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Study Protocol for an Observational Study to Find Out the Prevalence of Hyperuricemia W.S.R. To *Vatarakta* on the Basis of Etiological Factors, Blood Group and *Prakriti* of Patient

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KEYWORDS

Vatarakta, hyperuricemia, prakriti, Sandhi shula, blood group.

ABSTRACT:

Background: Hyperuricemia is inflammatory condition characterized by abnormally elevated level of serum uric acid. It is an independent risk factor for cardiovascular disease, metabolic syndrome, atherosclerosis etc. It corresponds to Vatarakta in ayurveda. There is strong association of etiological factors of hyperglycemia with genotype, predisposition and etiological factors. The study is an initial effort to explore relationship between etiological factors, prakriti and genotype with the occurrence of disease.

Aim and objective: The aim of the study is to find prevalence of Hyperuricemia w.s.r.to Vatarakta on the basis of etiological factors and its association with blood group and constitution.

Methodology: It will be an observational cross-sectional trial. Initial recruitment of participants will be done on the basis of clinical features of Vatarakta and diagnostic criteria of hyperuricemia. Those fulfilling criteria will be further assessed through objective and subjective parameters.

1. INTRODUCTION:

In modern era due to unhealthy food practices, sedentary life style, physical inactivity, many metabolic disorders are invited like hyperuricemia, Diabetes mellitus, hypertension, arthritis, ischemic heart disease etc. Hyperuricemia is an abnormally high level of uric acid in the blood.[1] Serum uric acid concentration greater than 6mg/dl for female and 7mg/dl for male is defined as hyperuricemia.[2] Gout is a form of inflammatory arthritis characterized by deposition of monosodium-urate-monohydrate crystals in articular

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and non articular structures.[3] Global incidence of Gouty arthritis is 0.58-2.89 per 1000.[4] It corresponds to *Vatarakta* in classics. In *Vatarakta*, *Vata dosha* being afflicted by vitiated *Rakata dhatu.* Excessive consumption of alkaline, salty, pungent, dried food items, aquatic animals meat, red gram, black gram, curd, buttermilk, *sauvira* and *sukta* (vinegar), *Sura, asava* (alcohol) etc are the etiological dietary factors and excess walking in hot climate, anger, jumping, swimming, suppression of natural urges and indulgence in sexual activities are the *viharaja* factors leading to the manifestation of disease.[5] Thus aggravated *Vata* vitiates the *Rakta* producing complex effects leading to the condition *Vatarakta. Acharya Sushruta* described *Vatarakta* under *Vata-vyadhi* and it is named as *Vatashonita.* It affects hand and feet joints first and afterwards spread to the whole body like rat poison.[6] *Sandhi shula* (pain in Joints), *Sandhi shotha* (Swelling), *Sparsh Asahatvam* (Tenderness), *Daha* (Burning sensation), *Raga* (Erythema), *Twaka Vaivarnya* (Discoloration), *Stabdhta* (Stiffness) etc. are main symptoms of *Vatarakta*.[8] An individual's basic *Prakriti* (constitution) determines predisposition to a particular disease and its therapeutics in ayurveda**.** [8] As, *Vatika prakriti* persons are more prominent to the disease; therefore *prakriti* and disease correlation should be established to explore etiopathogenesis of such disease. [9]A blood type is a classification of blood based on the presence or absence of inherited antigenic substances on the surface of red blood cells.[10] Correlation of ABO genotype and inflammatory conditions is evidenced by clinical studies. [11-12]. In the above background the study is planned to explore the association of etiological factors, blood group and *Prakriti* of patient with the occurrence of Hyperuricemia.

2. RATIONALE OF THE STUDY:

Due to adoption of faulty dietary and lifestyle habits, the prevalence of hyperuricemia is increasing worldwide and most of the people suffering from it remains asymptomatic. Long term effect of Chronic hyperuricemia has been linked with disorders like metabolic syndromes, hypertension, cardiovascular disease, obesity and renal disease.[11-12] There are strong evidence of genetic predisposition of the disease. Therefore, in the above background the study was planned to explore etio-pathological factors, blood group and constitution of hyperurecimia in current scenario

3.AIM AND OBJECTIVE:

3.1.Aim: The aim of the study is to find prevalence of Hyperuricemia w.s.r.to Vatarakta on the basis of etiological factors and its association with blood group and constitution.

