

## **Clinical Study Conducted on G-Amrita**

### **EFFECT OF VATARAKTAHARA CAPSULES (G-AMRITA) IN VATARAKTA w.s.r. to HYPERURICAEMIA**

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#### **ABSTRACT:**

Hyperuricaemia/Gout is a metabolic disorder which is found in association with other diseases like NIDDM<sup>1</sup>, CAD<sup>2</sup>, metabolic syndrome<sup>3</sup> etc. The rate of gout has increased in recent decades possibly due to dietary and lifestyle changes. No. of self reported cases of gout in U.S.A. increased from 2.1 million to 3.0 million over a period of ten years(1990-1999) making it more prevalent than R.A.<sup>4</sup>.The disease has become a challenge in today's era not only due to its remittent nature but due to associated comorbidities. Ayurveda literature has description of an ailment namely "Vatrakta" which resembles "Gouty Arthritis". Various medicinal plants have been described for Vatarakta management such as *Guduchi*, *Trifla*, *Guggulu* etc. Researches have also been done on them for their anti-inflammatory and analgesic activity<sup>5,6,7</sup>. Current study was to assess the effect of formulation containing *Guduchi*, *Guggulu* etc. i.e. *Vataraktahara* Capsules on the patients of *Vatarkata*. Thirty patients of either sex, age between 18-70 yrs. with serum uric acid >6mg/dl in females and >7mg/dl in males and without any other chronic illness were selected after written informed consent. Drug was given in capsule form weighing 890 mg with the dose of 2 capsules TID. The formulation was provided by Shree Dhanwantri Herbals as their patent formulation G-Amrita. All the subjects continued the regimen for 60 days. The effect of trial formulation in 28 patients on various assessment criteria was obtained after statistical analysis of the data obtained. Study showed highly significant result in criteria. *Sandhi shool* (joint pain), *Sandhi shotha* (swelling), *Sparsha asahyata* (tenderness), *Raga* (redness), *Vidaha* (burning sensation) and *stabdhata* (stiffness) with statistical value  $p < 0.001$ . In *Tvak Vaivarnyata* (discolouration), 100% relief was noted after the trial. In *Shithilta*, significant improvement was recorded ( $p < 0.01$ ). Insignificant improvement ( $p > 0.05$ ) was seen in *Hritspandan* (palpitation). No effect was found in *Sandhi vikriti* (joint deformity). 18.92 % reduction of serum uric acid was recorded after the trial with highly significant result. The trial formulation, *Vataraktahara* Capsules (G-Amrita) is a good combination of *vednasthapana*, *rasayana*, *shothaghna*, *mutral*, *deepan* and *amapachak dravyas*, so it is quite effective in the management of gout to lower the symptoms and frequency of gout flares without any side effects.

**Key words: Vatrakta, Hyperuricaemia, Gout, Sandhi, Vednasathapan.**

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## Material and Methods

### **Research design-**

**Sample:** The present study was designed to be open trial with single group study. Total 30 patients were selected randomly from OPD and IPD of Department of Kayachikitsa, RGGPG Ayurvedic Hospital, Paprola from the month January 2011 to September, 2011.

**Selection of subject:** Patients having age between 18-70years, serum uric acids level >7mg/dl in males and >6mg/dl in females and not having any associated chronic ailments were registered. Individual with age < 18 yrs. and >70 yrs., suffering from other arthritic disorder like RA, Diabetes mellitus, Chronic renal disease, Thyroid disorder, Haemolytic anemia, ALD and Myeloproliferative disorders were excluded from the study.

The study was approved by Institutional Ethical Committee, RGGPG Ayurvedic Hospital, Paprola (H.P.). Prior to the trial subjects were explained about the drug and trial in the form of patient information sheet. After that, the volunteers were recruited and written informed consent was obtained by them.

