTROPHILS (%) |                                                     |       |                                                    |       |                                  |
|-----------------|-----------------------------------------------------|-------|----------------------------------------------------|-------|----------------------------------|
| Time interval   | Group A (n=25)                                      |       | Group B (n=25)                                     |       | Inter Group p-value <sup>1</sup> |
|                 | Mean                                                | ±SD   | Mean                                               | ±SD   |                                  |
| BT              | 75.30                                               | ±3.59 | 77.00                                              | ±4.03 | 0.996                            |
| AT              | 72.40                                               | ±2.22 | 73.20                                              | ±3.16 | 0.66                             |
| Intra Group     | M.C. = 2.90±1.45<br>p-value <sup>2</sup> < 0.0001*  |       | M.C. = 3.80±2.75<br>p-value <sup>2</sup> = 0.0018* |       |                                  |
| LYMPHOCYTES (%) |                                                     |       |                                                    |       |                                  |
| Time interval   | Group A (n=25)                                      |       | Group B (n=25)                                     |       | Inter Group p-value <sup>1</sup> |
|                 | Mean                                                | ±SD   | Mean                                               | ±SD   |                                  |
| BT              | 22.70                                               | ±5.29 | 21.00                                              | ±4.00 | 0.81                             |
| AT              | 25.90                                               | ±4.07 | 24.70                                              | ±2.98 | 0.75                             |
| Intra Group     | M.C. = -3.20±1.81<br>p-value <sup>2</sup> = 0.0003* |       | M.C. = -3.70±4.14<br>p-value <sup>2</sup> = 0.02*  |       |                                  |
| EOSINOPHILS (%) |                                                     |       |                                                    |       |                                  |
| Time interval   | Group A (n=25)                                      |       | Group B (n=25)                                     |       | Inter Group p-value <sup>1</sup> |
|                 | Mean                                                | ±SD   | Mean                                               | ±SD   |                                  |
| BT              | 1.70                                                | ±0.95 | 0.90                                               | ±0.74 | 2.10                             |
| AT              | 1.40                                                | ±0.52 | 1.10                                               | ±0.88 | 0.93                             |
| Intra Group     | M.C. = 0.30±0.82<br>p-value <sup>2</sup> = 0.28     |       | M.C. = -0.20±0.92<br>p-value <sup>2</sup> = 0.51   |       |                                  |
| MONOCYTES (%)   |                                                     |       |                                                    |       |                                  |
| Time interval   | Group A (n=25)                                      |       | Group B (n=25)                                     |       | Inter Group p-value <sup>1</sup> |
|                 | Mean                                                | ±SD   | Mean                                               | ±SD   |                                  |
| BT              | 0.90                                                | ±0.74 | 0.50                                               | ±0.53 | 1.39                             |
| AT              | 1.10                                                | ±0.74 | 0.70                                               | ±0.82 | 1.14                             |
| Intra Group     | M.C. = -0.20±0.92<br>p-value <sup>2</sup> = 0.51    |       | M.C. = -0.20±0.42<br>p-value <sup>2</sup> = 0.17   |       |                                  |
| BASOLHILS (%)   |                                                     |       |                                                    |       |                                  |
| Time interval   | Group A (n=25)                                      |       | Group B (n=25)                                     |       | Inter Group p-value <sup>1</sup> |
|                 | Mean                                                | ±SD   | Mean                                               | ±SD   |                                  |
| BT              | 0.30                                                | ±0.48 | 0.20                                               | ±0.42 | 0.49                             |
| AT              | 0.20                                                | ±0.42 | 0.30                                               | ±0.48 | 0.49                             |
| Intra Group     | M.C. = 0.10±0.74<br>p-value <sup>2</sup> = 0.68     |       | M.C. = -0.10±0.57<br>p-value <sup>2</sup> = 0.59   |       |                                  |

<sup>1</sup>Unpaired t-test <sup>2</sup>Paired t-test \*Significant, M.C= Mean Change

