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A COMPARATIVE STUDY TO CHECK THE EFFECTIVENESS OF CARDIOSPERMUM HALICACABUM OVER SIMILLIMUM IN IMPROVING THE QUALITY OF SLEEP IN PATIENTS HAVING CHRONIC OSTEOARTHRITIC PAIN.

1. INTRODUCTION

1.1. Osteoarthritis (OA):

Osteoarthritis (OA) is a degenerative joint disease, characterized by the deterioration of joint cartilage, which results in bones rubbing together and creating stiffness, pain, and impaired movement. ^{[4][5]} It shows a strong association with aging and is a major cause of pain and disability in the elderly.^[6]

Among the chronic rheumatic diseases, hip and knee osteoarthritis (OA) is the most prevalent and is a leading cause of pain and disability in most countries worldwide. Osteoarthritis of knee has a significant economic impact on our health system. It commonly affects the knee joint especially when the age advances.^[7]

1.2. <u>Sleep and sleep deprivation:</u>

Circadian and seasonal rhythms are essential factors of living organisms and their organelles. These biological rhythms are controlled by the central pacemaker, which is situated in the Suprachiasmatic Nucleus of the hypothalamus and communicate with the tissues through bidirectional neuronal and hormonal pathways.^[1]

Sleep disturbances are common symptoms in adults and are related to various factors, including the use of caffeine, tobacco, and alcohol; sleep habits; and comorbid diseases. ^[2] Among older adults, osteoarthritis is one of the most common comorbidities associated with poor sleep, affecting 50% of persons age 65 or older. In the United States, 60% of arthritis sufferers report pain during the night and pain secondary to arthritis is one of the most common factors predicting sleep disturbance in the population. It is well established that pain interferes with sleep and, in turn, that disturbed sleep reduces pain thresholds. ^[3]

1.3. <u>Cardiospermum halicacabum:</u> Cardiospermum halicacabum is commonly known as Balloon vine, found in tropical and subtropical areas of world. The roots, leaves, stem, and seeds of this plant are employed as herbal medication. ^[8] The leaves are rubefacient, they are applied as a poultice in the treatment of rheumatism. ^[9] It is an official drug of German Homoeopathic Pharmacopoeia where the mother tincture is made of flowering tops. ^[10]

Indications of Cardiospermum halicacabum:

Extremities: Arthritis pain. Swelling and pain of the extremities. Swelling of the joints. Swelling in the fingers, knees, and feet. Pain accompanied by sciatica. Stitching pain in the fingers and hips. Cramping in the legs.

Sleep: Restless sleep with frequent waking. Sleeplessness.^[11]

1.4. <u>Homoeopathic standpoint:</u>

Aphorism 153;"In this search for a homoeopathic specific remedy, that is to say, in this comparison of the collective symptoms of the natural disease with the list of symptoms of known medicines, in order to find among these an artificial morbific agent corresponding by similarity to the disease to be cured, the more striking, singular, uncommon and peculiar (characteristic) signs and symptoms1 of the case of disease are chiefly and most solely to be kept in view; for it is more particularly these that very similar ones in the list of symptoms of the selected medicine must correspond to, in order to constitute it the most suitable for effecting the cure. The more general and undefined symptoms: loss of appetite, headache, debility, restless sleep, discomfort, and so forth, demand but little attention when of that vague and indefinite character, if they cannot be more accurately described, as symptoms of such a general nature are observed in almost every disease and from almost every drug."

Aphorism 154; "If the antitype constructed from the list of symptoms of the most suitable medicine contain those peculiar, uncommon, singular and distinguishing (characteristic) symptoms, which are to be met with in the disease to be cured in the greatest number and in the greatest similarity, this medicine is the most appropriate homoeopathic specific remedy for this morbid state; the disease, if it be not one of very long standing, will generally be removed and extinguished by the first dose of it, without any considerable disturbance."^[12]

2. BACKGROUND & NEED FOR THE STUDY

Background:

The prevalence of OA is increasing day-by-day. I have seen many OA patients, having disturbed sleep due to the pain. I wanted to analyse the correlation between the quality of sleep and pain in OA patients. Since ancient days, the leaves of Cardiospermum halicacabum are used traditionally by Indians in the Siddha system of medicine, for treating arthritis and are found to produce a complete cure. ^[13] This gave me a spark to check the effect of Homoeopathic preparation of the same medicine in treating OA pain and also its effect in improving the sleep quality. This study is to be undertaken against this background.

