A Comparative Random Clinical Trial to Compare Efficacy of Jalaukavcharan and Cupping Therapy in the Management of Janu Sandhivata W.S.R. to Osteoarthritis of Knee Joint -A Study Protocol

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***Abstract*—Sandhivata is a Vata-predominant disorder that produces both inflammatory and degenerative changes within the joints. The knee joint is most commonly affected because it bears maximum mechanical stress during routine daily activities. Janusandhivata is a leading cause of disability among the elderly and typically presents with shoola (pain), shotha (inflammation), vāta-pūrṇa-dṛti-sparśa (a sensation resembling air-filled bags on palpation), and pravartitavedanā (pain during joint movements). Due to similarities in etiology and clinical manifestations, Janusandhigata Vata closely correlates with osteoarthritis of the knee, the most prevalent form of arthritis. Osteoarthritis is characterized by progressive degeneration of articular cartilage, subchondral bone changes, synovial inflammation, and osteophyte formation, which collectively result in pain, stiffness, restricted mobility, and diminished quality of life, particularly in older adults. Sandhivata remains a challenging condition for clinicians because of its chronic, progressive nature, limited curability, and potential complications. Modern allopathic treatments primarily address symptom relief; however, the underlying pathology often persists due to the lack of definitive therapeutic options and long-term use of these medications may lead to side effects and adverse reactions. Ayurvedic management of Janusandhivata emphasizes strengthening the affected joint and reducing pain and inflammation through natural therapies supported by appropriate dietary and lifestyle modifications. Jalaukavacharana helps alleviate pain, tenderness, and inflammation while enhancing microcirculation through bioactive enzymes and pharmacologically active substances secreted by the leech. Cupping therapy has been shown to improve muscle function and enhance tissue metabolism by increasing local blood flow. Therefore, it is essential to undertake research comparing the effectiveness of Jalaukavacharana and Cupping Therapy in the management of Janusandhivata with special reference to knee osteoarthritis**

***Index Terms*—Jalaukaavcharan, Cupping therapy, Osteoarthritis of knee joint, Janusandhivata.**

I. INTRODUCTION

Janusandhivata is a Vata-dominant disorder in which aggravated Vata localizes in the knee joint (Janusandhi). It is manifested by symptoms such as shoola (joint pain), shotha (swelling), prasaraṇa–ākunchana-yoḥpravṛttivedanā (pain during flexion and extension of the knee), and vāta-pūrṇa-dṛti-sparśa (coarse crepitus)[1]. According to Acharya Sushruta, Sandhigata Anila occurs when vitiated Vata becomes lodged in the joints, leading to functional impairment accompanied by pain and swelling[2]. Acharya Madhavakara further mentions Atopa (crepitation) as an important feature in place of shotha. The major etiological factors for Sandhivata include rukshaahara, atimaithuna, ativyayama, sheetabhojana, dhātukṣaya, and roga-atikarshana. This condition closely resembles

osteoarthritis of the knee, a progressive degenerative disorder characterized by the breakdown of articular cartilage resulting in pain, stiffness, swelling, and reduced mobility. Osteoarthritis is the most prevalent form of arthritis worldwide, particularly affecting older adults, with a higher incidence in postmenopausal women. Since the knee is a weight-bearing joint, prolonged mechanical stress makes it highly susceptible to wear and tear. As the protective cartilage deteriorates, bone surfaces begin to rub against one another, causing inflammation, discomfort, sclerosis, and soft-tissue hypertrophy[3]. Osteoarthritis is classified[4] as primary or secondary, based on etiology. Primary OA develops due to multifactorial influences such as age, gender, mechanical overload, inflammation, metabolic factors, immunity, and genetics, whereas secondary OA arises from trauma, congenital articular deformities, or iatrogenic injuries. Pathology involves active degenerative and reparative imbalances rather than simple passive deterioration.

Ayurvedic management of this condition includes both BāhyaChikitsā (external therapies) and AbhyantaraChikitsā (internal therapies). Treatment aims to pacify aggravated Vata and enhance śleṣaka kapha to improve joint lubrication and mobility. Recommended procedures include snehana, swedana, mridusamshodhana, basti, vataharaaushadha, along with appropriate ahara and vihara. Practices such as upanaha, agnikarma, raktamokshana, bandhana, and mardana are also described in classical texts. Internal medications often include ghritas, guggulu formulations, and Shallaki preparations.

