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TO EVALUATE THE EFFICACY OF PANCHATIKTA GHRITA GUGGULU VATI AND GANDHA TAILA IN JANU SANDHIGATA VATA WITH SPECIAL REFERENCE TO OSTEOARTHRITIS OF KNEE JOINT - A COMPARATIVE CLINICAL STUDY

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Abstract

- Sandhi gatavata is vatapradhanavyadhi as mentioned in ayurvedic classics, clinically sandhi gatavata presents "vatapoornadrutisparsha, shotha, prasaranaakunchanasavedana"^{1,2}, "shool"^{3,4}, "atopa"⁴. In modern medical science⁵ this condition can be correlated to osteoarthritis which shows clinical features like pain, restricted movement, crepitation & swelling. Osteoarthritis⁵ is a degenerative articular cartilage & connective tissue disorder leading to pain & disability. Hip & Knee joint are the commonest joints involved in OA.⁶With irrespective of sex, Over the AGE of 45 years⁵ OA is the most common cause of disability with prevalence of 22 % to 39 % (1.255 billion) Indians, > 20 million Americans, > 35 to 40 million Europeans⁶ are affected. In spite of vigorous research with different modalities of treatment like non-narcotic analgesics, NSAID's, Intra articular injections, Arthroscopic surgeries which give better relief from the symptoms but leads to cartilage damage⁵. Thus there is no effective pharmacotherapy capable of restoring the original structure & function of damaged cartilage which is becoming a rising global burden⁶ & thus the thriving area of research. Hence this research work has been designed to explore an effective management for SANDHIVATA w.s.r. to OA.
- Charakaacharyahas emphasized shamana procedures like snehana with "sarpi-vasa-taila-majja" to provide better relief from the signs & symptoms in vatavyadhi, whereas Sushrutaacharya has emphasized "snehana" etc. in order to restore the mobility in sandhivata. PANCHATIKTA GHRITA GUGGULU VATI [PTGGV] Explained in Bhaishajyaratnavali is said to be PRABHALA VATAROGA SHAMAKA where as GANDHA TAILA [GT] Explained in AstangaHrudaya is said to be vata-pitta shamaka& also is ASTISTHAIRYAKARA. Hence it is planned to evaluate & compare the efficacy of panchatiktaghrita gugguluvati & gandhataila in janusandhigatavata [JSGV] w.s.r. to Osteoarthritis [OA] of knee joint.

INTRODUCTION:-

- Sandhi gatavata is shoolapradhaanavatajanaanaatmajavyadhi and having the laxanas like Sandhi shoola, Sandhi shotha, Prasaranaakunchanasavedana, Atopa& Sandhi griha. In modern science it simulates Osteoarthritis which is characterised by pain, Inflammation, Restricted movements, Crepitus & stiffness in joints. The prevalence of OA rises progressively with Age, such that by 65 years 80% of people have radiographic evidence of OA, though only 25-30% are symptomatic. The knee & Hip are the principle large joints involved, affecting 10-25% of those aged over 65 years.
- Janu, identified as the knee joint owing to its complexity of articulation & its major weight bearing capacity is vulnerable to wear & tear because of daily routine activities. Obvious age changes in the joint has a major role in the prevalence of JSGV in the elderly, and the sedentary urban life style has brought about step increase in the prevalence of the disease amongst younger generation as well. There is a steady rise in the prevalence from the age 45 years such that by the 65 years of age 80% of people have radiographic evidence of OA. Hence, Osteoarthritis of knee joint has silently occupied a major place among the gamut of degenerative disease, the existing treatment of which is only palliative involving analgesics, anti-inflammatory & topical applications.
- Ayurveda, the science of life & ancient system of Indian medicine have suggested many medicines to pacify the painful condition without causing any complications & thus preventing further damage or degenerative changes of joints. Pain is caused due to vitiation of vatadosha in sandhies, Sandhi gatavata is the shudhavatavyadhi, use of vatashamaka drugs relieves the symptoms of JSGV, PTGGV explained in BhaishajyaRatnavali& GT explained in AstangaHrudaya supposed to be a good remedy in relieving pain & other symptoms of JSGV.

