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CLINICAL STUDY TO ASSESS THE **EFFICACY OF "SHUSHKAMULAKADY** TAILA ABHYANGA AND KALA BASTI IN THE MANAGEMENT OF SANDHIGATA VATA SA-AMAVASTHA W.S.R. TO OSTEOARTHRITIS OF KNEE JOINT", 1, 2, 3.

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ABSTRACT:

Acharya Charaka has defined Sandhigat Vata- 'Provoked Vata locates in the Sandhi, it causes Shotha which on palpation appears like bag inflated with air and the movements of extension and flexion are accompanied with pain'. Its in modern science called Osteoarthritis (O.A.). Its a common degenerative disease of the joint, affects approximately 10% of all the adults (man & women) and the prevalence increases with the age. The disease is characterized by local areas degeneration of articular cartilage, sclerosis of the bone, formation of osteophytes and hypertrophy of the soft tissues. O.A. must commonly affect the weight-bearing joints in particular the knee, hip and spine and the interphalangeal joints of the hand. The wrist, shoulder and ankle are less often involved. In present study the Shushkamulakady taila abhyanga and Kala Basti (Matra Basti of Dashmoola taila and Niruha Basti of Triphla Kwath) therapy applied on patients. The Sandhishula reduced up to 73.2%, Sandhigraha by 79.49%, Sandhiatopa by 65.22%, Sandhiaushnyata by 67.57% and Sandhigaurava by 74.67%. Thus it can be concluded that the treatment with Shushkamulakady Taila Abhyang and Kala Basti in the management of Sandhigata Vata Sa- Amavastha enhanced.

KEY WORDS: Sandhigatavata, Osteoarthritis, Shushkamulakady taila, Matrabasti- Dashmoola taila, Niruhabasti- Triphla Kwath.

INTRODUCTION:

Sandhigatavata is most common form of arthritis whose more than 10 million cases per year reported in India. It shows strong association with ageing, obese and females. It begins asymptomatically in 3rd & 4th decade of life prevalantly more among menopausal womens [1]. Sandhigatavata is one of the "Vata Vyadhi", which is described as a separate clinical entity even though it is not included in 80 types of Nanatmaja Vata Vikara. Although Sandhigatavata cripples a large number of persons, it rarely kills any person but affects quality of life. Study also shows that type of cases, where prolonged duration of it leads to total joint destruction and the last option is joint replacement. Acharya Charaka has defined the disease that when provoked *Vata* locates in the *Sandhi*, it causes *Shotha* which on palpation appears like bag inflated with air and the movements of extension and flexion are accompanied with pain^[1].

Sandhigatavata is Madhyama Rogamarga, Situation in Marma Asthi Sandhi, Vitiation of Asthi and Majja, Dhatukshya. Vriddhavastha makes it Kastasadhya. It may be Nija or Agantuja and Sa-Ama or Nirama. After Nidan sevana(Aharaj, Viharaj, Vata Prakopaka) aggravated vata enters in the sandhi and get vitiated there by producing shotha (swelling of the joint), which is felt like a bag filled with air and the shoola (pain) occurs mainly during the flexion and extension movements of the joint [2].

Vayu get vitiated by two ways. (1) Dhatukshayajanya: Kshaya of Dhatus is the main cause of Vatavyadhi. (2) Margavarodhajanya: The primary cause of margavrodha of Srotasa by Ama, kapha, meda or Anya dosha. The vitiated vata dosha get lodges in the specific adhisthan and creates the syndrome are: 1. Dhatu-Asthi, majja, rakta,twaka. 2. Upadhatu-Twaka, rakta. 3. Indriya-Kshotra, netra. 4. Avayava-Amashaya, Pakwashaya, Guda. 5. Other- Sarvanga, Koshtha, Dhatukshaya takes place in Vriddhavastha kala due to increased Vata which diminishes Sneha from Asthidhatu due to its opposite qualities to Snehan and develop Khavaigunya (Rikta Srotas) in Asthi which is responsible for the production of Sandhigatavata