Jalaukavacharana (leech therapy) is indicated in conditions with Pitta predominance. It provides analgesia through antinociceptive and counter-irritant effects. Leech saliva contains pharmacologically active substances like hirudin and hyaluronidase, which exhibit analgesic, anti-inflammatory, and mild anesthetic properties[5]. Studies suggest that leech therapy may be more effective than topical analgesics or NSAIDs. It enhances superficial skin perfusion up to approximately 16 mm around the bite site and produces noticeable analgesic and anti-phlogistic effects due to its enzymatic components.

Cupping therapy is a widely practiced traditional technique used globally. It has been reported to benefit various conditions including hypertension, rheumatoid arthritis, diabetes mellitus, mental disorders, and cardiac ailments, as well as dermatological, musculoskeletal, and allergic disorders[6]. Therapeutically, cupping functions through suction. A cup is applied to the skin and negative pressure is created either mechanically or thermally, drawing the skin into the cup. This causes localized congestion, redness, warmth, and increased blood flow. Strong suction may result in subcutaneous or intracutaneous bleeding. Cupping also enhances muscle function by improving blood supply to specific regions[7].

II. NEED FOR THE STUDY

With the rising prevalence of this disorder, it has become a significant public health concern and societal burden, as it gradually reduces an individual's working capacity and increases dependency. [8]According to the 2011 Census, individuals aged 60 years and above constituted 8.6% of the total population, amounting to 103 million people, and osteoarthritis of the knee is one of the most common conditions affecting this age group. The disease restricts essential daily activities such as walking, dressing, and bathing, often rendering affected individuals partially or even completely dependent.

Knee osteoarthritis is a chronic and troublesome condition. Although it is not life-threatening, the recurrent episodes and persistent pain severely impair the patient's quality of life. In modern times, patients seek rapid and long-lasting relief from pain. Current conventional treatment options include NSAIDs, physiotherapy, and surgical interventions. However, NSAIDs are associated with several adverse effects such as gastritis, mucosal ulceration, and heartburn, making them unsuitable for long-term use. Physiotherapy can be time-consuming and expensive, and surgery is often costly and carries inherent risks and complications.

Therefore, there is a growing need for safe, conservative, and cost-effective therapeutic alternatives for managing knee osteoarthritis. Jalaukavacharana and Cupping Therapy offer promising options. In Jalaukavacharana, leeches release a variety of biologically active substances such as hirudin, histamine, bdellins, eglins, and carboxypeptidase into the bloodstream, which help reduce pain, tenderness, and inflammation while enhancing microcirculation by lowering blood viscosity- thereby improving overall quality of life. Cupping therapy strengthens specific muscle groups, enhances blood supply, and promotes tissue metabolism by increasing local circulation.

Both procedures are OPD-based, easy to perform, require

minimal setup, and can be effectively used as therapeutic interventions. Hence, the present study aims to evaluate the efficacy of Jalaukavacharana and Cupping Therapy in reducing pain and stiffness and in improving the quality of life in patients suffering from knee osteoarthritis.

AIM:-
TovalidateaneffectivemodalityinmanagementofJanus andhivataw.s.rtoOsteoarthritisof Knee joint.

OBJECTIVE:-
Togivesymptomaticrelieftoosteoarthriticpatient.
To increase their quality of life.

RESEARCH QUESTION:-
Is thereany significant difference between efficacy of Jalaukavcharan and Cupping Therapy in management of Janu sandhivata w.s.r to Osteoarthritis of Knee joint?

HYPOTHESIS:-
RESEARCH HYPOTHESIS:-
There is significant difference between efficacy of Jalaukavcharan and Cupping Therapy in management of Janusandhivataw.s.r. to osteoarthrithis of knee joint

NULL HYPOTHESIS:-
There is no significant difference between jalaukavcharan and Cupping Therapy in management of Janusandhivata w.s.r.to Osteoarthrithis of knee joint

CASESTUDY:-
Due to the limited time period for research work completion and due to high expense of research, it is not feasible to take all the patients calculated according to sample selection criteria. Therefore, Total 60 patients will be selected forthe study who had been diagnosed with Janu sandhivatawith ages ranging from 35 years to 70 years, irrespective of gender, religion, occupation, socio-economic status etc. Patients were divided into 2 groups and given specific treatment and observations were noted during its follow up .

STUDYDESIGN:-
Study Type: Interventional
Sub Type: Control Trial
Purpose: Treatment
Timing: Prospective
Masking: Open trial
Sampling Method: Simple Random using computer assisted randomization with allocation concealment

End Point: Efficacy

GROUP:-
Twogroupsofthirty-thirtypatientswillbemadetocomparetheefficacyofJalaukavcharanand Cupping Therapy in management of Janu sandhivata w.s.r to Osteoarthritis of knee joint
GroupA Group B

GROUPS	NUMBER OF THE PATIENT	TYPEOFDRUG /THERAPYUSED	DURATION
GROUP A	30	Jalaukavcharan	49DAYS
GROUP B	30	CuppingTherapy	49DAYS

PROCEDURE:-
GROUPA: (JALAUKAVCHARAN)-
The procedure performed in three stages as Poorva Karma, Pradhan Karma and Paschat Karma as mentioned by Acharya Shushruta.

