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Clinical Evaluation of ‘*Punarnava Amrita Guggulu*’ in the Management of *Vata-Rakta* (Gout)

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Abstract: An unusual metabolic condition is *Vata-Rakta*. The chronic relapsing and intermittent nature of *Vata-Rakta* illness makes it extremely distressing. The overall prevalence of hyperuricemia is 25.8%, with a larger percentage of men than women having increased serum uric acid. *Vatarakta* is the name for the illness that is characterised by *Raktadhatu* aberration brought on by *Vata Dosha* morbidity. At the current study, *Punarnava Amrita Guggulu* was taken twice daily with lukewarm water in doses of 1gm (two 500mg tablets each). Results revealed that *Vidaha* (Burning sensation) (58.33%), *Sandhi Shoola* (reduced by 65.71%), *Sandhi Shotha* (reduced by 54.76%) were all statistically very significant outcomes of the current study. *Raga* (Redness in joints) (60.71%), *Toda* (Pricking sensation) (57.95%) and *Twakvaivarnya* (Discoloration) (61.25%). *Sparsha Asahyata* (Tenderness in joints) (52.47%) *Visphota*(58.60%) *Sandhi Akunchana Prasara*na Vedna(63.49%) *Sandhi Vikriti* (Deformity Status) (47.14%).

Keywords: *Vata-rakta*, *Punarnava Amrita Guggulu*, *Vatavyadhi*, *Vata Dosha*

I. INTRODUCTION

Despite significant progress in modern science, there are still several diseases that plague humans. The chronic relapsing and intermittent nature of *Vata-Rakta* illness makes it extremely distressing. *Vata-Rakta* is a special metabolic condition, and *Vatavyadhi* is one of them. One of the effects of these changes is the occurrence of *Vatarakta*. This *Vatarakta* can be related to modern medicine's Gouty Arthritis based on the indications and symptoms. One of the effects of these changes is the occurrence of *Vatarakta*. This *Vatarakta* can be related to modern medicine's Gouty Arthritis based on the indications and symptoms. One to four percent of the overall population has gout. The overall prevalence of hyperuricemia is 25.8%, with a larger percentage of men than women having increased serum uric acid. The prevalence increases to 10% in men and 6% in women in Western countries, where it occurs in 3-6% of men and 1-2% of women. Gout affects 2.68 out of every 1000 people annually¹.

II. DISEASE REVIEW

Fast food and a fast lifestyle both upset the *Vata*. *Rakta* is the primary *Dhusya* and *Vata* is a dominating *Dosha* in *Vata-Rakta* at the same time as *Dushita Rakta* gives birth to *Vata-Rakta*. It is brought on by the vitiation of both *Vata* and *Rakta*. With vitiated *Raktadhatu*, the vitiated *Vata* becomes the vitiated *Aavruta*. The entire *Rakta* is tainted by *Vridhhi* and blocked *Vata*, which emerges as *Vata-Rakta*. *Vatarakta*, also known as "*Vata Dushtam Raktam Yatra Roga Visheshah*"², is a condition marked by aberrant *Raktadhatu* as a result of *Vata Dosa* morbidity. It mentions nidanas such as *Katu*, *Amla*, *Ushna*, *Vidahi Aaharas*, *Gaja*, and *Ushtra Yaana*. It consists of the *Uthana* and *Gambheera* stages. The main complaint of the patient is severe joint pain, which starts at *Hasta Pada Mulagata Sandhi* and spreads to all other joints in a manner resembling the spread of *Akur visha*.³ *Vatarakta* is thought to be one of the *Maha Vyadhis* where severe joint pain is a predominate symptom and disrupts the day-to-day life of the individual by immobilising the affected joints of the limbs. *Sushruta Shamita* describes it under *Vatavyadhi Chikitsa*, however *Acharya Charka* emphasises it in a separate chapter after *Vatavyadhi Chikitsa* called *Vata-rakta*. The type of arthritis that is best understood and described is gout. Gout is a purine metabolism condition characterised by hyperuricemia and repeated acute synovitis episodes. There is invariably hyperuricemia (6.0 mg/dl) before it. Mono-sodium urate crystallisation in joints, tendons, and surrounding tissue is a result of hyperuricemia brought on by excessive uric acid synthesis or reduced excretion. The main gout symptom that interferes with patients' daily lives is pain. Inflammatory joint disease is most prevalent in men and elderly women. 4.

