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A Concept of Research on change in Inflammatory Markers in patients of *Aamwata* (w. s. r., Rheumatoid Arthritis) treated with Leech Therapy

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Abstract:

Amavata can be correlated to Rheumatoid Arthritis which is characterized by the inflammatory type of arthritis, of severe and debilitating nature. No doubt modern medical science has got an important role to play in overcoming the agony of pain, restricted movement and disability and prolonged use of modern medicines are not only giving rise to many side effects, toxic symptoms and adverse reactions but also more serious complications are caused, Hence the management of this disease is merely insufficient in other systems of medicine and patients are continuously looking with a hope towards Ayurveda to overcome this challenge. Leech Therapy has been established as one of the most efficacious therapies in the management of various skin conditions like psoriasis, Eczema, cysts, abscess, and cellulitis etc. and musculoskeletal disorders. The present study primarily aims at studying the change in inflammatory markers such as C reactive proteins (CRP), Erythrocyte Sedimentation Rate (ESR), TLC (total

leukocyte count), and DLC (differential leucocyte count) in two groups of patients of Aamvata. From numerous researches, it is evident that CRP, ESR, TLC, and DLC are important inflammatory markers and found to increase in various conditions like Rheumatoid Arthritis, Myocardial Infarction, Alzheimer's Disease, Diabetes Mellitus, and other diseases where there is the inflammatory process in the body. . The present study aims at determining the changes in inflammatory markers like CRP, ESR, TLC, and DLC in the patients of Aamvata treated with Leech Therapy.

Keywords: Aamvata, Leech Therapy, Inflammatory Markers, Musculoskeletal disorders, Cellulitis

Introduction:

Ayurveda is a science which deals with the basic fundamentals of Balanced diet and Healthy lifestyle to lead a disease free life. With the advancing time,man is adapting changes in most of the dietary habits, social structure, life style, and environment. Occurrence of Amavata which is commonest among chronic inflammatory joint diseases, is an outcome of this change, in which joints become swollen, painful, and stiff. Amavata was first described as an independent disease in Madhava Nidana.¹ It is a disease of Madhyama Roga Marga as it affects Sandhi and Hridaya Marma. It is a debilitating disease in view of its chronicity and complications.²Therefore, has secured foremost place among the joint the disorders. It continues to pose challenge to physicians due to its severe morbidity and crippling nature and claiming the maximum loss of productivity making it a biggest health issue worldwide, irrespective of races.³ It can be equated with Rheumatoid Arthritis, an inflammatory autoimmune joint disorder. The lives of more than one million people are physically impaired due to Rheumatic disorders and one fifth of these are severely disabled. New classification criteria overruled the "old" ACR criteria of 1987 and are adapted for early RA diagnosis. The "new" classification criteria, jointly published by the American College of Rheumatology (ACR) and the European League against Rheumatism (EULAR) establish a point value between 0 and 10. In these, 1 point is attributed to elevated ESR (Erythrocyte Sedimentation Rate), and or elevated CRP value (Creactive protein).⁴

Prolonged use of modern medicines is not only giving rise to many side effects, toxic symptoms and adverse reactions but also more serious complications are caused by them. Hence the management of this disease is merely insufficient in other systems of medicine and patients are continuously looking with a hope towards Ayurveda to overcome this challenge.

The first description of leech therapy, classified as <u>blood Letting</u>, was found in the text of *Sushruta Samhita* (dating 800 B.C.), who described 12 types of leeches (6

poisonous and 6 non-poisonous).⁵ Diseases where leech therapy was indicated were skin diseases, sciatica, and musculoskeletal pains etc. Medicinal leeches have been found to secrete saliva containing about 60 different proteins. Several of these secreted proteins serve as anticoagulants (such as hirudin), platelet aggregation inhibitors (most notably apyrase, collagenase, and calin). vasodilators, and proteinase inhibitors. It is also thought that the saliva contains an anaesthetic, as leech bites are generally not painful and enzymes containing analgesic and anti-inflammatory properties. Medicinal leeches are commonly Hirudo medicinalis, the European medicinal leech.⁶ Hence Leech Therapy has been established as one of the most efficacious therapies the in management of conditions like psoriasis, Eczema, cysts, abscess, and cellulites and musculoskeletal disorders etc.