POORVAKARMA:-
1. Activation of leech will be done by pouring the leech in water mixed with turmeric powder.
2. Part preparation-The affected part will be prepared by rubbing with cotton gauze piece to just remove superficial dead skin.Cleaning of part of body will be done with Distilled water and will be drapped with Surgical cut sheet.

PRADHANAKARMA:-
1. Leech will stick to desired area then leech will be held with small, white, wet gauge piece by covering body. If leech will not able to stick and bite to the desired are a then a drop of milk ,blood, ghee or honey will be dropped on the affected area part. If leech will not bite by doing so, then the skin will be pricked with a sharp and sterile needle and apply the leech through its oral sucker and cover the leech by wet gauge piece and cool water will be dropped.

2. Observation of leech - When leech bites the affected area and starts sucking, then anterior sucker assumes the shape of a horse shoe

(Ashwakhurawatananam, unnabhyavaskandham)[9].

3. When sensation of itching and pain occurs at the site of application , it indicates that leech started to suck the fresh blood , then leech will be removed.

4. Removal of leech-The leech will be removed by itself, or by application of turmeric powder on the leech after thirty minutes of application of leech.

PASCHATAKARMA:-

1. Careofwound-Thebleedingfromwoundwillbecheckedbyapplicationofturmericpowder.

2. Induction of emesis - The process of Vaman will be done , so that the same leech will be applied next time to the same patient.

GROUP B: (WET CUPPING THERAPY)– PURVAKARM:-

1. Informed and written consent of patient will be taken.
2. Proper counseling will be done to the patient about procedure and post operative scars.
3. The surface will be cleansed with disinfectant before Cupping Therapy.

PRADHANKARMA–

1. Cups will be applied to that area[10] (vastus intermedius, tibilisanterior , biceps femorlis inseration laterally , Tendons of sartorious, gracillus medially , Semitendinosus inferiorly , Vastus medialis superiorly) , then with help of pump handle , air suctioned out for 3-5 min ; then the cups will be removed.
2. Superficial pricking will be done by lancet on cupped area, then again cups will be applied.
3. Airwithin cupwill beevacuatedwith a smallhand heldpump.
4. The cup will be removed within 15-20 min or up to cup is filled 10-100ml of blood or bleeding stop automatically.

PASCHATKARMA:-

1. Dressing will be done with Turmeric Powder.
2. Patient will advisednot to take bath /shower with in 12 hrs of procedure,to take light, warm and digestible food, to take plenty of nutritious liquid.

THREE FOLLOW Ups:-

At 28th from day of the procedure, 35th from day of the procedure, 49th from day of the procedure.

SAMPLES ELECTION CRETERIA:-The sampling method will be simpler and om using computerized assisted randomization with allotment concealment.

INCLUSION CRITERIA:

Patient having sign and symptoms of second degree osteoarthritis of knee joint as explaine din modern text books andAyurvedic text books related to the topic.
Patient between the age of 35-70years.
Patients of both sex.
Patientswhowillbewillingforthetreatment.

EXCLUSION CRITERIA:-

1. Blood clotting disorder.
2. Allergic reaction to active substances of the leech.
3. PregnantWomen.
4. Secondary osteoarthritis (Amavata and Vatarakta etc.).
5. Patient with condition mentioned under contra-indication for Jalauk avcharan in Sushruta Samhita and Cupping Therapy.
6. Patients with systemic diseases like Uncontrolled Diabetes, Uncontrolled Hypertension, Patients with major disorder like Neo plastic conditions of knee.
7. T.B. Knee Joint.
8. Patient with condition Haemarthrosis Pyoarthorosis.
9. Patient undergoing other modalities of treatment for Janu Sandhivata.

WITHDRAWAL CRITERIA:-

Patients willing to quit in between will be allowed to quit. If any acute illness or complications develops; the patient will be treated accordingly and will be excluded from the study.

INVESTIGATION:-

CBC, CT, BT, ESR, RBS, Serum uric acid. HbA1C, CRP, Vit. D-(If needed)
RA factor (quantitative)
X-RaykneejointAPand lateralview.