## Showing effect of therapy on Blood Sugar (F/PP)

Table 14: Comparison of change in Blood Sugar (F/PP) before and after the trial

| Fasting B. Sugar (mg/dl)       |                                                 |        |                                                  |        |                                  |
|--------------------------------|-------------------------------------------------|--------|--------------------------------------------------|--------|----------------------------------|
| Time interval                  | Group A (n=25)                                  |        | Group B (n=25)                                   |        | Inter Group p-value <sup>1</sup> |
|                                | Mean                                            | ±SD    | Mean                                             | ±SD    |                                  |
| BT                             | 85.60                                           | ±13.19 | 84.00                                            | ±16.22 | 0.24                             |
| AT                             | 83.10                                           | ±12.88 | 81.00                                            | ±12.45 | 0.37                             |
| Intra Group                    | M.C.= 2.5±2.46<br>p-value <sup>2</sup> = 0.67   |        | M.C.= 3.0±6.05<br>p-value <sup>2</sup> = 0.15    |        |                                  |
| Post Prandial B. Sugar (mg/dl) |                                                 |        |                                                  |        |                                  |
| Time interval                  | Group A (n=25)                                  |        | Group B (n=25)                                   |        | Inter Group p-value <sup>1</sup> |
|                                | Mean                                            | ±SD    | Mean                                             | ±SD    |                                  |
| BT                             | 140                                             | ±20.81 | 141                                              | ±19.71 | 0.15                             |
| AT                             | 133.50                                          | ±23.72 | 134                                              | ±18.38 | 0.12                             |
| Intra Group                    | M.C.= 6.5±5.10<br>p-value <sup>2</sup> = 0.003* |        | M.C.= 6.8±4.24<br>p-value <sup>2</sup> = 0.0007* |        |                                  |

<sup>1</sup>Unpaired t-test <sup>2</sup>Paired t-test \*Significant, M.C.= Mean Change



## Showing effect of therapy on Kidney Function Test (KFT)

Table 15: Comparison of change in Kidney Function Test (KFT) before and after the trial

| B. Urea (mg/dl)       |                                                   |       |                                                   |       |                                  |
|-----------------------|---------------------------------------------------|-------|---------------------------------------------------|-------|----------------------------------|
| Time interval         | Group A (n=25)                                    |       | Group B (n=25)                                    |       | Inter Group p-value <sup>1</sup> |
|                       | Mean                                              | ±SD   | Mean                                              | ±SD   |                                  |
| BT                    | 27.56                                             | ±3.19 | 30.03                                             | ±5.84 | 1.17                             |
| AT                    | 24.54                                             | ±2.93 | 26.27                                             | ±5.02 | 0.99                             |
| Intra Group           | M.C.= 3.02±1.32<br>p-value <sup>2</sup> < 0.0001* |       | M.C.= 3.67±1.97<br>p-value <sup>2</sup> = 0.0002* |       |                                  |
| S. Creatinine (mg/dl) |                                                   |       |                                                   |       |                                  |
| Time interval         | Group A (n=25)                                    |       | Group B (n=25)                                    |       | Inter Group p-value <sup>1</sup> |
|                       | Mean                                              | ±SD   | Mean                                              | ±SD   |                                  |
| BT                    | 0.95                                              | ±0.17 | 1.06                                              | ±0.29 | 1.04                             |
| AT                    | 0.86                                              | ±0.13 | 0.93                                              | ±0.18 | 0.99                             |
| Intra Group           | M.C.= 0.09±0.10<br>p-value <sup>2</sup> = 0.019*  |       | M.C.= 0.13±0.19<br>p-value <sup>2</sup> = 0.03*   |       |                                  |

<sup>1</sup>Unpaired t-test <sup>2</sup>Paired t-test \*Significant, M.C.= Mean Change

## Showing effect of therapy on Liver Function Test (LFT)

Table 16: Comparison of change in Liver Function Test (LFT) before and after the trial