III. DRUG SELECTION

Punarnava Amrita Guggulu was chosen for this inquiry, which displays in *Chakradutta* in *Vatarakta Prakarana*, because *Vata* and *Rakta* vitiation are predominant in *Vatarakta*. In Ayurvedic writings, these medications are referred to as having *Vatashamaka*, *Deepana*, *Pachana*, *Vedanahara*, *Anulomana*, and *Shothhara* characteristics.

A. Ingredients *Punarnava Amrita Guggulu*⁵ (*Chakradutta Vaatarakta chikitsa* 58/64)

Guduchi (*Tinospora cordifolia*) 2 Part, *Rakta Punarnava* (*Boerhaavia diffusa*), *Guggulu* (*Commiphora mukul*) *Haritaki* (*Terminalia chebula*) *Vibhitaki* (*Terminalia bellirica*) *Amlaki* (*Embllica officinalis*) 1 part each.

Danti (*Baliospermum montanum*) *Shunthi* (*Zingiber officinale*) *Chitraka mula* (*Plumbago zeylanica*) *Pippli* (*Piper longum*) (*Vidang* (*Embllica ribes*) *Guduchi* (*Tinospora cordifolia*) *Nishoth* (*Operculina trepenthum*) *Haritaki* (*Terminalia chebula*) *Vibhitaki* (*Terminalia bellirica*) was used as *prakshepa dravyas* in the ratio of 1/40part.

B. Method of Preparation of the Trial Drug

Above contents of *Punarnava Amrita Guggulu* will be taken in above explained ratio and coarse powder will be made of *Guduchi*, *Triphala*, *Guggulu* and *Punarnava*. Then 16 parts of water will be added and boil till 8 parts of water remains (i.e. *Kwatha*). Then after filtering it and filtered decoction will be again boiling, until it become *Ghana*. Then added *Prakshepa Dravya* in above ratio as per requirement and condensed on the medium flame. After complete mixing of all the material pills (*Vati*) of 500 mg each will be prepared and stored. This drug was prepared in pharmacy of DSRRAU, Jodhpur

C. Mode of Administration

Dose of *Punarnava Amrita Guggulu*- 2 *vati* (each *vati* 500 mg) twice in a day with lukewarm water for 45days.

IV. AIMS AND OBJECTIVES

- 1) Conceptual and Clinical Evaluation of *Vata-rakta* (Gout) and its management with time tested Ayurvedic principle.
- 2) Clinical Evaluation of *Punarnava Amrita Guggulu* in the management of *Vata-rakta*.
- 3) To Evaluate the Adverse Drug Reaction of the trial drug.

A. Ethical Clearance

This study was approved by Institutional Ethical Committee (IEC) DSRRAU, Jodhpur vide letter no. Sr.No./DSRRAU/UCA/IEC/19-20/254 on dated 08/07/2020.

CTRI REGISTRATION [CTRI No. - CTRI/2021/04/033171 registered on 27/04/2021]

V. MATERIAL AND METHODS

A. Materials

1) *Literary*: Various literary sources of Ayurveda and modern medical science have been explored to study the subject *Vatarakta* or *Gout* respectively.

2) *Clinical*: This includes the observations of patients, investigations and trial procedures.

Following material and methods will be adopted for conducting the present research project-

a) *Selection of Case*: The study was conducted on 40 clinically diagnosed patients of 'Vatarakta' (Gout) selected from OPD / IPD of UPGIAS&R, DSRRAU, Jodhpur. The case selection was random regardless of sex, age, occupation and socio-economic conditions. Patients were taken after evaluation of the clinical features of Vatarakta (Gout) for the study. A regular record of assessment of all patients was maintained according to proforma prepared for the purpose.

B. Selection Criteria

1) Inclusion Criteria

- a) Patients between the age group of 20-60 years of either sex presenting with clinical features of *Vata-rakta*.
- b) Diagnosed and confirmed case of *Vata-rakta* (Gout).
- c) Patients having serum uric acid level more than 6 mg/dl with or without any associated features like joint pain and inflammation
- d) Patients having any disorders like Diabetes mellitus, Cardiac disease etc.