1. Plan of Study:

The present study primarily aims at studying the change in inflammatory markers such as C reactive proteins (CRP), Erythrocyte Sedimentation Rate (ESR), TLC (total leukocyte count), and DLC (differential leucocyte count) in Aamvata patients of (Rheumatoid Arthritis) treated by Leech Therapy. From numerous researches it is evident that CRP, ESR, TLC and DLC are important inflammatory markers and found to increase in various conditions like Rheumatoid Arthritis, Myocardial Infarction, Alzheimer'sDisease, Diabetes Mellitus, and other diseases where there is inflammatory process in body^{7-15.}

2. Rationale of the Study:

RA affects between 0.5 and 1% of adults in the developed world with

between 5 and 50 per 100,000 people newly developing the condition each year. The goal of treatment is to reduce pain, decrease inflammation. and improve person's overall a functioning. Pain medications, steroids, and NSAIDs are frequently used to help with symptoms. There is scope for the establishment for newer modalities of treatment in RA to arrest the disease progress in its early stages and to avoid the certain side effects of NSAID"S like severe Gastritis, Nephrotoxicity and Hepato toxicity.¹⁶ Leech Therapy(Jallloukavacharana) is a known therapy treatment in the of shopha.¹⁷Aamvata is disease a characterised by shopha in sandhisthana. **Similarly** RA is characterised by inflammatory type of Arthritis. Most of the researches done on Arthritis and Leech Therapy are based on subjective parameters but not on objective parameters like inflammatory markers,^{18,19} With the citation of various articles n texts, it has been found that TLC, DLC, CRP and ESR have been mentioned as important markers of inflammation in variety of diseases like RA. Diabetes etc.^{20,21}Considering all these aspects about Aamvata (Rheumatoid Arthritis). Markers of inflammation and Leech Therapy a research is proposed titled "Study of inflammatory markers in patients of Rheumatoid Arthritis (wsr, Aamvata) treated by Leech Therapy" has been selected for study. After obtaining the clearance from IEC (institutional Ethics Committee), the present study is proposed for research in the criteria formatted.

3. AIM AND OBJECTIVES

Aim:To assess of efficacy of Leech Therapy on Inflammatory Markers in the patients of *Aamvata* (Rheumatoid Arthritis) Objectives:

1) To assess the antiinflammatory effect of Leech Therapy in patients of *Aamvata* (Rheumatoid Arthritis)

2) To assess the efficacy of Leech Therapy on Pain

3) To assess the effect of Leech Therapy on joint movement

5. REVIEW OF LITERATURE

5.1 Historical Review of Aamvata-The entity Amavata is available since the period of Charaka as a reference in the context of various treatments.^{22,23,24} However, Amavata as a separate disease entity was described for the first time in detail by Madhavakara (900 AD) who devoted a full chapter of Amavata in his treatise Madhava Nidanam famous dealing with the aetiopathogenesis of the disease in a systematic manner besides the signs, symptoms, complications and prognosis.²⁵Amavata has been described since ancient period which can be understood in the following manner:

I. Vedic Kaal (Ancient Period)

II. Samhita Kaal (Classical Period)

III. Sangraha Kaal (Medieval Period)

IV. Adhunika Kaal (Modern Period)

Adhunika Kaal:

Shri Gananath Sen has classified the joint diseases into five types including an entity termed as Rasavata which has been suggested as a synonym of Amavata in order to highlight the role of incompletely 4

processed Rasa in the initiation of the disease process. Four types of Manya stambha have been described by him in Ayurveda Rahasya Deepika in which one type is Amavata Manyastambha.²⁶ Prof.Y. N. Upadhyaya and others have equated Amavata with

5.2 Review of Leech Therapy:

The first description of leech therapy, classified as bloodletting, was found in the text of Sushruta samhita (dating 800 B.C.) written by Acharya Sushruta, who was also considered the father of surgery. He described 12 types of leeches (6 poisonous and 6 nonpoisonous). Diseases where leech therapy was indicated were skin diseases, sciatica. and musculoskeletal pains etc.²⁷A recorded use of leeches in medicine was also found during 200 B.C. by the Greek physician Nicander in Colophon. Medical use of leeches was discussed by Avicenna in The Canon of Medicine (1020's) and by Abd-el-latif al-Baghdadi in the 12th century. The use of leeches began to become less widespread towards the end of the 19th century.²⁸