| S. Bilirubin (mg/dl)           |                                                 |        |                                                    |        |                                  |
|--------------------------------|-------------------------------------------------|--------|----------------------------------------------------|--------|----------------------------------|
| Time interval                  | Group A (n=25)                                  |        | Group B (n=25)                                     |        | Inter Group p-value <sup>1</sup> |
|                                | Mean                                            | ±SD    | Mean                                               | ±SD    |                                  |
| BT                             | 0.84                                            | ±0.26  | 0.79                                               | ±0.30  | 0.396                            |
| AT                             | 0.68                                            | ±0.14  | 0.70                                               | ±0.22  | 0.246                            |
| Intra Group                    | M.C.= 0.16±0.18<br>p-value <sup>2</sup> = 0.02* |        | M.C.= 0.09±0.12<br>p-value <sup>2</sup> = 0.04*    |        |                                  |
| S. Alkaline Phosphatase (IU/L) |                                                 |        |                                                    |        |                                  |
| Time interval                  | Group A (n=25)                                  |        | Group B (n=25)                                     |        | Inter Group p-value <sup>1</sup> |
|                                | Mean                                            | ±SD    | Mean                                               | ±SD    |                                  |
| BT                             | 208                                             | ±45.90 | 223                                                | ±49.62 | 0.71                             |
| AT                             | 175                                             | ±19.10 | 200.10                                             | ±42.12 | 1.71                             |
| Intra Group                    | M.C.= 33±32.27<br>p-value <sup>2</sup> = 0.01*  |        | M.C.= 22.90±17.09<br>p-value <sup>2</sup> = 0.002* |        |                                  |
| SGOT (IU/L)                    |                                                 |        |                                                    |        |                                  |
| Time interval                  | Group A (n=25)                                  |        | Group B (n=25)                                     |        | Inter Group p-value <sup>1</sup> |
|                                | Mean                                            | ±SD    | Mean                                               | ±SD    |                                  |
| BT                             | 30.10                                           | ±8.17  | 29.10                                              | ±8.28  | 0.27                             |
| AT                             | 27.40                                           | ±5.75  | 25.70                                              | ±4.85  | 0.71                             |
| Intra Group                    | M.C.= 2.7±3.37<br>p-value <sup>2</sup> = 0.03*  |        | M.C.= 3.4±4.11<br>p-value <sup>2</sup> = 0.028*    |        |                                  |
| SGPT (IU/L)                    |                                                 |        |                                                    |        |                                  |
| Time interval                  | Group A (n=25)                                  |        | Group B (n=25)                                     |        | Inter Group p-value <sup>1</sup> |
|                                | Mean                                            | ±SD    | Mean                                               | ±SD    |                                  |
| BT                             | 27.90                                           | ±5.59  | 31.60                                              | ±3.78  | 1.73                             |
| AT                             | 24.10                                           | ±3.28  | 28.80                                              | ±2.35  | 3.68                             |
| Intra Group                    | M.C.= 3.8±3.46<br>p-value <sup>2</sup> = 0.007* |        | M.C.= 2.8±1.62<br>p-value <sup>2</sup> = 0.0004*   |        |                                  |

<sup>1</sup>Unpaired t-test <sup>2</sup>Paired t-test \*Significant, M.C.= Mean Change

## Overall assessment of the result:

The result was assessed on the basic of symptomatic relief and improvement in terms of lab investigation. The efficacy of the drugs was divided in following categories-

1. Relieved (>75% relieve in all terms)
2. Moderate Improvement (75-57.5% relieve in all terms)
3. Mild Improvement (<57.5-40% relieve in all terms)
4. Unchanged (<40 % relief)
5. Worsens

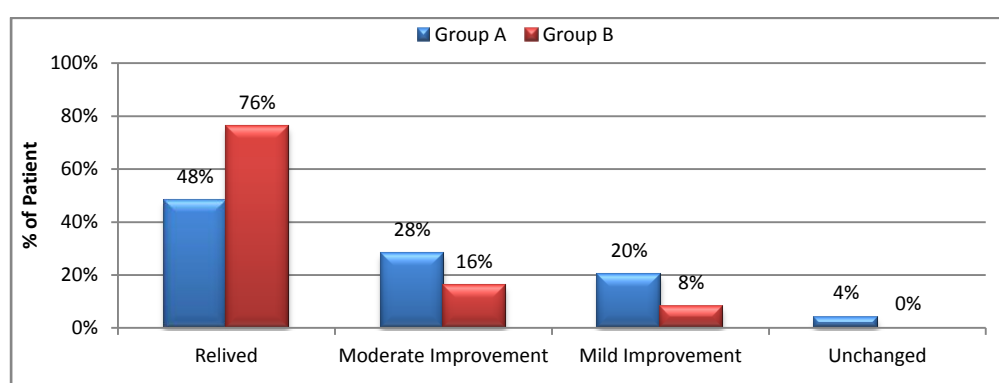
Table 17: Overall assessment of patients after the treatment