In the early stage of Osteoarthritis, the chondrocytes proliferate. This process is accompanied by biochemical changes. The two major component of cartilage: a special type of chollagen (type 2) and proteoglycans, both secreted by chondrocytes i.e. both balance is maintained by chondrocytes [4]. Risk of Osteoarthritis increased in direct proportion to bone density, and high level of estrogens. The level of certain molecular messengers, including IL-1, TNF and nitric oxide, are increased in osteoarthic cartilage, which is responsible for the decreased number of functional chondrocytes. Symptoms of Osteoarthritis are similar as of Sandhigatavata i.e. Joint pain, Swelling, Stiffness Disability and Crepitating over joint. Degenerative type of arthritis mainly occurs in old age. It is a chronic degenerative disorder of multifactorial aetiology characterized by loss of articular cartilage and peri-articular bone remodelling. The risk factors for osteoarthritis are old age, obesity, female sex, major joint trauma, repetitive stress, genetic factors, prior inflammatory joint diseases and metabolic or endocrine disorders. In modern science, till date, no treatment is available that can reverse or slow or block the disease process. Only palliative treatment for Osteoarthritis which help in reducing the pain and swellings with Analgesics, Anti oxidants e.g. vitamin A,B,C,E etc. – to prevent the joint from oxidative damage. Weight reduction by 11 pound weight cuts 50% risk for Osteoarthritis. 5% weight loss in over weight patients gives 18% gain in overall function. So weight reduction is very essential for the treatment of Osteoarthritis [5].

The Samshodhan therapy consists of a number of physiologic measures advocated in the treatment of the diseases. It is divided into 3 major parts viz. Purva Karma (Preparatory methods like Oleation and Fomentation), *PradhanaKarma* (Main Samshodhana measures) and *Paschata Karma* (Post therapy regimen) [6]. The *Pradhana Karma* should always be preceded by suitable *Purva Karmas* in order to mobilize the *Doshas* from the discrete parts of the body (*Shakha*). It is believed that imbalanced *Doshas* spread from the Koshtha to the Shakha due to various cause and thus be able to produce various types of diseases depending upon the *Dosha Dushya-Adishthana* pattern. To eradicate the imbalanced Doshas, it is essential to mobilize the vitiated Doshas in the Shakha and to bring them back to the Koshtha by various ways of *Panchakarma* [7].

Acharya Charaka has mentioned repeated use of Snehana, Svedana, Basti and Mrudu Virechana for the treatment of Vatavyadhi [8]. It happens with the treatment of Vatashamana and Samprapti Vighatana with the drugs mentioned in the article like Nirgundi, Eranda, Bala etc are having excellent vatahara property and they act as rasayana, balya and kapha vardhaka properties which Increase Snigdha guna, Rasayana, [9, 10] Yoga exercise Bhujangasan, Trokonasan, Veerabhadrasan etc. focus solely on strengthening the quadriceps muscles make surrounding tissue strong – Muscles, ligaments and tendons which are responsible for the joint stability [11].

Objectives:

- To understand the aetiopathology, symptomatology and progression of Sandhigat Vata.
- To assess the efficacy of Shuskamulakady taila Abhyanga [12] and Kala Basti (Matra Basti of Dashmoola taila and Niruha Basti of Triphla Kwath) in the management of Janusandhigata Vata Samavastha.

MATERIAL AND METHODOLOGY:

Sample Source:

Patients having Sandhigat Vata were selected from OPD and IPD at Pandit Pyarelal Ramadatta Vaidya Chikitsalaya and Vaidya Yagya Dtta Sharma Ayuryeda Mahayidyalaya irrespective of sex. religion. economical status, education, occupation etc. for the research work. Its single group pre and post assessment based, open random, prospective study and systemic sampling method adopted with a patient quantity of total selected 30 Patients. The cases was selected strictly as per the preset exclusion and inclusion criteria. Clinical trials were conducted on them and the data obtained from the trial was analyzed with proper statistical method.

Study Design:

It is single group, open random and systemic sampling method of study.

Inclusion Criteria-

- Age: 40 to 70Years.
- Patient who will give written consent.
- Patients not taking any other treatment for same disease.
- Patient with Primary Osteoarthritis knee joint(s) fulfilling the diagnostic criteria of osteoarthritis recommended by the American College of Rheumatology i.e. Knee pain and; At least three of the following 6 criteria: 30 years of age or older, stiffness lasting less than 30 minutes, crepitus, bony tenderness, bony enlargement, no warmth to the touch.
- Pain in the affected knee joint(s) > 3 months (with radiological changes as per Grade I to III of Kellgren & Lawrence Radiological scale).