Medicinal leech therapy made an international comeback in the 1970s in microsurgery, used to stimulate circulation to salvage skin grafts and other tissue threatened by postoperative venous congestion particularly in finger reattachment and reconstructive surgery of the ear, nose, lip, and eyelid" Other clinical applications of medicinal leech therapy include varicose veins, muscle thrombophlebitis, cramps, and osteoarthritis, among many varied conditions. The therapeutic effect is not from the blood taken in the meal, but from the continued and steady bleeding

from the wound left after the leech has detached, as well as the anesthetizing, anti-inflammatory, vasodilation and properties of the secreted leech saliva. The most common complication from leech treatment is prolonged bleeding, which can easily be treated, although allergic reactions and bacterial infections may also occur.²⁹ Jalloukavacharana has been an established therapy of Raktamokshana by Anushastras, others being Ghatiyantra, Shringa karma and Alabu Karma.³⁰

Indications for *Raktamokshana* (bloodletting):

- Vranashopha(Cellulites)
- Kushtha(Skin Diseases),
- Visarpa(Erysipelas)
- *Pidaka*(Skin eruptions)
- *Raktapitta*(Bleeding disorders)
- Gudapaka(Proctitis)
- > *Pleeha*(Splenomegaly)
- Vatarakta(Gout)
- Arsha(Haemorrhoids)
- Vidradhi(Abscess)
- Arbooda(tumour)
- Shwitra(Leucoderma)
- *Dadru*(ring worm)

Types of Jalloukas (Leeches):

- Savisha(Poisonous)
- Nirvisha(non-poisonous)

Savisha Jalloukas (Poisonous Leeches) are not indicated to treat the patients.³¹

Complications of *Jalloukavacharan* (Leech Therapy)

Shotha(swelling),Kandu(SevereItching), Murcha(Shock),Jwara(fever),Daha(local Burning),Chardi(Vomiting).³²

- ➤ Kingdom Animals
- Phylum Annelida
- Class Clitellata
- > Order Hirudinea
- ➢ Family Hirudinadae
- Genus Hirudo
- Species H.Medicinalis, H.Manillensis

There are many other species of leeches in medicinal use. In Asia H. Manillensis is used for treatment and in Europe H. Medicinalis is used for treatment. Along with this other species like H.Verbana, H.Orientalis are also used for treatment purpose.³³

5.3 Rheumatoid Arthritis Review

Rheumatoid arthritis (RA) is a long-lasting autoimmune disorder that primarily affects joints. It typically results in warm, swollen, and painful joints. Pain and stiffness often worsen following rest. Most commonly, the wrist and hands are involved, with the same joints typically involved on both sides of the body.

Joints-Arthritis of joints involves inflammation of the synovial membrane. Joints become swollen, tender and warm, and stiffness limits their movement. With time, multiple joints are affected (it is a polyarthritis). Most commonly involved are the small joints of the hands, feet and cervical spine, but larger joints like the shoulder and knee can also be involved. Synovitis can lead to tethering of tissue with loss of movement and erosion of the joint surface causing deformity and loss of function.

RA typically manifests with signs of inflammation. with the affected joints being swollen, warm, painful and stiff, particularly early in the morning on waking or following prolonged inactivity. Increased stiffness early in the morning is often a prominent feature of the disease and typically lasts for more than an hour. Gentle movements may relieve symptoms in early stages of the disease. These signs help distinguish rheumatoid from noninflammatory problems of the joints, often referred to as osteoarthritis. In arthritis of non-inflammatory causes, signs of inflammation and early morning stiffness are less prominent with stiffness typically less than one hour. and movements induce pain caused by mechanical arthritis. The pain associated with RA is induced at the site of inflammation and classified as nociceptive as opposed to neuropathic. The joints are often affected in a fairly symmetrical fashion, although this is not specific, and the initial presentation may be asymmetrical.

Constitutional symptoms

Constitutional symptoms including fatigue, low grade fever, malaise, and morning stiffness, loss of appetite and loss of weight are common systemic manifestations seen in people with active RA.