| Group          | Relieved<br>(>75% relief) |       | Improved                      |       |                            |       | Unchanged<br>(< 40% relief) |      |
|----------------|---------------------------|-------|-------------------------------|-------|----------------------------|-------|-----------------------------|------|
|                |                           |       | Moderate<br>(75-57.5% relief) |       | Mild<br>(<57.5-40% relief) |       |                             |      |
|                | No. of pts.               | %     | No. of pts.                   | %     | No. of pts.                | %     | No. of pts.                 | %    |
| Group A (n=25) | 12                        | 48.0% | 7                             | 28.0% | 5                          | 20.0% | 1                           | 4.0% |
| Group B (n=25) | 19                        | 76.0% | 4                             | 16.0% | 2                          | 8%    | 0                           | 0%   |

In group 'A' 12 (48.0%) patients were relieved, 7 (28.0%) patients were moderately improved, 5 (20.0%) patient were mildly improved and 1 (4.0%) patient did not show any response by administration of drug therapy.

In group 'B' 19 (76.0%) patients were relieved, 4 (16.0%) patients were moderately improved, 2 (8.0%) patient were mildly improved by administration of drug therapy. There was no case recorded in unchanged group and worsen group.

The overall relived was higher in group 'B' (76.0%) compared to group 'A' (48.0%). The moderately improved class was higher in group 'A' (28.0%) than group 'B' (16.0%) also the mildly improved class was higher in group 'A' (20.0%) than group 'B' (8.0%). In group 'A' one patient was recorded as unchanged while no patient was recorded as unchanged in group 'B'.



Graph 1: Showing overall assessment of patients after treatment in both the groups

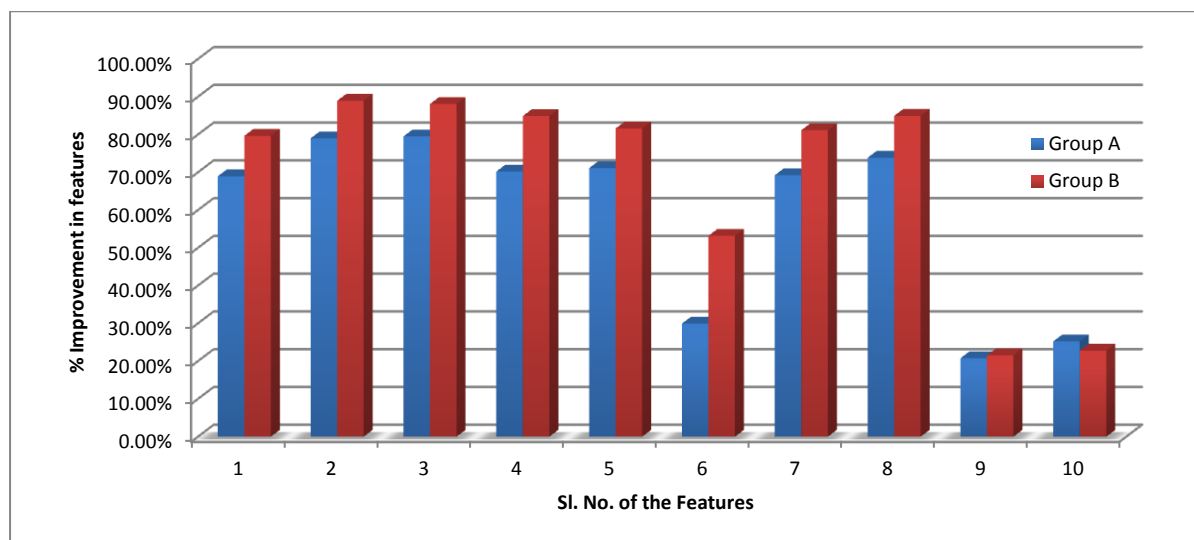
## DISCUSSION

Aim of this clinical trial entitled as "A clinical study to evaluate the efficacy of *Patoladi Kwatha* (*Su. Chi.*) with & without *Rasnadi Pradeh* (*Ch. Su.*) in cases of *Vatarakta* (w.s.r. to Gouty arthritis)" was to do comparative clinical evaluation of *Rasnadi Pradeh* as local application in cases of *Vatarakta* with special reference to gouty arthritis. Result calculated for