3. <u>REVIEW OFLITERATURE</u>

3.1. Osteoarthritis (OA):

3.1.1. <u>Definition</u>: Osteoarthritis (OA) is a chronic degenerative disorder of multifactorial aetiology characterized by the loss of articular cartilage, hypertrophy of bone at the margins, subchondral sclerosis, and range of biochemical and morphological alterations of the synovial membrane and joint capsule. ^[14] Simply it can be defined as the slow, progressive, degenerative disease, affecting the articular cartilage of the joints and ultimately causing its destruction leading to disability. ^[15]

3.1.2. <u>Epidemiology:</u> There is a steady rise in the prevalence from age 30 such that by 65, 80% of people will have radiographic evidence of OA though only 25-30% is symptomatic.^[6] About 9.6% of men and 18.0% of women have symptomatic OA, among them 80% will have limitations in movement, and 25% cannot perform their major daily activities of life. ^[4] The prevalence of OA hip is 19.6% and 4.2% with radiographic and symptomatic OA respectively. The prevalence of OA knee is 25.4% and 15.4% with radiographic and symptomatic OA. The prevalence of OA foot is ranging from 0.1 to 61%. Some people have OA of multiple joints.^[16]

3.1.3. Causes:

The joint vulnerability and joint loading are the two major contributing factors for the development of OA. The risk factors of OA are:

- Demographic characteristic there is increased risk for aged females and the people from low socio-economic status; African-American race.
- Hereditary factor- high chance of inheritance in the later stages of life, if any one of the parents is having OA.
- Obesity and overweight- obesity cause overload to the already suffering joint. So, being overweight increases the risk of OA in weight bearing joints and also worsens the symptoms.
- Bone or joint shape more commonly involving hip and knee joints valgus / varus
- Injury / trauma
- Occupation and physical activity- people having an occupation that demands repetitive use their joints have higher risks than those with moderate physical activities. OA of hip and OA of knee & spine are more common among farmers and miners respectively. Sports persons are also at higher risk.
- Hormonal factors- oestrogen insufficiency, aromatase inhibitors.
- Nutritional and vitamin factors- recent studies show that milk intake is associated with less joint space narrowing. And the incidence was high in deficiency of vitamins D, K1 and E.^[6, 17]
- Increased BMD is associated with sub-chondral sclerosis than with joint space narrowing

3.1.4. Pathophysiology:

OA is a disease characterized by degeneration of cartilages. Cartilage has 80% matrix, 18% collagen and proteins, 1-2% chondrocytes. Normally, there is a balance between the matrix, and enzymatic activities of cartilage in dynamic remodelling of cartilage. In OA, this balance is altered. There is over-expression of degrading enzymes that leads to loss of collagen and proteoglycans in the matrix, in turn increasing the degradation of structural components of cartilage. The cartilage is vulnerable for injuries.

When the cartilage undergoes stress or injury, it develops fissuring leading to the formation of vertical clefts. Sclerosis of bone occurs with deposition of calcium pyrophosphate and calcium phosphate crystals in abnormal cartilage. Subchondral cyst develops from subchondral bone stiffness. Fibrocartilage produced at the joint margin undergoes endochondral ossification resulting in osteophyte formation. Bone remodelling and cartilage thinning alters the

shape of the bone. Hyperplasia and inflammatory changes takes place in the synovial membrane, because of which the synovial fluid becomes less viscous. ^[6]

Progression of osteoarthritis: The etiopathogenesis of osteoarthritis has been divided into three stages, as follows:

