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### **Original Research**

## Traditional Ashtavaidyan Ayurvedic Therapy in the Functional Improvement of Patients with Gouty Arthritis

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#### Abstract

In this study, 30 patients of both the sexes having 20-60 years age, diagnosed on the basis of both objective and subjective parameters as of gouty arthritis were treated at IPD (21 days) and OPD levels (21 days). Initially the inpatients were subjected to modified Shastika-Shali-Pinda Sveda for 14 days followed by Abhyanga with Pinda Taila for next 7 days and simultaneously internal medicines comprising of Varunadi Kahaya (100 ml twice a day), Chandra-Prabha Gutika (1 tablet twice a day) and Kokilakshakam Toyam (1 liter/day for drinking in place of water) was given. Thereafter they were treated at OPD level and were asked to continue the same internal medicine along with daily application of Pinda Taila all over the body and Balaguluchyadi Taila over scalp for the next 21 days.

The results of this study showed significant reduction in serum uric acid and significant improvement in functional parameters, evaluated by using the DAS-28 score, disability index, SF-36 (quality of life index) and global assessment of disease activity scale. The laboratory parameters used to evaluate the liver and kidney functions indicated that the prescribed treatment is safe.

Keywords: Gouty arthritis, uric acid, Vatarakta, Shastika-Shali-Pinda Sveda, Varunadi Kashaya, Kokilakshaka, Pinda-Taila

#### INTRODUCTION:

Gout is an inflammatory disease characterized by episodic acute and chronic arthritis, due to deposition of monosodium urate in and around synovial joints. The prevalence of gout varies between populations but is approximately 1-2%, with 5:1 male preponderance.2 Lifestyle factors, such as a diet with high-purine foods, obesity and excessive alcohol use, especially, heavy beer can contribute to development of consumption hyperuricemia and gout.<sup>3</sup> The classical presentation is with an acute mono-arthritis, which in over 50% of cases affects the first metatarsophalangeal (MTP joint). Other common sites are ankle, mid-foot, knee, small joints of hands, wrist and elbow.4 Crystals may deposit in the joints and soft tissues to produce irregular firm nodules called tophi<sup>5</sup> which has a white color and can ulcerate leading to discharging of white gritty material, become infected or induce a local inflammatory response, with erythema and pus in the absence of secondary infection.<sup>6</sup>

The diagnosis of gout can be confirmed by the identification of urate crystals in the aspirate from joint, bursa or tophus. A biochemical screening, including renal function, uric acid, glucose and lipid profile, is essential because of the association with metabolic syndrome. <sup>7-8</sup>

The mainstay of treatment during an acute attack is the administration of anti-inflammatory drugs such as nonsteroidal anti-inflammatory drugs (NSAIDs), colchicine or glucocorticoids.

Classical Ayurvedic description of the etiopatogenesis and clinical features of Vatarakta can be correlated to the description of gouty arthritis and on critical analysis of the signs and symptoms it may be diagnosed as Pittadhika Vatarakta.

In this study, traditional line of management of Ashtavaidyan comprising of combined internal and external therapeutic procedures has been taken up to evaluate their effectiveness and safety in Vatarakta (gouty arthritis). The course of treatment includes Shashtika Pinda Sveda (Sataila Navarakizhi) and Abhyanga with Pinda Taila<sup>10</sup> along with Shirobhyanga by Balaguluchyadi Taila<sup>11</sup> and Varanadi Kashaya<sup>12</sup>, Chandraprabhavati<sup>13</sup> and Kokilakshaka choorna<sup>14</sup> Toyam administered internally.

#### AIMS:

Evaluation of efficacy and safety of traditional line of management of Ashtavaidyan comprising of combined internal and external therapeutic procedures

#### METHODOLOGY

This single centered clinical study was conducted at Vaidyaratnam Ayurveda foundation hospital Ollur in years 2011-16 with approval of the institutional ethics committee and was registered with clinical trial registry of India (CTRI/2018/10/015930). The protocol of the study and the case report form was prepared as per direction by C C R A S, New Delhi.

30 patients having the clinical features of gouty arthritis such as pain, burning sensation, tenderness, swelling, reddish discoloration of joints, difficulty in joint movements in the affected joints and swelling in the

metatarsal-phalangeal joint were selected for further diagnosis.

**Criteria of Diagnosis:** Elevation of serum uric acid at least 1 mg above the normal limit along with other characteristic feature of gout as mentioned above.

**Inclusion Criteria**: Patients of both the sexes, aged group of 20 to 60 years

**Exclusion Criteria:** Patients with complications of gouty arthritis, poorly controlled hypertension/diabetes mellitus and impaired cardiac, renal and hepatic functions and pregnant and lactating women were excluded.