Aims and objectives:-

1. To evaluate the efficacy of PanchatiktaGhritaGugguluVati as shamanaoushadha in janu sandhi gatavata.

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2. To evaluate the efficacy of GandhaTaila as shamanaoushadha in janu sandhi gatavata.

3. To compare the efficacy of Panchatiktaghritagugguluvati&Gandhataila in janu sandhi

gatavata.

Research / Study Design -

Inclusion Criteria -

1. Patients presenting with classical symptoms of Janu Sandhi gata vata. 1, 2, 3, 4

2. Patients of both the sex, Over the Age of 45 years.⁵

Exclusion Criteria-

1. Diagnosed Patients of fractures and dislocation of knee joint.

2. Diagnosed Patients of knee joint tuberculosis and tumours.

Material And Methods: -

A Randomized Comparative Clinical study.

Methodology

Evaluation of the patient will be done after detailed examination and the data will be recorded in a specially prepared proforma i.e. A separate case sheet will be prepared with a complete history, physical signs & symptoms, necessary lab investigations before treatment and at the

time of every follow up.

Withdrawal CriteriaDuring the course of treatment if any serious condition or any serious adverse effects occurs or pain / stiffness / swelling increases or patient himself / herself

wants to withdraw from the study- such patients may withdraw from the study

Diagnostic

Diagnosis would be done on the bases of signs & symptoms of janu sandhi gatavata as

explained in the classical text (Diagnosis will also be done according to subjective &

objective parameters)

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Statistical analysis

The both subjective & objective parameters will be scored on the basis of standard methods & will be analyzed statistically. i.e., The collected data & observations will be analyzed critically and scientifically by employing *Paired (Within the two groups) & Unpaired (Between the two groups) sample 't' Test.*

Sample size;

All the 40 patients selected will be placed under 2 groups i.e., group A and group B with 20 patients in each group.

Duration of Treatment – Shamanaoushadha will be given for 30 days in both groups.

Follow up period - Follow up will be done at once in 15 days in both groups for up to 60 days. i.e.

During treatment - follow up duration - 30 days [15^{th} & 30^{th} day] After treatment - follow up duration - 30 days [45^{th} & 60^{th} day] Total duration of study - 60 days

Assessment Criteria:

These criteria to be followed before, during & after the treatment

Subjective Parameters:

- a. Sandhi shola (Pain)
- b. Sandhi shotha(Inflammation)
- c. Prasaranaakunchanayohovedana(Painful movements)
- d. Sandhi Sphutana / atopa(Crepitation's)
- e. Sandhi graha (Stiffness)

Objective Parameters:

Goniometer (ROM of knee joint)

Interventions:

GROUP 'A': Patients under this group will be treated by PanchatiktaGhritaGugguluvati 500 mg 2 tid [3 maasha 11 = 3 gms = 3000 mg 12]- AF with sukhoshnajalaanupana for 30 days

GROUP 'B': Patients under this group will be treated by Gandha Taila -

10 drops bid ¹³- BF with sukhoshnajalaanupana for 3o day

Investigations: (If necessary) - X-Ray - AP & Lateral views of knee joint

Ethical Clearance:

The Study will be conducted on Human subjects (patients), for which Ethical clearance has been obtained from Institutional Ethic Committee (IEC), SDM Trust's Ayurvedic Medical College and hospital, Terdal - for the above said clinical trial.

Criteria for Assessment of Result-

Subjective & Objective Parameters with scores allotted

These subjective Defective parameters were assessed BT(0 th d), DT (15 th & 30 th d) & AT (45 th &60 th d)

| AC | PM | Findings | Gr |
|----|------------|--|----|
| | 1.SL | No pain during daily routine activities & even on long distance walk [*] | |
| | | No pain during daily routine activities but pain on long distance walk [*] | |
| | | Pain during daily routine activities & even on short distance walk [*] | |
| | | Unable to do even daily routine activities | 3 |
| SP | 2.ST | No inflammation | 0 |
| | | Slightly more inflammation as compare to normal | 1 |
| | | Inflammation covers all the prominences of joint | 2 |
| | | Much elevated inflammation, knee joint seems to be grossly deformed | 3 |
| | 3.PAS V | B.PAS No pain during daily routine movement & even on forceful movement of joint | |