Exclusion Criteria-

- Patients with Grade IV Kellgren & Lawrence Radiological scale.
- Patients with *sandhigatavata niramavastha* will be excluded.
- Patients with other joints deformities or diseases which are not related to Sandhigatavata such as Amavata, Vatarakta, fracture of joints, psoriatic arthritis and needs surgical care will be excluded.
- Patients having major illness since long time and systemic Pathogenesis eg. Cardiac, renal will be excluded.
- History of any trauma/ fractured joint / surgical/diagnostic intervention with reference to the affected ioint(s).
- Gross disability in performing daily normal routine i.e. Bed ridden patients or confined to a wheelchair.
- Patients with co morbidities such as gouty arthritis, rheumatoid arthritis and psoriatic arthritis.
- Patients having any deformity of knee, hip or back altering the gait and posture of the patient.
- Patients with Unstable cardiovascular diseases.
- Patients with uncontrolled diabetes mellitus { HbA1c>6.5% }
- Patients with evidence of malignancy.
- Patients on prolonged (> 6 weeks) medication with corticosteroids, antidepressants, anticholinergics, etc. or any other drugs that may have an influence on the outcome of the study.
- Patients with any severe renal or hepatic or any other disorder which may interfere in the study.
- Pregnant / lactating woman.
- Patients who have participated in other clinical trials within two months of duration.other clinical trial.
- Any other condition which the Principal Investigator thinks may jeopardize the study.

Lab Investigations:

Routine blood picture, R.A. factor, S. Uric acid and X-ray knee joint.

Total treatment duration is of 28 days. Patients symptom was assessed on every interval of 07 days.

Panchakarma Chikitsa:

<u>Firstly- Shushkamulakady taila Abhyanga</u> introduced twice a day.

Secondly-Nadi sweda with Dashmoola kwath for 15 minutes.

Thirdly- Kala Basti: (A) Matra Basti with Dashmoola taila [1,3,5,7,9,11,13,14,15,16thday].

(B) Asthapan/Niruha Basti- Lekhan basti with Triphla, Gomutra, Madhu, Yavakshara, Ushakadi Avap $[2,4,6,8,10,12^{th}day].$

Criteria of Asseement:

A. Subjective Parameter-

- 1. Shoola- Akunchan prasaran janya vedna (Pain & Tenderness)
- 2. Shotha (Swelling/ Oedema)
- 3. *Graha* (Stiffness)
- 4. Sandhi Atopa- Vatapoornadrutisparsha (Crepitition)
- 5. *Aushnyata* (Temprature)
- 6. Guruta (Heaviness)
 - B. Objective Parameter-
- 1. Oxford Pain Chart
- 2. Visual Analog Scale
- 3. WOMAC index score
- 4. WHO- QOL score
- 5. X- ray of Knee Joint

RESULT & OBSERVATION:

1. Age & gender wise distribution

> According to this distribution only 8 patients (26.4 %) was in the age group of 31 - 40 yrs. There were 5 patients (16.5 %) of the age group of 41 – 50 yrs. Maximum no. of patients i.e. 13 (42.9 %) were of the age group 51 – 60 yrs and 4 (13.2%) patients were in age group 61-70. The Male patients was 9 (30%) and Female was 21 (70%), i.e. Female patients are found more in number than male patients

Prakruti and Diet-wise distribution 2.

> The 07 (23.34%) patients was vegetarian and 23 (76.67%) patients was Non vegetarian in which 15 (50%) was Vata-kaphaj prakruti, 11 (36.67%) Vata-pittaj prakruti and 04 (13.33%) was Pitta-kaphaj prakruti.

3. Joint-wise distribution (Single type & Multiple type)

The 28 (93.33%) patients found with single joint osteoarthritis and in 02 (06.67%) patients the multiple joints involvement found. In 20 (66.67%) patients unilateral side involved and in 10 (33.33%) patients with bilateral joint involvement.

The Janu/knee joint involved in 24 (80%), Gulfa/ankle joint involved in 04 (13.33%), Kati/sacral joint involved in 03 (10%) and kurpar/elbow joint in 01 (3.33%).

- Four patients out of thirty patients found markedly releaved from sign & symptoms after continuing 4. Abhyanga for 16 days, 7 days of Abhyanga is not sufficient for these 4 patients.
 - ❖ Patient no. 10th, 14th, 20th & 26th (4 patients) Abhyanga for 16 days along with Kala Basti (Dashmoola matra basti for 10 days & Triphla kwath lekhan basti for 06 days).
 - Abhyanga for 07 days along with Kala Basti (Dashmoola matra basti for 10 days & Rest 26 patients Triphla kwath lekhan basti for 06 days).