#### **Drugs and Doses:**

During initial course of 21 days the patients were kept in the hospital and Satila Navarakizhi was performed for 14 days followed by Abhyanga with Pinda Taila for 7 days. Simultaneously the internal medicines comprises of Varunadi Kahaya (100 ml twice a day), Chandra-Prabha Gutika (1 tablet twice a day) and Kokilakshakam Toyam (1 liter/day for drinking in place of water) were given. Shirobhyanga with Balaguloochyadi Taila was also performed once daily for all the 21 days.

After 21 says course of the therapy, the patients were discharged and continued the treatment at OPD level. During this period, internal medicines as mentioned above were continued and simultaneously application of Pinda Taila all over the body and Balaguluchyadi Taila over scalp was advised.

The raw materials of trial medicines were identified and authenticated and undergone strict quality control evaluation as per the guidelines described in Ayurvedic Formulary of India in the laboratory of CARE Keralam, Thrissur. Trial medicines were prepared in the Vaidyaratnam Oushadhasala Pvt. Ltd. Thrissur which is GMP certified Ayurveda pharmacy.

Primary outcome was expected to be the change in uric acid level and secondary outcome was the functional improvement of patients.

The assessment of result was made based on the scores provided to each signs and symptoms recorded periodically on 21 and 42 days of the treatment and compared the changes to the baseline. Laboratory investigations were performed for all the patients at baseline and after the full course of the treatment. This includes hemogram, biochemical parameters namely blood glucose, serum cholesterol, uric acid, liver function test, renal function test, C- reactive protein and ASO titter. X-ray of affected joint was also taken. The functional improvement was recorded using the validated scales - visual analogue pain rating scale, DAS score, SF-36, disability index and global assessment scale. Statistical analysis was done using SPSS version 20 Friedman's test and repeated measures ANOVA and details are given in the result section.

#### RESULTS

The effect of the therapy on uric acid is shown in Table-1 and on various functional parameters in Table-2. The hematological and biochemical investigations were carried before and after the treatment and the results along with statistical data are presented in Table-3. The last table-4 is concerned with the effects of the therapy on liver and renal function parameters.

Table-1
Effect of the Combined Therapy on Serum Uric Acid

| • | Effect of the Combined Therapy on Serum Citie Heit |                          |      |  |  |  |
|---|--|--------------------------|------|--|--|--|
|   | Period   | Mean Serum uric acid mg% |      |  |  |  |
|   | First day  | 7.49                     | 0.09 |  |  |  |
|   | 21 <sup>st</sup> day                               | 6.08                     | 0.19 |  |  |  |
|   | 42 <sup>nd</sup> day                               | 5.93                     | 0.23 |  |  |  |
|   | F-value  | 50.106                   |      |  |  |  |
|   | P-value  | < 0.001                  |      |  |  |  |

Table-2
Effect of the Combined Therapy on Various Functional Parameters

| Parameters                 | First day        | 21st day         | 42 <sup>nd</sup> day | Chi square<br>/ F value | p-value |
|----------------------------|------------------|------------------|----------------------|-------------------------|---------|
| Visual analogue pain score | $6.07 \pm 0.23$  | $2.07 \pm 0.25$  | $0.93 \pm 0.21$      | 53.411**                | < 0.001 |
| DAS score                  | $4.57 \pm 0.22$  | $3.61 \pm 0.16$  | $3.63 \pm 0.16$      | 17.172**                | < 0.001 |
| Disability index           | $0.99 \pm 0.09$  | $0.21 \pm 0.05$  | $0.08 \pm 0.02$      | 90.886**                | < 0.001 |
| Global assessment          | $39.33 \pm 2.30$ | $80.00 \pm 2.65$ | $91.17 \pm 2.11$     | 239.870**               | < 0.001 |
| disease activity scale     |                  |                  |                      |                         |         |

<sup>\*\*</sup>: significant at 0.01 levels, Means having same letter as superscript are homogenous

Table-3
Effect of the Combined Therapy on Hematological Parameters

| Period               | Mean ± SE    |             |               |  |
|----------------------|--------------|-------------|---------------|--|
|                      | ESR (mm/hr)  | CRP         | Hb. (gm %)    |  |
| First day            | 23.37 (3.42) | 6.61 (1.22) | 12.67 (0.28)  |  |
| 21 <sup>st</sup> day | 18.63 (3)    | 4.77 (0.48) | 12.88( 0.24)  |  |
| 42 <sup>nd</sup> day | 27.37 (4.49) | 5.82 (0.79) | 12.64 ( 0.23) |  |
| F-value              | 5.956        | 2.160       | 1.500         |  |
| P-value              | 0.006        | >.05        | >.05          |  |