2) Exclusion Criteria

- Patients below 20 years and above 60 years will be excluded.
- Patients suffering with other form of Arthritis like Rheumatoid arthritis, Osteoarthritis, Ankylosing spondylitis, Infective arthritis etc.
- Pregnant and lactating mother.
- Patients with evidence of malignancy.

3) Clinical Study

- Study Type:** Interventional, Open, Randomized, Clinical Study
- Study Design:** After the complete examination and investigation of 40 well diagnosed and confirmed patients of *Vata-rakta* will be administered *Punarnava Amrita Guggulu* in dose of 1gm (two tablets of 500mg each) twice a day with lukewarm water for 45 days.

4) Demographical Profile

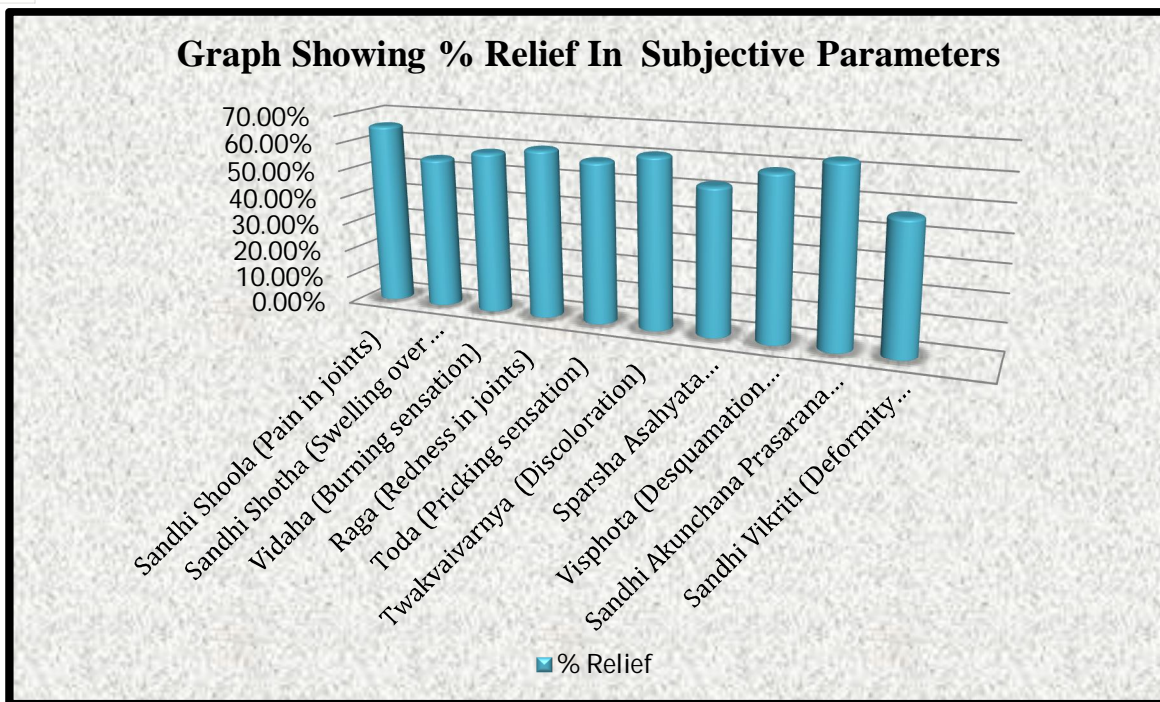
In the current investigation, a total of 40 vatarakta (gout) patients were examined. They ranged in age from 20 to 60, with a maximum of 16 patients in the 41–50 age range (40%). The majority of the patients in this series were male (77.5%), Hindu (97.5%), graduate-level educated (27.5%), from a lower socioeconomic class (47.5%), working in a private employment (17.5%), addicted to tea (30%), and married (100%).