| | | No pain during daily routine movement but pain on forceful movement of joint | | | | |
|----|---|--|---|--|--|--|
| | Pain during daily routine movement of joint | 2 | | | | |
| | Unable to move the joint | | | | | |
| | | No crepitation's during daily routine activities | 0 | | | |
| | 4.AT | Crepitation's are Palpable during daily routine movements of joint | 1 | | | |
| | | Crepitation's are audible during daily routine activities | 2 | | | |
| | | Crepitation's are audible even during slight movement of joint | 3 | | | |
| | 5.GR | No Stiffness during daily routine movement& even on forceful movement of joint | 0 | | | |
| | | No Stiffness during daily routine movement but Stiffness on forceful movement of joint | 1 | | | |
| | | Stiffness during daily routine movements of joint | 2 | | | |
| | | Unable to move the joint | 3 | | | |
| | | Above 110 ⁰ flexion (110 ⁰ -150 ⁰) | 0 | | | |
| OD | GNM (KF) | Up to 110 ⁰ flexion | 1 | | | |
| OP | | Up to 1000 flexion | 2 | | | |
| | | No free flexion | 3 | | | |

AC-Assessment criteria, PM-Parameters. Gr-Gradings, SP- Subjective parameters, OP-Objective parameter, SL-Shoola (pain), ST-Shotha (inflammation), PASV-PrasaranaAakunchanayohosavedanaa (painful movements), AT-Atopa / Sphutana (crepitation's), GR-Graha (stiffness), GNM-Goniometer, KF-Knee Flexion.

| Signs & Symptoms | Grades |
|------------------------------|--------|
| Normal / no signs & symptoms | 0 |
| Mild | 1 |
| Moderate | 2 |
| Severe | 3 |

[Knee Flexion [**]: Normal range-1300 – 1500, Knee Extension [***]: Normal range - 00 – 150]

* Average walking distance by a healthy person $\,$ - In India-4500 to 6533 steps/day (3 to 5 kms) (Short distance walk < 3 to 5 kms

< Long distance walk) In Hong Kong- 10000 steps / day (6 to 7 kms)Convert steps into kms.... www.healthline.comwww.mashable.comwww.mayoclinic.org.

Result:-

STATISTICAL ASSESSMENT OF RESPONSE IN 'GROUP-A'

EFFECT OF PANCHA TIKTA GHRITA GUGGULU

| | | Mean | | Differe | Percen | SE | T | P |
|------|---------------------|------|------|---------|--------|------|------|-------|
| s.n. | Lakshanas | BT | AT | nce in | tage | | | |
| | | | | Mean | | | | |
| 1 | Shoola | | 1.15 | 0.7 | 30 | 0.21 | 3.3 | 0.001 |
| 2 | Shotha | 0.9 | 0.3 | 0.6 | 57.143 | 0.19 | 3.13 | 0.002 |
| 3 | Prasaranaaakunchana | 1.7 | 0.9 | 0.8 | 38.889 | 0.25 | 3.18 | 0.001 |
| 4 | Atopa | 0.9 | 0.3 | 0.6 | 57.143 | 0.19 | 3.13 | 0.002 |
| 5 | Graha | 1.7 | 0.9 | 0.8 | 38.889 | 0.25 | 3.18 | 0.001 |
| 6 | Goniometer | | 0.25 | 0.6 | 58.333 | 0.21 | 2.9 | 0.003 |

Shoola: The initial mean score was 1.85 which reduced to 1.15 after treatment. The percentage of relief was 30% which was statistically significant at the level of 0.05

Shotha:The initial mean score was 0.9 which reduced to 0.3 after treatment. The percentage of relief was 57.143% which was statistically significant at the level of 0.05

Prasaranaakunchana: The initial mean score was 1.7 which reduced to 0.9 after treatment. The percentage of relief was 38.889% which was statistically significant at the level of 0.05