Table-4
Effects of the Combined Therapy on Biochemical Parameters Related to Liver and Kidney

| Parameters             | Day 1              | Day 21             | Day 42            | F-value             | P-value |
|------------------------|--------------------|--------------------|-------------------|---------------------|---------|
| Blood urea             | $31.27 \pm 0.96$   | $25.23 \pm 0.65$   | $27.93 \pm 0.92$  | 18.851**            | 0.358   |
| Serum Creatinine       | $0.83 \pm 0.02$    | $0.81 \pm 0.02$    | $0.8 \pm 0.02$    | 0.812 <sup>ns</sup> | 0.504   |
| SGOT                   | $25.4 \pm 1.58$    | $26.3 \pm 1.6$     | $23.53 \pm 1.66$  | 2.307 <sup>ns</sup> | 0.014   |
| SGPT                   | $28.9 \pm 2.07$    | $25.43 \pm 1.65$   | $28.03 \pm 1.93$  | 2.116 <sup>ns</sup> | 0.166   |
| Total Protein          | $7.64 \pm 0.13$    | $7.45 \pm 0.11$    | $7.6 \pm 0.09$    | 1.122 <sup>ns</sup> | 0.962   |
| S. Albumin             | $4.04 \pm 0.06$    | $4.02 \pm 0.06$    | $4.16 \pm 0.04$   | 4.008*              | 0.023   |
| S. Globulin            | $4.01 \pm 0.5$     | $3.93 \pm 0.49$    | $3.77 \pm 0.33$   | 0.961 <sup>ns</sup> | 0.372   |
| S. Bilurubin           | $0.74 \pm 0.05$    | $0.82 \pm 0.06$    | $0.78 \pm 0.05$   | 2.545 <sup>ns</sup> | 0.087   |
| S. alkaline Phosphates | $176.87 \pm 10.63$ | $169.67 \pm 10.05$ | $180.9 \pm 12.45$ | 0.807               | 0.426   |

<sup>\*\*</sup> Significant at 0.01 level; \* significant at 0.05 level; ns - non significant

#### DISCUSSION

In this clinical study, the traditional Ashtavaidyan line of management has been tried to evaluate its effectiveness in gouty arthritis. The course of treatment included Shashtika Pinda Sveda (Sataila Navarakizhi) and Sarvanga Abhyanga with Pinda Taila along with Balaguluchyadi Taila for Shirobhyanga; simultaneously Varanadi Kashaya, Chandraprabha Vati and Kokilakshaka Toyam were given internally.

**Pain score:** Analysis of visual analogue pain score between different treatment intervals was made using Friedman's test showed significant decrease at 21<sup>st</sup> day and 42<sup>nd</sup> day compared to the baseline data (Table-2).

DAS score analyzed as per ANOVA showed that there is a significant reduction from the first day to 21<sup>st</sup> day. No significant difference was noted on the day 42 (Table-2).

ANOVA analysis of disability index showed that there is a significant reduction (Table-2).

Analysis of score of global assessment of disease activity scale showed that there is a significant decrease in score from first day to day 21 and also on day 42. No significant difference was noted between day 21 and day 42 (Table-2). Comparison of SF-36 score using paired t-test showed that there exists significant difference in SF-36 score on the last day compared to the pretreatment period.

ESR shows reduction on 21<sup>st</sup> day and then it again increased on 42<sup>nd</sup> day, whereas there was non-significant decrease of C-reactive protein and hemoglobin was well maintained throughout the treatment

All laboratory parameters at different measurement time were compared by using ANOVA followed by LSD test. Significant variation was observed only in the case of blood glucose, total serum protein, serum albumin, serum globulin and serum alkaline phosphatase. All other parameters showed no significant difference during the period of study. In the case of blood glucose, no significant difference was noted at day 1 and day 21. However significant increase was noted in day 42.

Serum uric acid level showed significant reduction in comparison to the first day to 21<sup>st</sup> and 42<sup>nd</sup> day.

The data derived from the statistical assessment of the response of the therapy clearly indicate that the prescribed method of management have highly significant in the management of gout. The statistical analysis of the effect of the treatment has shown significant improvement in the functional ability of the patients also.

#### CONCLUSION

Traditional Ashtavaidyan Ayurveda therapy comprises of administration of Varanadi Kashaya, Chandraprabha Vati and Kokilakshaka Toyam inernally and simultaneous performing of Shashtika Pinda Sveda (Sataila Navarakizhi) and Sarvanga Abhyanga with Pinda Taila along with Shirobhyanga with Balaguluchyadi Taila externally for 42 days.

The therapy significantly reduced the serum uric acid in Vatarakta vis-à-vis gouty arthritis patients.

The therapy provided significant relief in chief complaints such as pain and swelling in the joints,

The therapy significantly reduced the DAS score, disability index, global assessment of disease activity scale and SF-36 score. Thus it provided significant improvement in the functional ability of the patients.

The data derived from the statistical assessment of the response of the therapy clearly indicate that the prescribed method of management have highly significant in the management of gout.

Moreover, there was no adverse drug reaction recorded during the therapy, which indicates that the therapy is safe without producing any adverse drug effects.

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