5) Clinical Profile

- The majority of patients, according to the Dashavidha Pariksha biostatistics, had Vata-Pitta Deha Prakriti (45%), Rajasika Mansika Prakriti (52.5%), Madhyama Satva (55%) Mamsa Sara (57.5%), Madhyama Satmaya (52.5%), Madhyama Samhanana (52.5%), Avara Vyayama Shakti (62.5%), Madhyama Abhyavahara
- The majority of patients, 36 (90%) had Rooksha, Amla, Sheetala ahara, and Kashaya Tikta ahara, while 33 patients (82.5%) had Vidahi ahara and Teekshna ahara, 23 patients (57.5%), Ratri Jagrana, Vatakara ahara, and Mithyashana, which was gained by the greatest number of patients, 34 patients (85%).
- Among the patients, the following were the most common complaints: pain in joints, which was reported by all 40 patients (100%); swelling over joints, which was reported by 36 patients (90%); burning sensation, which was reported by 29 patients (72.5%); redness, which was reported by 28 patients (70%); pricking sensation, which was reported by 38 patients (95%); and tenderness in joints, which was reported by 39 patients (97.5%). Desquamation was present in 30 patients (75%), pain during joint movement was present in 38 patients (95%), deformity was present in 23 patients (57.5%), and analysis of the doshika involvement revealed that all patients had Vatadosha Dushti Lakshanas, with associated Pitta and Rakta dushti lakshanas in 88.88% of cases.
- Review of *Srotodusti Lakshanas* reveals that 100% patients were having *Raktavaha Srotodushti Lakshnas*. *Majjavaha* (97.67%) and *Asthivaha* (41.86%) *Sroto Dushti Lakshnas* were also present
- X-ray investigation showed that All the patients in this study were having some sort of pathological changes in ankle and toe joint as per radiological investigation. Majority of the patients of this series i.e. 50.23% were diagnosed as having Gouty changes with presence of Ostophytes.
- Interrogation regarding treatment history revealed that maximum number of patients had taken allopathic medication (80%).

VI. EFFECT OF THERAPY

- In the present study *Punarnava Amrita Guggulu* in dose of 1gm (two tablets of 500mg each) twice a day with lukewarm water for 45 days. Results showed that Statistically very significant results were also found in present study i.e. *Sandhi Shoola* was reduced by 65.71%, *Sandhi Shotha* (54.76%) and *Vidaha* (Burning sensation) (58.33%) which were statistically extremely significant. *Raga* (Redness in joints) (60.71%), *Toda* (Pricking sensation) (57.95%) and *Twakvaivarnya* (Discoloration) (61.25%). *Sparsha Asahyata* (Tenderness in joints) (52.47%) *Visphota*(58.60%) *Sandhi Akunchana Prasarana Vedna*(63.49%) *Sandhi Vikriti* (Deformity Status) (47.14%)



- 2) No major changes were observed in laboratory investigations e.g. TLC, DLC, ESR, PCV, Hb, FBS and X-ray. Although there was significant change in serum uric acid level (51.74%)