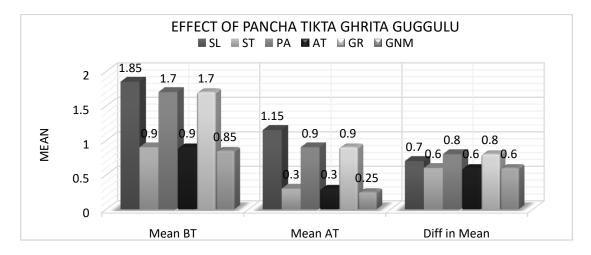
Atopa :The initial mean score was 0.9 which reduced to 0.3 after treatment. The percentage of relief was 57.143% which was statistically significant at the level of 0.05

Graha: The initial mean score was 1.7 which reduced to 0.9 after treatment. The percentage of relief was 38.889% which was statistically significant at the level of 0.05

^{**}https://www.scranton.edu.

^{***&}lt;u>https://www.benefits.va.gov</u>.

GNM: The initial mean score was 0.85 which reduced to 0.25 after treatment. The percentage of relief was 58.333% which was statistically significant at the level of 0.05



STATISTICAL ASSESSMENT OF RESPONSE IN 'GROUP-B'

EFFECT OF GANDHA TAILA

| | | | n | Differe | Percen | SE | Т | P |
|-----|---------------------|-----|------|---------|--------|------|------|-------|
| S.n | Lakshanas | BT | AT | nce in | tage | | | |
| | | | | Mean | | | | |
| 1 | Shoola | 1.5 | 1.05 | 0.45 | 25 | 0.2 | 2.2 | 0.017 |
| 2 | Shotha | 0.9 | 0.4 | 0.5 | 50 | 0.17 | 2.99 | 0.002 |
| 3 | Prasaranaaakunchana | | 0.75 | 0.65 | 36.842 | 0.21 | 3.11 | 0.002 |
| 4 | Atopa | | 0.55 | 0.55 | 47.368 | 0.17 | 3.27 | 0.001 |
| 5 | Graha | | 8.0 | 0.6 | 36.842 | 0.22 | 2.76 | 0.004 |
| 6 | Goniometer | | 0.4 | 0.4 | 38.462 | 0.19 | 2.08 | 0.022 |

Shoola: The initial mean score was 1.5 which reduced to 1.05 after treatment. The percentage of relief was 25 % which was statistically significant at the level of 0.05

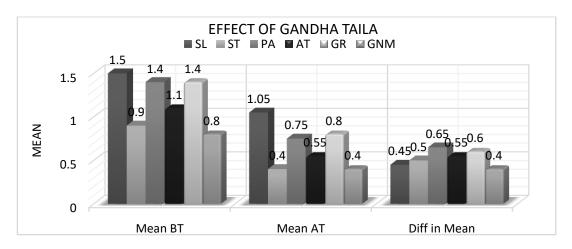
Shotha: The initial mean score was 0.9 which reduced to 0.4 after treatment. The percentage of relief was 50 % which was statistically significant at the level of 0.05

Prasaranaakunchana: The initial mean score was 1.4 which reduced to 0.75 after treatment. The percentage of relief was 36.842% which was statistically significant at the level of 0.05

Atopa: The initial mean score was 1.1 which reduced to 0.55 after treatment. The percentage of relief was 47.368% which was statistically significant at the level of 0.05

Graha: The initial mean score was 1.4 which reduced to 0.8 after treatment. The percentage of relief was 36.842% which was statistically significant at the level of 0.05

GNM: The initial mean score was 0.8 which reduced to 0.4 after treatment. The percentage of relief was 38.462% which was statistically significant at the level of 0.05



INTERGROUP COMPARISON OF RESPONSE BETWEEN 'GROUP-A' AND 'GROUP-B'