50 patients, 25 in each group who completed the trial. We observed that action of the drugs was slow, steady & progressive. The trial drug in both group had shown the effect in almost all the symptomatology but the overall relief was higher in group 'B'

Table 18: Summarization of improvement in all features

| S. N. | Features                                                                   | Percentage of relief |         |
|-------|----------------------------------------------------------------------------|----------------------|---------|
|       |                                                                            | Group A              | Group B |
| 1.    | <i>Sandhishu Ruka</i><br>(Pain in the affected joint)                      | 68.96 %              | 79.66 % |
| 2.    | <i>Sandhishu Raga</i><br>(Redness in the affected joint)                   | 79.00 %              | 88.94 % |
| 3.    | <i>Sandhishu Swathu</i><br>(Swelling in affected joint)                    | 79.50%               | 88.10 % |
| 4.    | <i>Sparsh-ashatvam</i><br>(Tenderness in affected area)                    | 70.20 %              | 84.90 % |
| 5.    | <i>Sandhishu Kathinya</i><br>(Decreased/Restricted movements of Joints)    | 71.10 %              | 81.63 % |
| 6.    | <i>Sandhishu Twagbahaya Tamra</i><br>(Skin discoloration of affected area) | 29.94 %              | 53.20 % |
| 7.    | <i>Sandhishu Kandu</i><br>(Itching in the affected joint)                  | 69.23 %              | 81.14 % |
| 8.    | <i>Sandhishu Daha</i><br>(Burning sensation in affected joint)             | 73.85 %              | 84.94 % |
| 9.    | Serum Uric acid (mg/dl)                                                    | 20.76 %              | 21.53 % |
| 10.   | ESR mm/1 <sup>st</sup> hrs. (Westerngreen Method)                          | 25.22 %              | 24.79 % |



Graph 2: Showing Percentage of improvement in different Features

### Probable mode of action of Trial drugs:

In *Ayurveda*, the action of the drug is determined by Pharmacodynamic factors like *Rasa*, *Guna*, *Veerya* and *Vipaka* and some special property called as *Prabhava*, which cannot be explained on by four pharmacodynamic factors. These factors work against the *Dosha* and *Dushya* to break the

pathogenesis (*Samprapti Vighatana*) causing relief in symptoms.

### 1. Patoladi Kwath-

**Contents** – *Patol Patra*, *Trifla* (*Haritaki*, *Vibhitaki*, *Amalki*), *Satavari*, *Guduchi* & *Katuki*.

Table 19: Properties of different ingredients of the *Patoladi Kwath*

| Name of drug             | Patol                       | Amalaki                                      | Haritaki                                        | Vibhitaki                               | Satavari                   | Guruchi                               | Kutki                                       |
|--------------------------|-----------------------------|----------------------------------------------|-------------------------------------------------|-----------------------------------------|----------------------------|---------------------------------------|---------------------------------------------|
| Latin name               | <i>Trichosanthes dioica</i> | <i>Embolica officinalis</i>                  | <i>Terminalia chebula</i>                       | <i>Terminalia bellirica</i>             | <i>Asparagus racemosus</i> | <i>Tinospora cordifolia</i>           | <i>Picrorhiza kurroa</i>                    |
| Family                   | Cucurbitaceae               | Euphorbiaceae                                | Combretaceae                                    | Combretaceae                            | Liliaceae                  | Menispermaceae                        | Scrophulariaceae                            |
| Part used                | Leaf                        | Fruit                                        | Fruit                                           | Fruit                                   | Root                       | Stem                                  | stem                                        |
| Rasa                     | Tikta                       | Pancha rasa except lavana, amla rasa pradhan | Pancha rasa except lavana, kashaya rasa pradhan | Kashaya                                 | Madhur, Tikta              | Tikta, Kashaya                        | Tikta                                       |
| Guna                     | Laghu, ruksha               | Guru, ruksha, sheet                          | Laghu, ruksha                                   | Ruksha, laghu                           | Guru, snigdha              | Guru, snigdha                         | Ruksha, laghu                               |
| Veerya                   | Ushna                       | Sheet                                        | Ushna                                           | Ushna                                   | Sheet                      | Ushna                                 | Sheet                                       |
| Vipak                    | Katu                        | Madhur                                       | Madhur                                          | Madhur                                  | Madhur                     | Madhur                                | Katu                                        |
| Chemical properties      | —                           | Gallic acid, Tannic acid, Calcium, Vit-C     | Chebulagic acid, Chebulinic acid                | Chebolic acid, Gallic acid, Tannic acid | Saponin                    | Berberin, Geloins                     | Picrorrhizin, Kutkin, Kutkiol, Kutikisterol |
| Prabhav (special action) | Saravdosha shamak           | Saravdosha shamak mainly pitta shamak        | Saravdosha shamak mainly vatashamak             | Saravdosha shamak mainly kaphashamak    | Vata pitta shamak          | Saravdosha shamak mainly pitta shamak | Kaph pitta shamak                           |