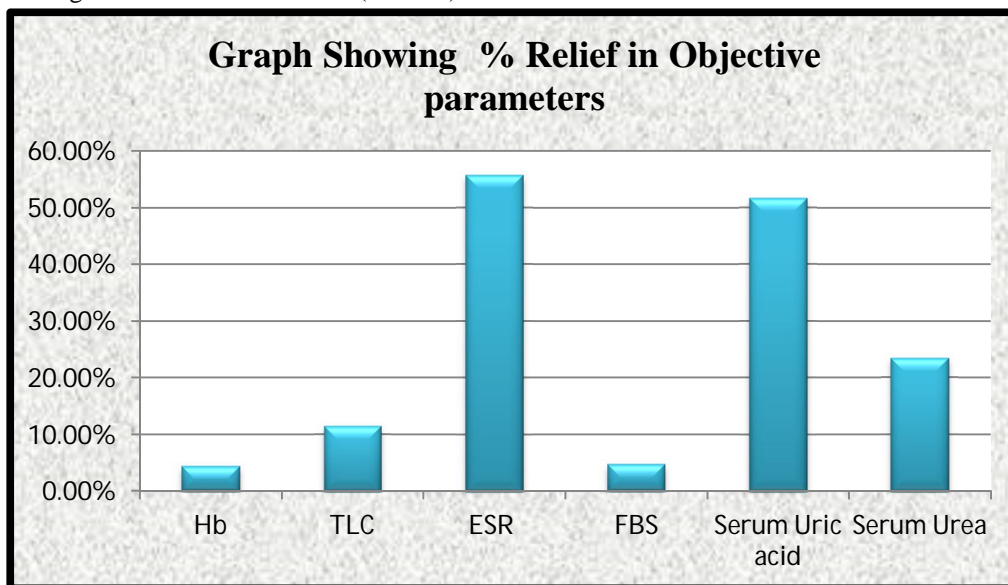
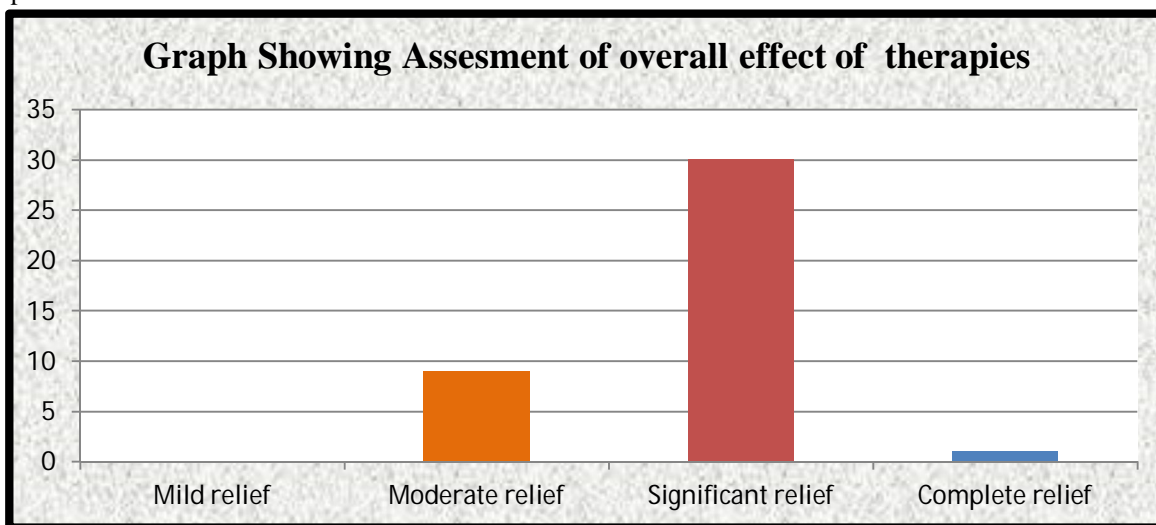


Table No. 01: Assessment of overall effect of the therapies

S. No.	Symptoms	Grading	No. of patients
1.	Less than 25%	Mild relief	00
2.	25% to 50%	Moderate relief	9
3.	50% to 75%	Significant relief	30
4.	75% to 100%	Complete relief	01

In the present study 9 patients had moderate relief in symptoms, while 30 patients and significant relief. Only 1 patient had complete relief in symptoms of Vatarakta.



- 3) Overall symptomatically, **58.50%** relief was observed in present clinical trial. So it can be say that significant / satisfactory relief was found during this research
- 4) In laboratory findings overall, **25.17% relief** was observed during this clinical trial. So it can be say that mild relief in objective parameters was found in during research.