DISCUSSION:

Discussion on Clinical Study:-

1. Joint Signs and symptoms involvement

This study shows *janu sandhi* is chiefly involved in *Sandhigata vata samavastha*. As it is well known that Janu sandhi is weight bearing joint, which invites kha vigunya.

Sandhi shula is bestly relieved followed by sandhi shotha with the Ahyanga of Shushkamulakadya taila and Kala Basti (Dashmoola taila basti & Triphla kashaya basti). This is due to sthanika ama dosha pachana and vednahara effect achieved by the oil & Basti Karma.

Sandhishoola/ Pain-

Sandhishoola reduced up to 73 % of the enrolled 09 male & 21 Female patient. The t- value first visit 17.712 improved in fourth visit to 25.161. The distribution relation chart of pain Vs Knee joint shows improvement from 2.53 to 0.74. This is relieved due to the shoolahara, Vedanasthapana, Yogwahi and Naadibalya effect of Shushkamulakyadi taila and Kala basti dravya.

This oil no doubt about its safety and have its effect of local application, massaging due to presence of methyl salicylate, Pluchicin, zinziberine, sisamine, ,menthol etc .Often they are used in addition to oral NSAIDS medication.

Graha/ Stiffness/ Restricted joint movement-

Stiffness reduced to 79.49 % of 09 Male & 21 Female patients *Snigdha Ushna virva* effect of oil & *Basti*. The t-score improved from 15.321 to 17.501. The distribution relation chart of Stiffness Vs Knee joint shows improvement from 2.09 to 0.44.

Shotha/ Swelling-

The swelling reduced 71.35 % of 09 Male & 21 Female patients. The t-score improved from 22.854 to 26.354. The distribution relation chart of Shotha Vs Knee joint shows improvement from 39.43 to 36.65. Its relieved due to shothahara/Shofahara effect of the drug used.

➤ Ushnata/ Aushanyata:-

Ama gets accumulated at that Sandhi and leads to Samayastha in the disease treated with the deepan. pachan, agnivardhan, bhedana and anuloman effect of the Basti drvva along with Triphala and other.

Sandhiatopa/ Vatapurnadratisparsha / Crepitus of Knee Joint-

The Atopa resulted due to the increased Ruksha and Khara guna in dhatus due to shleshmakashayata. Thus particular sound produced due friction of dhatus. The sandhi atopa reduced to 65.22 %, with improved t-score 11.938 to 11.789. The distribution relation chart of Crepitus Vs Knee joint shows improvemet from 1.56 to 0.59. Its minimised due to Snigdha, Shookshma, Guru, Vyavayi and Laghu effect of the drug used..

- Various drug (i.e. Punarnava, Rasna, Triphala and Godugdha) used have Mineral content and Rasayan effect on joint modalities.
- The Sandhigata vata is Vata-Kapha predominent and the drug used have Vata-Kapha Shaman effect, which helped in treating the disease.

2. VAS

The overall assessment of betterment in patient's condition is improved as he was able to carry on his day to day work without needing support from others. In this study VAS shows improvement by 68.08%, which indicates this treatment is highly effective in patients of sandhigatavata samavastha.

3. Statistical view

This treatment also convince its effect on the ground of statistics. As statistical t-tests, applied to all the assessment criteria found extremely significant. The t-value of shoola at first visit 17.712 changes to final visit 25.161 due to the drug effect, the t-value of shotha changes from 22.854 to 26.354 and so on Graha(stiffness) from 15.321 to 17.501, Sandhiatopa(crepitus) from 11.938 to 11.789. Thus it can be strongly concluded that this treatment is useful in Sandhigatavata samavastha.

Discussion on Probable Mode of Action of Shushkamulakady taila Abhyanga:-

Pharmacological Action:

Shushkamulakyadi oil is used for osteoarthritis. Many other including oils have been marketed in topical formulations (mostly as gel) for application over painful joints. It is believed that the drug would penetrate to the adjacent tissues attaining high concentrations in the joints, while maintaining low blood levels.

This oil no doubt about its safety and have its effect of local application, massaging due to presence of methyl salicylate, Pluchicin, zinziberine, sisamine, ,menthol etc. Often they are used in addition to oral NSAIDS medication.

Measurement of drug concentration attained in tissues underlying the site of appliation, as well as concurrent blood levels has been shown that the systemic absorption from the topical oil preparation is slow taking ~10 times longer time to attain peak concentration empared to oral dosing.