*Patol Patra* is *Pitta Shamak*, *Haritaki* is *Vatarakta Nashak* & has anti-arthritis action<sup>11</sup>. *Vibhitaki* cures *Dhatu-Gata Dosha* & has analgesic effect<sup>12</sup>. *Amalki* is a *Rasayan*, *Pitta Shamak*, uricosuric due to presence of Vit-C & causes immunomodulation<sup>13</sup>. *Satavari* is *Balya* & *Vata-Pitta-Rakta Janya Shopha Nashak*, has anti-urolithic action<sup>14</sup> & causes immunomodulation<sup>15</sup>, *Guduchi* is best drug to cure *Vatarakta*, it is *Tridosha Shamak*, it contains *Tinosporin* which has anti-

uremic action<sup>16</sup> & its anti-inflammatory action resemble to NSAIDs<sup>17</sup>. *Katuki* is *Lekhaniya* & *Bhedaniya* which eliminates *Doshas* from the body, has *Shoth*, *Daha*, *Kusth Nashak* property & has anti-inflammatory property<sup>18</sup>.

### 2. Rasnadi Pradeh-

**Contents**– *Rasna Patra*, *Guduchi*, *Yastimadhu*, *Bala*, *Atibala* And *Vidari*

Table 20: Properties of different ingredients of the *Rasnadi Pradeh*

| Name of drug                    | Rasna                             | Guruchi                               | Yastimadhu                                         | Bala                           | Atibala                 | Vidari            |
|---------------------------------|-----------------------------------|---------------------------------------|----------------------------------------------------|--------------------------------|-------------------------|-------------------|
| <b>Latin name</b>               | Pluchea lanceolata                | Tinospora cordifolia                  | Glycyrrhiza globera                                | Sida cordifolia                | Abutilon indicum        | Pueraria tuberosa |
| <b>Family</b>                   | Compositae                        | Menispermaceae                        | Leguminosae                                        | Malvaceae                      | Malvaceae               | Leguminosae       |
| <b>Part used</b>                | Leaf                              | Stem                                  | Root                                               | Root                           | Root                    | Rhizome           |
| <b>Rasa</b>                     | Tikta                             | Tikta, kashaya                        | Madhur                                             | Madhur                         | Madhur                  | Madhur            |
| <b>Guna</b>                     | Guru                              | Guru, snigdha                         | Guru, snigdha                                      | Laghu, snigdha, picchil        | Laghu, snigdha, picchil | Guru, snigdha     |
| <b>Veerya</b>                   | Ushna                             | Ushna                                 | Sheet                                              | Sheet                          | Sheet                   | Sheet             |
| <b>Vipak</b>                    | Katu                              | Madhur                                | Madhur                                             | Madhur                         | Madhur                  | Madhur            |
| <b>Chemical properties</b>      | Quersitine, Isoraimnetin, Pluchin | Berberin, Giloin                      | Glycyrrhizin, Isoliquiritin, Liquiritin, Asparagin | Ephedrine, Sterol, Phytosterol | Asparagin               | Carbohydrate      |
| <b>Prabhav (special action)</b> | Vata kapha shamak                 | Saravdosha shamak mainly pitta shamak | Vata pitta shamak                                  | Vata pitta shamak              | Vata pitta shamak       | Vata pitta shamak |