COMPARISON OF THE EFFECT OF TREATMENT IN BOTH THE GROUPS

| S.n | SS | Group A mean | | % of relief | Group B mean | | % of relief | Difference in % of relief |
|-----|---------------------|-----------------|------|-------------|-----------------|------|-------------|---------------------------------|
| | | BT | AT | | BT | AT | | Tellel |
| 1 | Shoola | 1.85 | 1.15 | 30 | 1.5 | 1.05 | 25 | 5 |
| 2 | Shotha | 0.9 | 0.3 | 57.143 | 0.9 | 0.4 | 50 | 7.143 |
| 3 | Prasaranaaakunchana | 1.7 | 0.9 | 38.889 | 1.4 | 0.75 | 36.842 | 2.047 |
| 4 | Atopa | 0.9 | 0.3 | 57.143 | 1.1 | 0.55 | 47.368 | 9.775 |
| 5 | Graha | 1.7 | 0.9 | 38.889 | 1.4 | 0.8 | 36.842 | 2.047 |
| 6 | Goniometer | 0.85 | 0.25 | 58.333 | 8.0 | 0.4 | 38.462 | 19.871 |

Shoola: In group-A the percentage of relief is 30% & In group-B the percentage of relief is 25%

Difference in % of relief between group-A and group-B is 5%

Hence group A is statistically significant by 5% than group-B

Shotha:In group-A the percentage of relief is 57.143% & **In group-B** the percentage of relief is 50%

Difference in % of relief between group-A and group-B is 7.143%

Hence group A is statistically significant by 7.143% than group-B

Prasaranaakunchana: In group-A the percentage of relief is 38.889% & **In group-B** the percentage of relief is 36.842%

Difference in % of relief between group-A and group-B is 2.047%

Hence group A is statistically significant by 2.047% than group-B

Atopa:In group-A the percentage of relief is 57.143% & **In group-B** the percentage of relief is 47.368%

Difference in % of relief between group-A and group-B is 9.775%

Hence group A is statistically significant by 9.775% than group-B

Graha:In group-A the percentage of relief is 38.889% & **In group-B** the percentage of relief is 36.842%

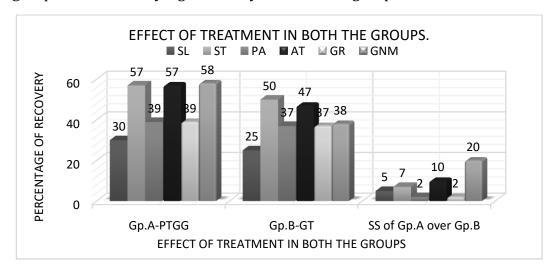
Difference in % of relief between group-A and group-B is 2.04 %

Hence group A is statistically significant by 2.047% than group-B

GNM :In group-A the percentage of relief is 58.333% & **In group-B** the percentage of relief is 38.462%

Difference in % of relief between group-A and group-B is 19.871%

Hence group A is statistically significant by 19.87% than group-B.



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Discussion:

The present study entitled "TO EVALUATE THE EFFICACY OF PANCHATIKTA GHRITA GUGGULU VATI AND GANDHA TAILA IN JANU SANDHIGATA VATA WITH SPECIAL REFERENCE TO OSTEOARTHRITIS OF KNEE JOINT"- A COMPARATIVE CLINICAL STUDYwas carried on 40 patients assigned into two groups viz. Group A & Group B respectively. Patients in group A were given panchatiktaghritagugguluvati as internal medicine whereas patients of group B were given gandhataila as internal medicine.

Discussion on disease:

Sandhi gatavata is one among the vatavyadhi which generally occurs in jaraavastha (old age) but can affect even in young & middle age due to vatavardhakaaahaaravihaara. The present study also revealed that many cases were registered from middle age group indicative of alarming rise in the incidence of sandhi gatavata prior to the actual phase of old age which draws more attention for better treatment that can be served through vata hara aahaaravihaara&oushadha.

Discussion on results:

Effect of treatment on Shoola :In group-A the percentage of relief is 30% &**In group-B** the percentage of relief is 25%, Difference in % of relief between group-A and group-B is 5%, Hence group A is statistically significant by 5% than group-B

Effect of treatment on Shotha : In group-A the percentage of relief is 57.143% & **In group-B** the percentage of relief is 50%, Difference in % of relief between group-A and group-B is 7.143%, Hence group A is statistically significant by 7.143 % than group-B

*Effect of treatment on Prasaranaakunchana :*In group-A the percentage of relief is 38.889 % & In group-B the percentage of relief is 36.842 %, Difference in % of relief between group-A and group-B is 2.047 %, Hence group A is statistically significant by 2.047 % than gp-B