- Stage 1 Proteolytic breakdown of the cartilage matrix occurs.
- Stage 2 Fibrillation and erosion of the cartilage surface develop, with subsequent release of proteoglycan and collagen fragments into the synovial fluid.
- Stage 3 Breakdown products of cartilage induce a chronic inflammatory response in the synovium, which in turn contributes to further cartilage breakdown. ^[18]

3.1.5. Clinical features:

Symptoms:

- Pain
- Stiffness (brief in the morning <15minutes and after a period of rest)
- Restricted joint movements.
- Locking, or buckling of the joint especially in knee OA
- Heberden's and bauchard's nodes in generalised nodal OA

Signs:

- Swelling of joint
- Tenderness
- Pain on passive movement
- Palpable bony crepitus (sometimes audible) on joint movement
- Joint enlargement with irregular joint margins
- Limitation of joint movement
- Deformity
- Muscle weakness and wasting^{[6][17]}

3.1.6. Investigations:

Biochemical markers are potential indicators of OA that is non-invasive.

- Careful analysis of synovial fluid, mainly directed to leukocyte count and crystal detection, is still essential for diagnosis, but also for the evaluation of the levels of important markers of local inflammation, such as metalloproteinases and cytokines, which seem to be crucial in the pathogenesis of OA.
- OA markers may be determined in three biological fluids, serum, synovial fluid (SF) and urine. Obviously, since serum and urine are commonly available, their determination is easier in these fluids than in SF; however, SF offers information which better reflects local changes occurring in joints affected by OA.^[19]

3.1.7. Diagnosis:

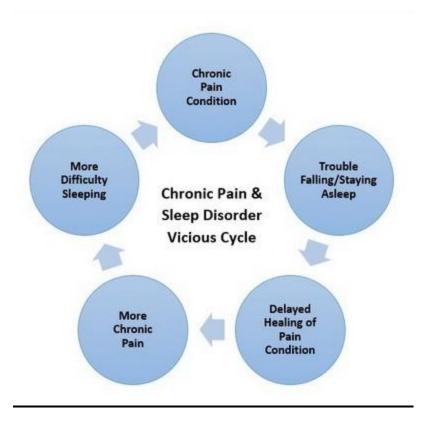
Diagnosis of a case is obtained by detailed history taking and based on the clinical presentation of the case. Further imaging methods like radiographs, MRI, etc. along with laboratory investigation findings help in confirming the diagnosis.

3.2. <u>Sleep disturbance and its effects on health:</u>

It is a well-known fact that sleep deprivation has an influential impact on health. It has shown to have an overall decrease in the positive effects when compared to a well-rested individual. There occurs a pathophysiological change in all the spheres of an individual when he is exposed to chronic sleep deprivation. It is worthy to note that the requirement of proper quantity as well as quality sleep at night is mandatory to maintain proper homoeostasis.^[1]

3.3. <u>Relationship between OA and chronic sleep disturbance:</u>

Sleep disorders in OA patients is related to pain, and women are the found to be most affected. ^{[20][21]} There are evidences that, chronic pain is the etiologic factor for sleep disorder in a general medical condition. ^[22] About 31% of OA patients have problems with sleep onset, 81% with sleep maintenance, and 51% with early morning awakenings. ^[23] Sleep and pain are bidirectional; pain can interfere with sleep and sleep disturbance can exacerbate pain. ^[24] In emerging researches, it has been found that OA pain has become centralized. This means that pain pathway becomes over excited and pain is amplified beyond the damage in the joint. ^[25]



3.4. <u>A Homoeopathic view on the relationship between osteoarthritis and chronic sleep</u> <u>disturbance:</u>

In the Organon of Medicine, Aphorism 4: The physician is likewise a preserver of health if he knows the things that derange health and cause disease, and how to remove them from persons in health.^[12]