ASSESSMENT CRITERIA:-
OBJECTIVE CRITERIA :-Stiffness, Restriction of flexion of knee joint .

SUBJECTIVE CRITERIA:-Pain,Tenderness, Swelling, Crepitus.
GRADING OF ASSESMENT CRETERIA:-

SHOOLA:-

SHOOLA(PAIN)	GRADE
No pain (0)	0
Mild pain (1-3)	1
Moderate pain but no difficulty in walking (4-6)	2
Severe difficulty in walking (7-9)	3
Severe pain, patient avoid to walk (10)	4

SWELLING:-

SWELLING	GRADE
No swelling	0
Joint swelling may not be apparent on casual inspection ,but should be recognized to an experienced Physician	1
Joints welling obvious even on casual observation	2
Markedly abnormal swelling	3
Joints welling to amaximally abnormal degree	4

RESTRICTION OF FLEXION OF KNEE JOINT:-

RESTRICTION OF MOTION	GRADE
Normal joint movement	0
Range of motion of flexion restricted to105^0	1
Range of motion of flexion restricted to 70^0	2
Range of motion of flexion restricted to 35^0	3
100% loss of motion or complete ankylosis of joint	4

TENDERNESS OF KNEE JOINT :-

TENDERNESSOFKNEEJOINT	GRADE
No tenderness	0
Mild to lerable discomforton palpation	1
More into lerable pain on ordinary palpation ,which the patient prefers not to tolerate	2
More into lerable pain even on light palpation	3
Pain may becaused by even amild stimulus such as sheet touching the joint	4

CREPITUS:-

CREPITUS	GRADE
Absenceof crepitus	0
Palpable crepitus through1\3ofRangeof Motion	1
Palpable crepitus through 1\3 -2\3 of Range of Motion	2
Palpable crepitus through greater than2\3of Range of Motion	3
Audible crepitus	4

STIFFNESS OF KNEE JOINT :-

STIFFNESSOFJOINT	GRADE
Nomorning stiffness	0
Morning stiffness for 0-10 min duration	1
Morning stiffness for 10-20 min duration	2
Morning stiffness for 20-30 min duration	3
Morning stiffness for 30-40 min duration	4

MANAGEMENTOFTHEDATA:-
Theprincipalinvestigatorwillberesponsiblefor codingthedata.

ETHICS AND DISSEMINATION:
Research ethical approval after critical evaluation and presentation to the ethical committee has taken on research topic no.CTRI/2024/07/070194.

CONSENT AND ASSESSMENT:
Subjects will be given information in their native language regarding the specifics of their therapy in great detail.The patients will then be asked to provide their written consent before the beginning of the trial. The DISSEMINATION POLICY will be taken the form of presentations as well as the publication of papers.

III. DISCUSSION

Osteoarthritis of the knee, correlated with Janu Sandhivata or Janu Sandhigata Vata in Ayurveda, presents with pain, swelling, crepitus, and restricted movement caused by degeneration of joint structures and vitiation of Vata dosha in the Sandhi. Modern management provides symptomatic relief but is often inadequate for long-term functional improvement, leading many patients to seek traditional therapeutic modalities. Among these, Jalaukavcharan (leech therapy) and wet cupping therapy have gained attention for their potential to reduce pain and inflammation through localized bloodletting.

In Ayurvedic theory, Jalaukavcharan pacifies aggravated Vata and Rakta dushti by removing vitiated blood and delivering bioactive salivary components that exert anti-inflammatory and analgesic effects. Wet cupping therapy similarly promotes local detoxification, reduces stagnation, and improves microcirculation. Although both therapies aim to reduce Srotorodha and restore joint function, there is insufficient comparative evidence evaluating their relative efficacy specifically within the pathological framework of Janu Sandhivata.

This study protocol proposes a randomized clinical trial to assess and compare Jalaukavcharan and wet cupping therapy using standardized Ayurvedic parameters- such as Shoola, Sotha, Sparsha-asahatva, and Prasarana-Akunchana vedana- alongside contemporary outcome measures like VAS Scale and range of motion. Through a rigorous design incorporating randomization, uniform treatment schedules, and validated assessment tools, the study aims to establish an evidence-based foundation for selecting the more effective modality in treating knee osteoarthritis corresponding to Janu Sandhivata.

IV. STATISTICALANALYSIS

Appropriate statistical method will be used to analyze the data collected in above observations and suitable conclusion drawn. This is a comparative study of Jalauka vcharan and Cupping Therapy in management of Janusandhi vata w.s.r to Osteoarthritis of Knee Joint.

V. CONCLUSONS

Conclusion will be mentioned after the analyzing data.

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