Effect of treatment on Atopa : In group-A the percentage of relief is 57.143 % & In group-B the percentage of relief is 47.368 %, Difference in % of relief between group-A and group-B is 9.775 %, Hence group A is statistically significant by 9.775 % than group-B

Effect of treatment on Graha : In group-A the percentage of relief is 38.889 % & In group-B the percentage of relief is 36.842 %, Difference in % of relief between group-A and group-B is 2.047 %, Hence group A is statistically significant by 2.047 % than group-B

Effect of treatment on GNM: In group-A the percentage of relief is 58.333 % & In group-B the percentage of relief is 38.462 %, Difference in % of relief between group-A and group-B is 19.871 %, Hence group A is statistically significant by 19.871 % than group-B.

The overall assessment of data results in statistical significance of PTGG than GT, it is due to tikta rasa praadhaanyataa as it is known to relieve aama& moreover statistical significance may be because of more guggulu&ghrita in PTGGV.

Mode of Action of Drugs used in treatment -

The *pharmacodynamics*[How the drug behaves (Disintegration etc.) towards the body] of the drug depends on its physiochemical properties, which includes rasa, guna, veerya, vipaka, doshaghnata, prabhaava karma, etc., whereas the *pharmacokinetics* [How the body behaves (Absorption etc.) towards the drug] depends on the body condition like pravara, madhyama, avara etc.

Hypothetical explanation of mode of action of PTGGV - .

• The ingredients of PTGGV are madhura, TIKTA& Kashaya rasa pradhaana, laghurukshaguna, ushnaveerya, katuvipaka&vatakaphahara properties.

Hypothetical explanation of mode of action of GT -

• The ingredients of GT are madhura, katu, tikta& Kashaya rasa pradhaana, guru-snigdhaguna, ushnaveerya, katu&madhuravipaka&Tridoshaghna properties.

By overall considerations of the drugs used in the treatment disease, it is clear that – they possess vata hara properties which help in treating the disease & reducing the symptoms like pain, inflammation, restricted movements of the joints, crepitus & stiffness associated with janusandhigatavata. The guggulu used in both the drug combinations plays a vital role in curing the pain. The drugs used in PTGGV acts as shothahara&shoolahara (vedanasthapana). The ghrita used in PTGGV provides snehana property to joints, hence reducing crepitus & pain, easing to relieve the signs & symptoms, thus making the joint

more easily mobile whereas the taila by nature it provides SNEHANA property to the joints & thus helps in reliving the signs & symptoms & there by making the joint freely movable i.e.

The TilaTaila used in GT is being madhura, Kashaya, ushnaveerya&madhuravipaka acts as vatashamaka& moreover it serves the purpose of *asthistairyakara* as it is BRANHANA in nature. The padmakadiganadravyas used in the GT, also acts as shothahara&shoolahara.

Conclusion:-

- ▶ Janu sandhi gatavata is correlated with osteoarthritis of knee joint which is the most frequently affected joint as it has to bear the body weight. In this study it is observed that the middle age group [45 to 54 30 %] as well as the old age group [65 to 74 30 %] have equally suffered from JSGV. This rectifies that the modern life style has pushed the middle-aged generation towards the early manifestation of the disease. In this study it was observed that, the more no. of males got affected with left knee joint & females got affected with right knee joint OA. The overall effect of treatment in JSGV has shown statistically significant result at the level of 0.05 (P-0.05) in both the groups. But, the t value of both the groups revealed that, the patients in group A treated with PTGGV had better result than group B treated with GT. Moreover, the phytochemical analysis has zoomed that the PTGG is chemically more effective as it has flavonoids which is proved for analgesic & anti-inflammatory action.
- ➤ PanchaTiktaGhritaGuggulu can be further studied by comparing it with other formulations with larger sample size & longer duration

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{(charaka- 3 maasha = 3 grams) (sharangdharasanhita- 4 maasha = 3 grams)
(1 gunja = 1 ratti = 125 mg) 8 gunja = 1 maasha (1000 mg = 1 gm)}
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13. http://ayurmedinfo.com