The ACR/EULAR Rheumatoid Arthritis Classification Criteria

In 2010 the ACR / EULAR Rheumatoid Arthritis Classification Criteria were introduced. The new criterion is not a diagnostic criterion but a classification criterion to identify disease with a high likelihood of developing a chronic form. However a score of 6 or greater unequivocally classifies a person with a diagnosis of rheumatoid arthritis.

These "new" classification criteria overruled the "old" ACR criteria of 1987 and are adapted for early RA diagnosis. "new" The classification criteria. jointly published by the "American College of Rheumatology" (ACR) and the "European against League Rheumatism" (EULAR) establish a point value between 0 and 10.

In clinical practice, the following criteria apply:

- two or more swollen joints
- morning stiffness lasting more than one hour for at least six weeks
- The detection of rheumatoid factors or autoantibodies against citrullinated protiens (ACPA), autoantibodies to mutated citrullinated vimentin MCV can confirm the suspicion of RA. A negative autoantibody result does not exclude a diagnosis of RA.

Treatment- There is no cure for rheumatoid arthritis. But recent discoveries indicate that remission of symptoms is more likely when treatment begins early with strong medications known as disease-modifying ant rheumatic drugs (DMARDs).

Medications

NSAIDs- Nonsteroidal antiinflammatory drugs (NSAIDs) can relieve pain and reduce inflammation. Over-the-counter NSAIDs include ibuprofen (Advil, Motrin IB) and naproxen sodium (Aleve). Stronger NSAIDs are available by prescription. Side effects may include ringing in your ears, stomach irritation, heart problems, and liver and kidney damage.

Steroids- Corticosteroid medications, such as prednisone, reduce inflammation and pain and slow joint damage. Side effects may include thinning of bones, weight gain and diabetes. Doctors often prescribe a corticosteroid to relieve acute symptoms, with the goal of gradually tapering off the medication.

Disease-modifying anti-rheumatic drugs (DMARDs). These drugs can slow the progression of rheumatoid arthritis and save the joints and other tissues from permanent damage. Common **DMARDs** include methotrexate (Trexall, Otrexup, Rasuvo), leflunomide (Arava), hydroxychloroquine (Plaquenil) and sulfasalazine (Azulfidine). Side effects vary but may include liver damage, bone marrow suppression and severe lung infections.³⁴

5.4 Review of Inflammatory Markers:

 CRP(C reactive proteins) and ESR(erythrocyte sedimentation rate)

The 'acute phase response' refers to a large number of patho-physiological changes that occur in the setting of inflammation. Despite the name, many of the features of the acute phase response also occur in response to more chronic conditions, including malignancy and infection. Acute-phase reactants are proteins whose concentrations in blood increase or decrease by 25% or more during inflammation. The acute-phase reactants most commonly used for C-reactive diagnostic purposes are protein (CRP) and the ervthrocvte sedimentation rate (ESR). Although these two markers lack the specificity to distinguish among the many possible causes of inflammation, they are a simple, cost-effective and valuable diagnostic tool to distinguish inflammatory from non-inflammatory conditions and to monitor the response to treatment for a number of disorders. The plasma half-life of CRP is 19 hours and its clearance is constant, meaning that it is the rate of synthesis that determines its concentration.

The ESR is defined as the distance that ervthrocytes settle in anticoagulated whole blood, under gravity, in one hour. It is measured as the length in mm, of clear plasma at the top of a vertical tube. Thus it actually measures the amount of sedimentation in an hour as opposed to the rate per hour. The ESR is a simple and inexpensive test. In the laboratory, there are two main methods for measuring ESR: disease activity Assessment of of autoimmune/ inflammatory auto conditions (increase in serum CRP and ESR levels)

- Rheumatoid arthritis
- Juvenile idiopathic arthritis
- Seronegative arthritis
- Ankylosing spondylitis
- Reactive arthritis
- Psoriatic arthritis
- Crohn's disease

- Rheumatic fever
- Vasculitis
- Bechet's syndrome
- Polyarteritis nodosa
- Pancreatitis
- Assistance with diagnosis and monitoring of infection
- Bacterial endocarditis
- Abscess
- Postoperative infection
- Response to antibiotic therapy.

Along with CRP, ESR, TLC (total leucocyte count) and DLC (differential leucocyte count) will be done in every patient prior to treatment and after treatment.