In the Hahnemannian view, this association between sleep deprivation and osteoarthritis may be regarded as the fundamental cause of the disease. Such a fundamental cause i.e. the exited chronic miasm gets manifested as a chronic disease condition. Furthermore, such an obstacle to cure implies the relation as being a maintaining cause or the causa occasionalis of the disease. Thereby, it must be removed from the system so that the vital force could be completely receptive of the homoeopathic medications and obtain a complete cure. ^[12]

Dr. Hahnemann's view also states that "The awakening of the internal Psora which has hitherto slumbered and been latent, and as it were, kept bound by a good bodily constitution and favourable external circumstances, as well as its breaking out into more serious ailments and maladies, is announced by the increase of the symptoms given above as indicating the slumbering Psora, and also by a numberless multitude of various other signs and complaints.

Then when the itch-malady develops into a manifest secondary disease there appear the following symptoms which I have derived and observed altogether from accounts of disease which I myself have treated successfully and which confessedly originated from the contagion of itch, and were mixed neither with syphilis nor sycosis". He has explained about all sorts of rheumatic affections of joints under this. Also, explained about the difficulties to fall asleep due to nightly pains. ^[26]

According to H.A.Rberts's, accent of miasmas, OA is a tri-miasmatic disease (psorasyco-syphilitic) because in OA there is functional disturbance (psoric), osteophyte formation (sycotic) and degenerative changes in the joint cavity (syphilitic).

In H.A.Roberts' view, "The insomnia may be treated with crude palliative measures so that the patient secures sleep, but at best this is an unnatural sleep; while if the insomnia is considered as a part of his symptomatic picture, and given its proper place in that symptomatology and the man himself is treated-not alone one or two symptoms-he will gain his natural, refreshing sleep and he himself will be improved in general health.

Again, pain is one of the experiences from which human life has ever striven to free itself. The treatment of pain as a single trouble, and the fear of pain, has led to a wider use of narcotics than any other single factor. It is the cause of more drug addicts than can well be estimated. In a sympathetic attempt to relieve the patient from a temporary discomfort many a physician has been led to prescribe drugs, the initial effect of which is to relieve the suffering of the patient, but the lasting effects of which are to produce a drug addict.

Pain in itself is but a part of the symptom, however, for the physician must take into consideration the location: the kind of pain, whether steady or intermittent, and if intermittent, whether at regular intervals or upon motion, or is it dull, cutting, blunt or sharp, pressing, pulling, darting, cramping? Get at the type of pain as a characteristic symptom of the disordered condition; the times and circumstances of aggravation and amelioration, the reaction to thermic conditions, and all the concomitant symptoms that can be found. When the symptom of the pain

itself is complete, with the location, type, and aggravations and ameliorations, your picture is almost complete; but if in addition you can find those concomitants (which may lie in the conditions of aggravation or amelioration but which are often from seemingly unrelated symptoms) you have a sound basis for the selection of a remedy which will relieve the pain promptly, and the patient will be much more comfortable and happy in general than with any narcotic". ^[27]

Here, OA pain is considered as a maintaining cause for the sleep disturbance in those patients with OA. However, OA is a degenerative disorder which cannot be cured but can only be palliated. Also, sleep deprivation is not a disease by itself. If the cause/ reason for sleep deprivation are removed, then the patient is expected to get his usual normal sleep. But, the nature of the chronic disease is incurable here and hence; we are compelled to palliate the case with law of similars.

4. AIMS & OBJECTIVES

4.1. AIM

To evaluate the efficacy of Cardiospermum halicacabum in treating patients having OA pain and associated sleep disturbances.

4.2. OBJECTIVES

- To assess the Quality of Sleep in OA patients having chronic pain.
- To compare the effectiveness of Cardiospermum halicacabum over Simillimum in improving the quality of sleep in OA patients by reducing pain.

5. <u>METHODOLOGY</u>

5.1. STUDY SETTING

OA cases visiting OPD, IPD, and Rural centres of Sarada Krishna Homoeopathic Medical College.