VII. DISCUSSION ON RESULTS

A. The Effect Of Therapy On Subjective Parameters

- 1) *Sandhi Shoola* (Pain): In present study, the mean score before treatment was 10.500 which reduced to 3.600 after treatment, with $SD \pm 0.5071$ giving a relief of 65.71%, which is statistically extremely significant ($P < 0.001$). *Sandhi shoola* is mainly caused by *Vata Dosha*. Here *Dushita Rakta* does the *Avarana* of *Vikruta Vata Dosha*. Results observed from the present study shows that *Punarnva Amrita Gugulu* is the best remedy for *Vatarakta* and removes *avarana* and also it is the best remedy for *Pitta Dosha* as well as *Rakta Dhatu* and as it is also *Vatanulomaka*.
- 2) *Sandhi Shotha* (swelling): In Present study, the mean score before treatment was 8.400 which reduced to 3.800 after treatment, with $SD \pm 0.5164$ giving a relief of 54.76%, which is statistically extremely significant ($P < 0.001$). The vitiated *Vata Dosha* and *Rakta Dhatu* are responsible for *Sandhi Shotha*. Due to effect of drug *Vata Dosha* is expelled out, and so it is helpful to reduce *Sandhi Shotha*. *Virechana* due to presence of *Trivrutta* corrects the vitiation of *Pitta*, hence reduces the *Sandhi Shotha*.
- 3) *Vidaha* (Burning sensation): In Present study, the mean score before treatment was 8.400 which reduced to 3.500 after treatment, with $SD \pm 0.4577$ giving a relief of 58.33%, which is statistically extremely significant ($P < 0.001$). The vitiated *Pitta Dosha* and *Rakta Dhatu* are responsible for *Vidaha*. Due to effect of drug *Pitta Dosha* is expelled out, and so it is helpful to reduce *Vidaha*.
- 4) *Raga* (Redness in joints): In Present study, the mean score before treatment was 5.600 which reduced to 2.200 after treatment, with $SD \pm 0.6571$ giving a relief of 60.71%, which is statistically extremely significant ($P < 0.001$). The vitiated *Bhrajka Pitta* and *Rakta Dhatu* are responsible for *Raga*. Due to effect of drug *Pitta Dosha* is expelled out, and so it is helpful to reduce *Raga*.
- 5) *Toda* (Pricking sensation): In Present study, the mean score before treatment was 8.800 which reduced to 3.700 after treatment, with $SD \pm 0.4140$ giving a relief of 57.95%, which is statistically extremely significant ($P < 0.001$). *Toda* mainly occur due to vitiation of *Vata Dosha*. Due to effect of drug *Vata Dosha* is expelled out, and so it is helpful to reduce *Toda*.
- 6) *Twakvaivarnyata* (colour): In Present study, the mean score before treatment was 8.000 which reduced to 3.100 after treatment, with $SD \pm 0.5477$ giving a relief of 61.25%, which is statistically very significant ($P < 0.001$). *Pitta* and *Rakta Dhatu* are responsible for *Vaivarnyata*. Discoloration at joint cavity occur due to inflammation. As *Virechana*, which is not only *Pitta hara*, *Rakta prasada*, but also *Rakta Shodhaka*. Trial drug has significant role in *Rakta Prasada* and *Pitta shamana*.

- 7) *Visphota* (Desquamation status): In Present study, the mean score before treatment was 8.700 which reduced to 3.600 after treatment, with $SD \pm 0.5936$ giving a relief of 58.60%, which is statistically extremely significant ($P < 0.001$).
- 8) *Sparsha Asahyatva* (Tenderness in joints): In Present study, the mean score before treatment was 10.100 which reduced to 4.800 after treatment, with $SD \pm 0.7037$ giving a relief of 52.47%, which is statistically significant ($P = 0.4915$). As we know *Vata* is responsible for pain, "*Sparsahanebyo Adhiko Vayu Sparshanam cha Tvagashrayam.*" i.e. in skin *vata Dosha* predominantly present. Use of *Punarnava Amrita Guggulu* in the present study shows significant effect on tenderness of joint.
- 9) *Sandhi Akunchana Prasara Veda* (Pain on joints movements): In Present study, the mean score before treatment was 6.300 which reduced to 2.300 after treatment, with $SD \pm 0.3780$ giving a relief of 63.49%, which is statistically Extremely significant ($P < 0.001$). Pain occur during movements (due to tophi formation in the joint cavity) was significantly resolved by the use of trial drug.
- 10) *Sandhi Vikriti* (Deformity Status): In Present study, the mean score before treatment was 7.000 which reduced to 3.700 after treatment, with $SD \pm 0.7121$ giving a relief of 47.14%, which is statistically significant ($P = 0.0311$). Hyperuricemia results in deposition of uric acid crystals in the joint cavity, chronicity of the disease will gradually led to deformity of joints. Present study shows that our trial drug has significantly overcome the deformity. However prolonged use of medication will definitely results in normal joint functions.