TLC (Total Leucocyte Count):

Leucocytosis is very common in acutely ill patients. It occurs in response to a wide variety of conditions, including viral, bacterial, fungal or parasitic cancer, haemorrhage infections, and exposure to certain medications like steroids, beta agonists etc. It is frequently a sign of an inflammatory response, strenuous exercise. convulsions, pregnancy, labour. anaesthesia, emotional stress etc. There are five principal types of leucocytosis

DLC (Differential Leucocyte Count):

This gives relative percentage of each type of white blood cells and also helps reveal abnormal white blood cell population. Both are blood tests counted in lab under complete blood count (CBC)³⁵

5.5 Leech Review- Leeches Description:

- Kingdom Animals
- Phylum- Annelida

- Class- Clitellata
- ➢ Order- Hirudinea
- ➢ Family- Hirudinadae
- ➢ Genus- Hirudo
- Species- H.Medicinalis,
 H.Manillensis

There are many other species of leeches in medicinal use. In Asia H. Manillensis is used for treatment and in Europe H.Medicinalis is used for treatment. Along with this other species like H.Verbana, H.Orientalis are also used for treatment purpose.³⁶

6 MATERIALS AND METHODS

Materials:

TabletsofParacetamol,LeechesandLeechLabandotherprocurementsaspertherequirementsgiven in specific subheadings

Methodology:

The patients suffering from Aamvata (Rheumatoid Arthritis) who satisfy the criteria of case defination in the present study will be selected for the study. The patients will be subjected to detailed clinical examination and investigations per the specially as designed proforma.

The present clinical study comprises of 50 subjects which will be treated by leech therapy alternate day for 10 sittings. They will be considered as a single group ie, experimental group.

Leeching will be done on 1 or 2 painful joints at a time with 1 or 2 leeches applied to every joint. This procedure will be repeated for other painful joints on next sitting if required, with same plan. Changes in symptomatology will be noted simultaneously on the CRF. Similar procedure will be repeated on alternate days for 10 sittings. Investigations like CRP and ESR and TLC, DLC will be done prior to leech Therapy and after the completion of Leech Therapy. Any undesired reaction will be taken care of. Patient is given absolute liberty to opt out of study if not willing during the course of treatment. The patient who will be having severe pain during the study will be given tab paracetamol 500mg stat for pain relief if required.³⁷

These patients suffering from Aamvata (Rheumatoid Arthritis) will be selected from OPD of Shalya Tantra dept of MGACH and RC, Salod, Wardha, and OPD of dept of Kayachikitsa of MGACH and RC, Salod, Wardha.Written consent will be taken in every patient. Other investigations like Hb (haemoglobin), RBS(Random blood sugar), HIV(Human immune deficiency syndrome test). Hbsag(Australia antigen test), Bleeding Time(BT), Clotting Time(CT), Prothrombin time(PT) will be done prior to and after treatment in every patient and after treatment where required. Patients for Leech Therapy will be subjected to Purvakarma, Pradhana Karma and Paschtakarma

Purvakarma:

1) Procurement- table, Leeches, Gauze Cotton, mustard powder, Haridra Churna (Turmeric powder), Kidney Tray, Disposable Needles

2) Written Consent- Written Consent will be taken in local language (Marathi).

3) Leech storage and preservation will be done in a leech aquarium with muddy environment and adequate water. Care will be taken to change the water frequently. There will be separate jars to store used leeches.

4) Patient care - General health of the patient will be first examined. Mornings will be the preferred time to apply leeches. Pulse, blood pressure of the patient will be examined prior to application of Leech.

5) Care of the Leech (Leech disinfection) – Before use, leeches will be smeared with a paste of mustard and turmeric which acts as a disinfectant and increases their appetite and blood sucking. These disinfected leeches will be kept in a fresh jar of water for half an hour prior to use. *Pradhana Karma*:

The area where leech is to be applied will first be cleaned thoroughly with sterile water. Disinfectant or soap will be avoided, as this can irritate a leech and prevent it from attaching. The leech will be taken from its jar and its mouth placed precisely over the spot where the blood is to be removed. The leech's tail should be held until it begins to withdraw blood, at which time it can be gently released. The leech will be lightly covered with moist cotton (pads), while it works. This will be kept wet until the end of the procedure. Leeches normally suck about 5ml of blood. Leech will be allowed to finish on its own. The maximum amount of blood to be withdrawn from an individual patient will depend on the patient's general condition and the nature of the disease.