5.2. SELECTION OF SAMPLES

- Sample size: 30 cases (Two groups-15 each)
- Sampling technique: Simple random sampling

5.3. INCLUSION CRITERIA

- Both male and female patients presenting with symptomatic OA or radiographic evidence of OA and sleep disturbance (PSQI screening Method).
- Age group: Above 45 years

5.4. EXCLUSION CRITERIA

- Patients with previous history of insomnia without OA.
- Patients having psychiatric disorders or other chronic systemic diseases.
- Acute illness causing sleep disturbances.

5.5. STUDY DESIGN

- A comparative study of Cardiospermum halicacabum over simillimum using structured questionnaire and scale.
- The study will carried out in Sarada Krishna Homoeopathic Medical College.

5.6. INTERVENTION

- Group I: Administration of Cardiospermum halicacabum as a specific remedy.
- Group II: Administration of simillimum.

5.7. SELECTION OF TOOLS

- Pre-structured SKHMC case format.
- WOMAC scale for OA
- A standard questionnaire for assessing sleep (Pittsburgh Sleep Quality Index)

5.8. DATA COLLECTION & INTERVENTION

- Data presentation using charts, diagrams and tables.
- After consultation with the statistical experts, the patients score will be determined.

5.9. ETHICALCONSIDERATION

- Ethical clearance was obtained from the Institutional ethical committee of SKHMC.
- Written informed consent was obtained from all the patients in this study.

5.10. BRIEF METHODOLOGY

30 cases diagnosed with OA along with associated sleep disturbance have been taken for the study after screening around 50 patients. They are divided into 2 groups, each comprising of 15 patients. Group I were administered with Cardiospermum halicacabum and Group II were given medicine based on symptoms similarity.

All the cases were recorded in the pre-structured SKHMC case format. Necessary investigations have been done. Each patient was given a standard questionnaire (PSQI) on the first visit to assess sleep quality. This questionnaire was translated to the patient's colloquial language. And the intensity of pain was measured using WOMAC scale (Western Ontario and Mcmaster Osteoarthritis Index). Every month the patient's pain intensity and sleep quality was observed and measured through direct interrogation or through telephone and the scoring was done. Prescription in group II was done according to totality of symptoms with reference to standard Materia medica text books also. Selection of potency and repetition of dose was done according to the principles laid down by Master Hahnemann in his Organon of medicine.

The data collected from the patients with the help of the pre-structurered case format and questionnaires were analysed and the scorings were done. The pre and post assessment were compared. Finally, the patients are analysed in terms of overall quality of night sleep, ability to perform the day-to-day activities, and the extent to which the pain has reduced.

6. <u>OBSERVATION & RESULTS</u>

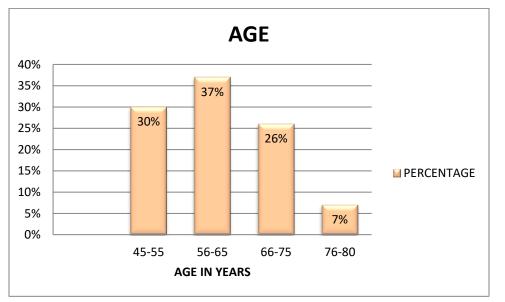
The data collected from 30 cases (2 group with15 cases each were included), who have attended the OPD, IPD, and rural centres of Sarada Krishna Homoeopathic Medical College, Kulasekharam, are given under this section. The observations were made and the results of this analysis are presented in the form of tables, diagrams and charts. The data collected from these patients were subjected to statistical analysis.

6.1. DISTRIBUTION OF CASES ACCORDING TO AGE:

Table 1:

AGE	GROUP I	GROUP II	
(in years)	(No. of cases)	(No. of cases)	PERCENTAGE
45-55	4	5	30%
56-65	6	5	37%
66-75	3	5	26%
76-80	2	0	7%

Chart 1:



Among the 30 cases, 9 patients (30%) were between the 45 - 55 years of age, 11 (37%) were between 56 - 65 years, 8 (26%) were between 66-75 years and 2 (7%) were between 76- 80 years of age. Maximum numbers of cases were from 56-65 years of age.