3.2. Objectives:

1.To find the prevalence of Vatarakta on the basis of etio-pathological factors

2.To find association between blood group, constitution and occurrence of hyperuricemia.

4. CASE DEFINITION

The case here were, those presented with clinical symptoms of *Vatarakta* as per classics and diagnosed as hyperuricemia (Serum Uric Acid > 6mg/dl in females and > 7mg/dl in males) as per modern medicine.

4.1. **Research question**

What is the prevalence rate of Hyperuricemia w.s.r. to *Vatarakta* disease on the basis of etiological Factors, blood Group and *Prakriti* of Patients?

4.2. **Hypothesis**

Research Hypothesis (H_1):-There is significant role of Etiological factors, Blood Group and *Prakriti* in the prevalence of Hyperuricemia w.s.r. to Vatarakta patients.

Null Hypothesis(H_0):-There is no significant role of Etiological factors, Blood Group and *Prakriti* in the prevalence of Hyperuricemia w.s.r. to Vatarakta patients.

4.3.Trial design:

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It will be an observational cross-sectional study conducted on the patient visiting I.P.D, O.P.D and clinical pathology lab of Shri Krishna Government Ayurvedic College & Hospital, Kurukshetra (Haryana).

5. METHODOLOGY

5.1. Study setting

The study will be executed on the patient visiting I.P.D, O.P.D and clinical pathology lab of Shri Krishna Government Ayurvedic College & Hospital, Kurukshetra (Haryana).

5.2. Clinical trial registration number

The study has been registered in CTRI under the reference number CTRI/2023/05/052927

5.3. Inclusion criteria

The participants of either sex between age group of 30-60 having clinical features of *Vatarakta* willing to participate in trial will be included.

The Diagnostic criteria will be:

Patients having Serum Uric Acid value: >6mg/dl(females); > 7mg/dl(Males) i.e. diagnosed as hyperuricemia.

5.4. Exclusion criteria

Subjects having age less than 30 and more than 60, suffering from psychiatric illness, any communicable and hormonal disease and special population (pregnant, children, lactating) will be excluded from the trial.

5.5. Sample size:

300 patients will be enrolled in the trial.

5.5.1. Sampling technique: Convenient type of sampling will be used in the study.

5.6.ASSESSMENT CRITERIA

5.6.1. Subjective Parameter

- Patient proforma (Questionnaire 1) based on the etiological factors, sign and symptoms of Hyperuricemia in relation to *Vatarakta*.

5.6.2. Objective Parameter –

- Serum Uric Acid
- Supporting Laboratory Test- CBC, ESR, CRP
- Blood Group- A positive, A negative, B positive, B negative, O positive, O negative, AB positive, AB negative.
- *Prakriti- Vata/ Pitta /Kapha/ Vata-Pitta/ VataKapha /PittaKapha/ Sannipataj*.

5.6.3. Statistical analysis:

Continuous variables will be analyzed using parametric test and discrete using non parametric tests. The continuous data will be represented in term of mean and median and categorical data as proportions with 95% confidence interval (CIs). Analysis will be performed using software SPSS 26 version and the results will be considered significant at $p<0.05$.

5.6.4. Time period:

Study will be executed with in 2 years.

6. DISCUSSION:

Hyperuricemia is a condition with abnormally high level of uric acid in the blood. Due to adoption of western life style its prevalence is rapidly increasing. Hyperuricemia remains unnoticed in initial stages and its long term effect has been linked with disorders like

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metabolic syndromes, hypertension, cardiovascular disease, obesity and renal disease.[12-14] Association of ABO genotype, constitution and hyprerurícemia has been evidenced in various studies. The correlation will be explored in the study and final discussion will be written on the basis of recorded observations on the targeted population.

6.1. Dissemination Policy:

After execution of study, the result will be disseminated through paper publication.

6.2. Informed consent:

Informed consent will be obtained from the participants.

6.3.Limitation:

This is an initial attempt to explore association of etiological factors, constitution and blood group of hyperuricemia with *Vatarakta*. The convenient sampling may introduce bias. Indeed, cause-effect association can be better demonstrated through perspective studies with large sample size. More objective parameters may be adopted to get more reliable and consistent data.

CONFLICTS OF INTEREST

Authors declare that they have no competing interests.

ETHICAL CONSIDERATION:

This study will be conducted according to the prevalent standard of Good Clinical Practices. This protocol and any amendments will be submitted to the Institutional Ethics Committee (IEC) for approval of the study conduct.

FINANCIAL SUPPORT:

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