Highest blood level remains below 12% of to same dose given orally. This is concistent with their lack of systemic toxicity. Local concentrations are high upto a depth of 3-5 mm, i.e. in dermis, but 20 mm depth in muscles, the concentration is low and the nearly same as in blood. The report on clinical efficacy of this and other topical oil are even more variable (24-82%.).

Properties of the content of Shushkamulakadi taila as follows-

<u>Mulaka</u>- Pachaka, Ushna, Pacify Vata dosha when Siddha in Sneha. Its also shoolahar and Shofahar.

Varshabhu- Shoolahara, Shothahara

Devdara- Laghu, Snigdha, Amapachaka, Shoolahara, Shothahara

Rasna- Ushna, Amapachaka, Guru, Amapachaka, Shoolahara, Shothahara

Shunthi- Ushna, Pachaka, Laghu, Snigdha, Deepan, Shoolahara, Shothahara

Tila taila- Snigdha, Pachaka, Vednasthapaka, Ushna, Shookshama, Vyavayi.

Shushkamulakadi taila, due to suksham guna of sneha, travels through different channels inbetween Twaka and Asthi-Sandhi, reaches the site of pathology and pacify Vata Dosha due to its Ushna, Snigdha and Shlakshana guna and digest sthanika Ama Dosha with Ushna, Suksham, Laghu properties. With the management of these two objectives, the signs and symptoms of Sandhigatavata Samavastha seem to be reduced significantly.

<u>Discussion on Probable Mode of Action of Kala Basti:</u>

Raspanchak of Dashmoola Taila:-

Rasa - Madhura Tikta

Vipaka - M<mark>adhura</mark>

Virya - Ushna

Guna - Guru Singdha

In Sandhigat vata, due to Vata prakopa & Shleshak Kapha kshaya, the Ruksha, Khara, Parusha gunas are increased at all over the body specially in sandhies. **Dashamoola** Taila decreases all above gunas with its Guru Snigdha gunas & pacifies Vata. Due to Madhura rasa & Madhura Vipaka it acts as Bruhana so ultimately Dhatukshaya was reduced.

Due to its Ksheerpaki nature it acts as kapha vardhaka. In strotorodha pradhan condition due to its Ushna Virya & Tikta anurasa it does the strotovishodhana & then pacifies Vata. Dashamoola Taila, pacify the symptoms like Shoola, Atopa, Shotha, Graha was redused, with its Snigdha Guna destroys Rukshata, with Guru Guna, Laghuta and with Ushna Virya, Sheetata of Vata.

Ushna. Tikshna. properties of Basti help in Amapachan and Kaphashoshan and Srotovishodhana. Madhu added in Basti scrapes out the Doshas which are producing Upalepa in the Srotas as by Lekhan Karma Saindhav with its Sukshma Guna carries the drug to minute parts and destroys whole therapy removes the Srotorodha and Vatakaphashaman also Avarodha. Thus, the occurs. Vatapurnadruti Sparsha, Prasaran Akunchan Vedana are the cardinal symptoms of Sandhigatvata, which are produced by Vayu. Basti by pacifies Vata relieves the symptoms. Also, it acts on other symptoms like Shotha Graha Aushnya by the Pachana and Kaphanashan karma. Thus, Basti acts on the Doshas, Dushyas, Srotasas involved in Sandhigatvata and also on its Rupas. It hits both the types of Samprapti i.e. Dhatukshyajanya and Margavrodhnajanya.

CONCLUSION:

- 1. Shushkamulakadya taila abhyang and Kala Basti (Dashmool Taila Matra Basti along with Lekhan Basti) in Sandhigatavata was found to be statistically highly significant.
- 2. Sandhishula reduced up to 73.2%, Sandhigraha by 79.49%, Sandhiatopa by 65.22%, Sandhiaushnyata by 67.57% and Sandhigaurava by 74.67%.
- 3. Overall assessment score shows 71.35% relief in all symptoms.

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- Dashmool Taila Matra Basti and Lekhan Basti (Kala Basti) was found to be good pachan and 4. Bruhana, vatashamana.
- 5. Kala BAsti with Dashmool Taila Matra Basti and Tiphala kwatha Lekhan Basti was highly effective in Shoola, Shotha+Aushnya+Dhatukshya+NavAvastha. It was also highly effective in the symptoms Atop, Graha.
- No adverse effect was found during or after treatment. 6.

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