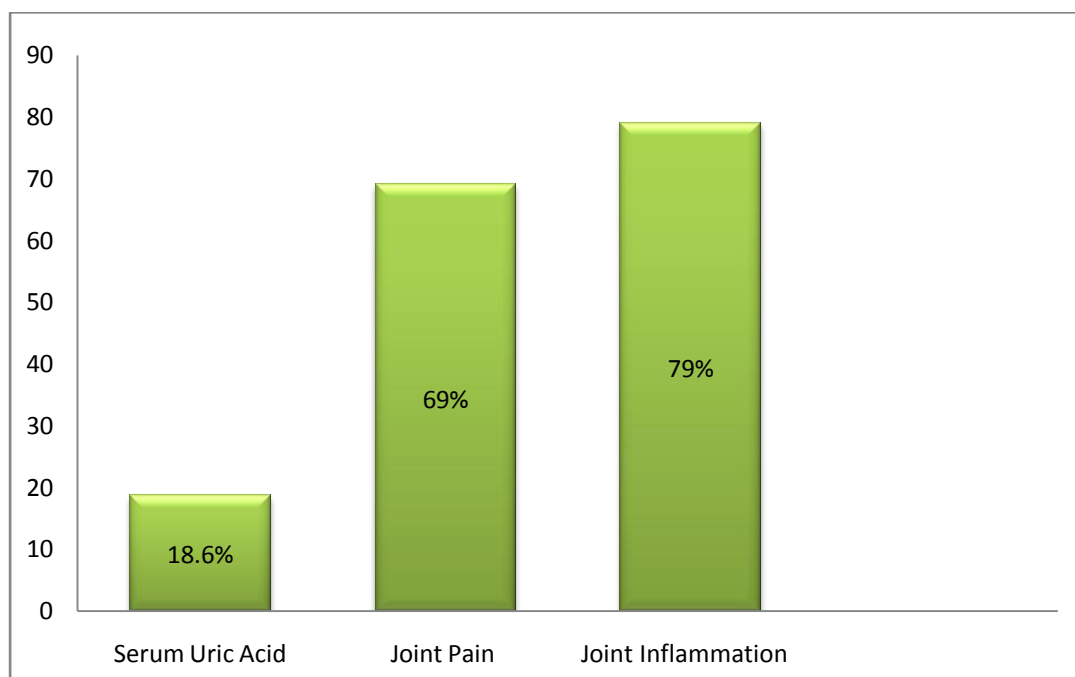
### **Test Drug**

The trial formulation, *Vataraktahara* Capsules (**G-Amrita Capsule**) is a polyherbal preparation, containing following indigenous drugs (each capsule weighing 890mg)

1. **Shudha Guggulu-** (399 mg)
2. **Extracts [5]-** Mass extract-173 mg each of:
  - 1) *Guduchi* 2) *Amalaki* 3) *Haritaki* 4) *Vibhitaki* 5) *Gokshura*
3. **Powder [10]-** 228 mg (each weighing 22.8 mg)
  - 1) *Dantimool* 2) *Vidang* 3) *Amrita* 4) *Trifla churna* 5) *Dalchini* 6) *Shunthi* 7) *Marich*
  - 8) *Pippalimool* 9) *Trivrit* 10) *Nagarmotha*.
4. **Inert Excipients** -90 mg

The trial drug was prepared and provided by Shree Dhanwantri Herbals, Amritsar by name of G-Amrita to the standard of GMP. A detailed controlled animal study had already been conducted by Department of Pharmaceutical Sciences, GNDU, Amritsar for its analgesic and inflammatory and anti-hyperuricemic effects which were found highly satisfactory.

## Overall effect of therapy:



Showing % Reduction in Serum Uric Acid, Joint Pain and Joint Inflammation

### Summary:

The analysis clearly indicates that the patients improved considerably as a result of Ayurvedic treatment (G-Amrita Capsules). There was statistically significant improvement in most of the criteria which were selected to evaluate the effectiveness of trial drug. The drug (G-Amrita capsule) showed highly significant results in signs and symptoms like swelling in joints, Joint pain Tenderness, Redness, Stiffness and Burning sensation. **Further it was also found that some patients had stopped taking allopurinol (XO inhibitor).** On the basis of observations of the study, it can be concluded that G-Amrita capsules is quite effective in the management of Gout to lower the frequency of gout flares without any side effects.

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