B. The Effect Of Therapy On Objective Parameters

- 1) *Haemoglobin*: In Present study, the mean score before treatment was 46.59 which increased to 48.63 after treatment, with $SD \pm 2.557$ giving a relief of 4.38%, which is statistically not significant ($P = 0.4915$). Slight increase in the level of haemoglobin was probably due to effect of *raktavardhaka* and *piita shamaka* properties of trial drug. But parameteric values are least to obtain significance of the drug.
- 2) *TLC*: In Present study, the mean score before treatment was 34039.0 which decreased to 3011.7 after treatment, with $SD \pm 1.269$ giving a relief of 11.52%, which is statistically significant ($P = 0.0311$). Increase in TLC was due to presence of inflammation in gout. Overall effect of trial drug had significantly lowered down the increased TLC due to anti-inflammatory effect of drug.
- 3) *ESR*: In Present study, the mean score before treatment was 256.4 which reduced to 113.4 after treatment, with $SD \pm 1.163$ giving a relief of 55.77%, which is statistically Very significant ($P = 0.0909$). Increased ESR states inflammation in the body, while present drug lowered the ESR depicts the anti-inflammatory effect of *Punarnava Amrita Guggulu*.
- 4) *Fasting Blood Sugar*: In Present study, the mean score before treatment was 367.5 which reduced to 349.9 after treatment, with $SD \pm 2.079$ giving a relief of 4.78%, which is statistically not significant ($P = 0.0879$). Higher value of Fasting blood sugar may led to precipitation of Gout. However, drug used in the present study had no significant action on blood sugar level.
- 5) *Serum Uric Acid*: In Present study, the mean score before treatment was 32.47 which reduced to 15.67 after treatment, with $SD \pm 1.901$ giving a relief of 51.74%, which is statistically Very significant ($P = 0.0041$). Hyperuricemia is the chief indicator for gouty arthritis, although increased uric acid level may show asymptomatic gout. But in the present study all patients found positive in subjective symptoms too. Moreover statistical analysis of the present study proves the significant effect of study.
- 6) *Serum Urea*: In Present study, the mean score before treatment was 105.1 which reduced to 80.4 after treatment, with $SD \pm 1.604$ giving a relief of 23.50%, which is statistically not significant ($P = 0.0911$).
- 7) *Radiological Abnormalities*: All the patients in this study were having some sort of pathological changes in ankle and toe joint as per radiological investigation. Majority of the patients of this series i.e. 50.23% were diagnosed as having Gouty changes with presence of Osteophytes.

VIII. CONCLUSION

Various Ayurvedic therapeutics of the ingredients used in the preparation of *Punarnava Amrita Guggulu*⁶ are discussed here to correlate the broad therapeutics of *Punarnava Amrita Guggulu*. The drug *Bibhitaki*, *Danti* and *Trivritta* shows *Pitta-Kaphahara* properties while *Vidanga*, *Twaka* and *Shunthi* are *Vata-Kaphahara*. *Haritaki*, *Pippali*, *Amrita* & *Amalaki* all are *Tridosha Nashaka*. Also *Pitta Saraka* properties of *Amrita* and *Trivritta* help to reduce *Pitta* and associated symptoms which can help in reducing inflammatory aspect of the disease. Most of these drugs show a characteristic of *Ushna Veerya* (hotpotency) with *Laghu* (easily digestible), *Ruksha* (dry) and *Tikshna Guna* (qualities), which helps in easy assimilation of drug in body whereas *Shunthi* and *Guduchi* are *Guru* (hard to digest) and *Snigdha* (oily) which further helps in *Vatahara* action of the drugs.

The *Vipaka* (post digestive effect) characteristic of *Haritaki*, *Bibhitaki*, *Amalaki*, *Amrita*, *Shunthi* and *Pippali* are *Madhura* (sweet) which have *Vata-pitta shamaka* (pacifying)⁷⁻⁸ Out of 13 ingredients, 10 show the property of *Vatarakta Shamaka* which finds a solid base for treatment of *Vatarakta* (Gout) with raised uric acid.

Overall, the aforesaid Ayurvedic therapeutics conclude that the preparation of *Punarnava amrita guggulu* with twelve ingredients are enriched for the properties that certainly prove better in *Vatarakta* as well as in other *Vata* diseases.

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