It was used for local application. *Rasna* is best *Vata Shamak* drug, it is *Shotha*, *Shoola* & *Vedanahar*. *Guduchi* is best drug to cure *Vatarakta*, it is *Tridosha Shamak* and contains *Tinosporin* whose anti-inflammatory action resemble to NSAIDs<sup>17</sup>. *Yastimadhu* is a potent *Shophya* & *Shotha Nashak*, has good anti-inflammatory<sup>19</sup> & analgesic action<sup>20</sup> when used locally. *Bala* & *Atibala* both are *Balya*, *Vatahar*, *Vatarakta Nashak* & has anti-inflammatory, analgesic property<sup>21,22</sup>. *Atibala* also has good anti-arthritis action<sup>23</sup>. *Vidari Kand* is *Balya*, *Vata-Pitta-Rakta Janya Shophya Nashak*, *Daha Shamak*, *Mutral* & has immunomodulatory action<sup>24</sup>. *Godugdha* and *Goghrit* both are *Vatapitta* & *Daha Shamak*. *Madhuchhista* is a potent *Vatarakta Nashak* & also cures *Kandu*, *Kustha* & *Vrana*.

Due to above properties both the selected drugs seem to be effective in *Vatarakta*.

## CONCLUSION

- The drugs used in Trial are **Patoladi Kwath** which was given orally in both the groups and **Rasnadi Pradeh** which was given for local application in group B only.
- The trial drugs were given in 50 selected patients (25 in each group) & it was observed that the effect of drugs was high on the symptoms of pain (*Sandhishu Ruk*), redness (*Sandhishu Rag*), swelling (*Sandhishu Swathu*), tenderness (*Sparsh-ashahatvam*), stiffness (*Sandhishu Kathinya*), itching (*Sandhishu kandu*) and burning sensation (*Sandhishu daha*). Grade of all these symptoms shows statistically significant ( $p < 0.05$ ) decrease in both the groups but the response was slightly higher in group 'B' than group 'A'.
- Rasnadi Pradeh* is useful in cases of both Acute Gouty Arthritis as well as Chronic Gouty Arthritis because along with good result in pain, redness, swelling it also showed good result in itching & discoloration.
- Estimation of change in Serum Uric acid (Percent change of 20.67% in group A & 21.53% in group B) & ESR (Percent change of 25.22% in group A & 24.79% in group B) was statistically significant in both the groups.
- The trial drugs probably showed- analgesic (*Vednahara*), anti-inflammatory (*Shothahara*), blood purifier (*Rakta Prasadak*), immunomodulator, uricosuric effects, etc. Drug used for local application

also showed good effect on *Daha* (burning), *Kandu* (itching), etc.

- Trial drugs were well accepted & tolerated with good positive response except increased frequency of passage of stool in few cases. Probably *Haritaki* and *Katuki* in *Patoladi Kwath* has slight *kostha sodhak* property due to which 2 patient having *mandagni* and loose type of bowel habit complained of increased frequency of passage of stool & hence were withdrawn. So the dose of the drug should be titrated according to nature of *kosthagni*, type of *kostha* and type of bowel habit of patient in further trial. Other than increased frequency of passage of stool in few cases, the trial drug did not show any other major side effect regarding clinical and pathological parameters.
- It is suggested that both the drugs should be tested in large scale for the long duration trial and these drugs may prove a valuable contribution from Ayurveda towards the ailing humanity.

## REFERENCES

- Sushrut Samhita "Ayurvedatatwasandipika" by Kaviraj Ambikadatta Shastri; Chaukhamba Sanskrit sansthan, 2nd edition, 2010. Chikitsa Sthanam Adhyay 15/48
- Charaka Samhit "Savimarshvidyotini" commentary by Pt. Kashinath Pandey and Dr. Gorakhnath Chaturvedi; Chaukhamba bharti academy, 9th edition, 2008. Sutra Sthanam Adhyay 1/15
- Charaka Samhit "Savimarshvidyotini" commentary by Pt. Kashinath Pandey and Dr. Gorakhnath Chaturvedi; Chaukhamba bharti academy, 9th edition, 2008. Chikitsa Sthanam Adhyay 29/10
- Sushrut Samhita "Ayurvedatatwasandipika" by Kaviraj Ambikadatta Shastri; Chaukhamba Sanskrit sansthan, 2nd edition, 2010. Nidan Sthanam Adhyay 1/48
- Charaka Samhit "Savimarshvidyotini" commentary by Pt. Kashinath Pandey and Dr. Gorakhnath Chaturvedi; Chaukhamba bharti academy, 9th edition, 2008. Chikitsa Sthanam Adhyay 29/20, 21, 22, 23
- Sushrut Samhita "Ayurvedatatwasandipika" by Kaviraj Ambikadatta Shastri; Chaukhamba Sanskrit sansthan, 2nd edition, 2010. Chikitsa Sthanam Adhyay 5/9
- Charaka Samhit "Savimarshvidyotini" commentary by Pt. Kashinath Pandey and Dr. Gorakhnath Chaturvedi; Chaukhamba bharti academy, 9th edition, 2008. Sutra Sthanam Adhyay 3/22
- Sharangdhara Samhita "Jiwanprada" Hindi Commentary by Dr. Smt. Shailja Srivastava: Chaukhamba Orientalia, Varanasi, Reprint Edition 2009. Madhyam Khand Adhyay 2/1