Paschata Karma:

a) Aftercare of patient - after the removal of leech, blood will be allowed to flow from the wound for a few minutes .Turmeric powder will be applied for its antiseptic, antibacterial effects

b) Care of the Leech - The same leech will be used with the same patient more than once, but it will be purified after each application. Massaging the leech from tail to mouth will help to vomit ingested blood. Keeping leeches in Turmeric water will also help to vomit the blood without force. Once the leeches are emptied of, they will be kept in dilute saline, turmeric water and plain water in sequence. The leeches will be placed in jars. The water in the jar will be changed every day to remove any toxins. Used, leeches will not be considered for use, for at least 7 days.³⁸

7 Complications and Special Agendas of Study:

1) **Infection** if any will be taken care of with administration of antibiotics.

2) Local hypersensitivity reaction, itching, blister forming, ulcerative necrosis and even local tissue damage due to existence of some toxins in leech saliva.

Appropriate treatment will be given if these symptoms occur.

3) Skin marks (scar) due to impaired healing of leech bites will be taken care of.

4) Blood loss because of prolonged haemorrhage will be taken care of.

5) Ethical issues about patient care will be promptly dealt.

6) Any complication or drug allergy or hypersensitivity like reaction will be promptly dealt with and will be treated adequately

7) Any Undesired results in patients will be taken care of.

All these things will be kept in mind while treating the patients with Leech Therapy and will be treated accordingly.³⁹

8. Inclusion Criterias:

- Patients in the age group 20 to 60 yrs. will be selected for study
- Patients with special features of RA will be selected for study
 - Two or more swollen joints
 - Morning stiffness lasting more than one hour for at least six weeks

• The detection of rheumatoid factors or autoantibodies against ACPA.

• A negative autoantibody result does not exclude a diagnosis of RA; this patient will be considered for study.

• Patients with elevated erythrocyte sedimentation rate, ESR, or elevated CRP value (C-reactive protein)

• Symptoms lasting six weeks or longer

- Patients who give written consent of study
- Patients of uncomplicated RA will be included in the study.

9. Exclusion Criterias:

- Anaemic patient in which Hb is below 8 gms
- Pregnant ladies
- Lactating Mothers
- Patient below 20 yrs. and above 60 yrs. of age
- > Children
- Patient who is HIV positive

- Patients having Hbsag positive
- Patient having IHD and on treatment
- Patient having bleeding disorders such as haemophilia and Arterial Insufficiency
- Allergy to leeches
- Patients having comorbid conditions like Diabetes, Obesity, Tuberculosis etc
- Patients with Psoriatic Arthritis
- Patients with Alzheimer's disease
- Patients with history of Myocardial Infarction
- Patients with any other systemic inflammatory disease like SLE
- Patients with Osteo Arthritis
- Patients with any Infective Diseases

10. **Study Type-** This is an observational Study

11. Specific Statistical Test to be applied

Mean, Standard deviation and level of significance will be calculated in the given sample.

12. Scope, Limitations and Implications of the proposed Study in health Science

The present study can help the medical world to accept and propose the anti-inflammatory effect of Leech Therapy in various other conditions in which, CRP, ESR, TLC, DLC is raise

There is a wide range of studies and researches being done on number of diseases with leech

therapy but on subjective parameters. This study is based on absolute objective parameters like inflammatory markers (CRP, ESR, TLC, and DLC) in patients of *Rheumatoid Arthritis (wsr Aamvata)* treated with Leech Therapy.

From all the probable researches it can be stated that Leech Therapy is an extremely popular, safe and beneficial treatment modality implemented worldwide with controllable side effects and no dangerous hazards.

13. DATA ANALYSIS

Data will be analysed by: Mean, Standard deviation and level of significance will be calculated in the given sample.

14. OBSERVATION AND RESULTS -The observations and results obtained from the clinical study will be analysed statistically to evaluate the significance of the curative properties of therapies.

15. DISCUSSION- The section of discussion will include the appraisal of the results obtained from the clinical studies.

16. CONCLUSION AND SUMMARY

The study will be concluded with the summary and conclusion of the entire work

In this way, a research study on a parasurgical tool called Leech is proposed in context of Aamvata with special reference to markers of inflammation in view of the antiinflammatory effect of leech therapy.

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