9. Bhavaprakash by Shri Haridhar Prasad Pande, Chowkhamba Sanskrit sansthan, 5<sup>th</sup> edition 1993. Haritkyadi Varga Shloka 146
10. Sharangdhara Samhita "Jiwanprada" Hindi Commentary by Dr. Smt. Shailja Srivastava: Chaukhamba Orientalia, Varanasi, Reprint Edition 2009. Madhyam Khand Adhyay 3/22
11. Nair V, Singh S, Gupta YK. Anti-arthritic and disease modifying activity of *Terminalia chebula* Retz. in experimental models. J Pharm Pharmacol. 2010; 62(12):1801-06
12. Sharma SU, Sharma US, Singh A, Sutar N, Singh PJ. Screening of *Terminalia bellirica* fruits extracts for its Analgesic and Antipyretic Activities. Jordan J of Bio Sci. 2010; 3(3):121-4.
13. Ganju, L., D. Karan, S. Chanda, K.K. Srivastava, R.C. Sawhney and W. Selvamurthy, Immunomodulatory effects of agents of plant origin. Biomed Pharmacother., 2003; 57(7):296-300.
14. Narumalla J, Somashekara SC, Damodaram G, Golla D, Study of antiurolithiatic activity of *Asparagus racemosus* on albino-rats, 2012; 44:576-579.
15. Dhuley JN, Effect of some Indian herbs on macrophage functions in ochratoxin-A treated mice. J. Ethnopharmacol., 1997, 58: 15-20.
16. Singh K P, Gupta A S, Pende V K, Mahatma M M, Experimental and Clinical Studies on *Tinospora cordifolia*, J Res Ind Med, 1975; 10(1):9.
17. Pandey SC, Singh SS, Srivastava S, Gupta VG, Patro B, Ghos AC, Chemistry & medicinal properties of *T. cordifolia*, Indian Journal of Pharmacology 2003; 35:83-91.
18. Simons JM, 't Hart BA, Ip Vai Ching TR, et al. Metabolic activation of natural phenols into selective oxidative burst agonists by activated human neutrophils. Free Radic Biol Med 1990;8:251-258
19. Visavadiya NP, Soni B, Dalwadi N. Evaluation of antioxidant and anti-atherogenic properties of *Glycyrrhiza glabra* root using In vitro models. International Journal of Food Sciences and Nutrition 2009; 60(2):135-149.
20. Korhalkar A, Deshpande Manasi, Lele Priya, Modak meera: A comprehensive review an threapeutic potential of *Glycyrrhiza glabra* in treatment of various disorders: An international Research Journal of Pharmacy & Plant Science Vol (2) Issue 1, No/Dec 2013.
21. Jain A, Choubey S, Singour OK, RajaK, Pawar RS. *Sida cordifolia* (Linn) – An overview. Journal of Applied Pharmaceutical Science 01 (02); 2011: 23-31.
22. Rajurkar R, Jain R, Matake N, Aswar P, Khadbadi SS, Antiinflammatory Action of *Abutilon indicum* (L.) Sweet Leaves by HRBC Membrane Stabilization. Research Journal of pharmacy and Technology, 2(2), 2009, 415-416.
23. Deshpande V, Jadhav VM, Kadam VJ, In-vitro anti-arthritic activity of *Abutilon indicum* (Linn.) Sweet, Journal of Pharmacy Research, 2009; 2(4):644-645.
24. Sawale PD, Singh RRB, Kapil S, Arora S, Rastogi S, Rawat AKS; International Journal of Dairy Technology; 2013; 66(2):202206.