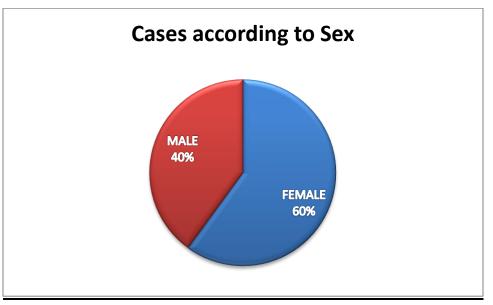
6.2. DISTRIBUTION OF CASES ACCORDING TO SEX

Table 2:

	GROUP I	GROUP II	
SEX	(No. of cases)	(no. of cases)	PERCENTAGE
FEMALE	12	6	60%
MALE	3	9	40%

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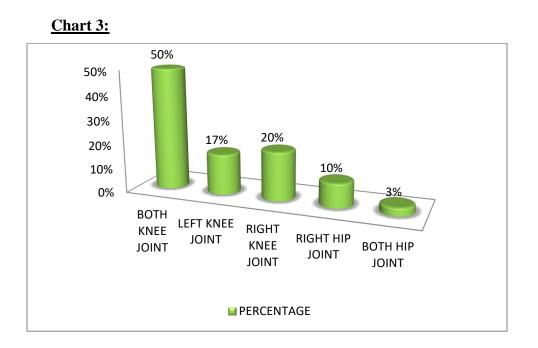


Among 30 cases, 18 of them were females (60%), and the remaining 12 were males (40%). This shows a female predominance.

6.3. DISTRIBUTION OF CASES ACCORDING TO JOINT LOCATION:

JOINT LOCATION	GROUP I (NO. OF CASES)	GROUP II (NO. OF CASES)	PERCENTAGE
BOTH KNEE JOINT	6	9	50%
LEFT KNEE JOINT	3	2	17%
RIGHT KNEE			
JOINT	4	2	20%
RIGHT HIP JOINT	1	2	10%
BOTH HIP JOINT	1	0	3%

Table 3:



Most of the patients out of 30 cases, suffered from osteoarthritis of both knee joint, about 15 cases (50%), 5 patients (17%) had OA of left knee joint, 6 patients (20%) had OA of right knee joint, 3 patients (10%) had OA of right hip joint and one patient (3%) had OA of both hip joint. About half of the sample size was affected with OA of both knees.

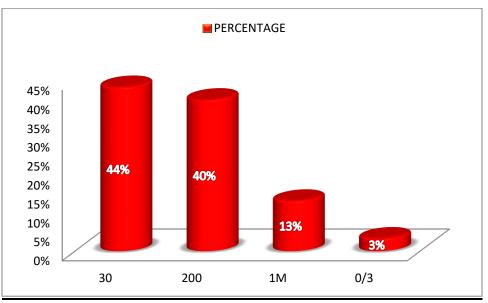
6.4. DISTRIBUTION OF CASES ACCORDING TO POTENCIES USED:

Table 4:

POTENCY	GROUP I	GROUP II	PERCENTAGE
30CH	6	7	44%
200CH	9	3	40%
1M	0	4	13%
0/3	0	1	3%

 $P_{age}1_{4}$





In GROUP I, only 30CH and 200CH has been used among which 30CH has been given for 6 cases (40%) and 200CH has been given for 9 cases (60%). Whereas in GROUP II 7 cases (47%) has been given medicines in 30CH, 3 cases (20%) has been given 200CH, 4 cases (26%) has been given 1M and 1 case (7%) was given 0/3 potencies respectively. On the whole 30CH potency has been widely used in 13 cases (44%), and 200CH potency is the next most commonly used in 12 cases (40%) in both GROUP I and GROUP II. 1M and 0/3 potencies where used only in GROUP II accounting for overall 113% and 3% respectively.

6.5. DISTRIBUTION OF CASES ACCORDING TO WOMAC SCALE IN GROUP I Table 5:

	BEFORE TREATMENT SCORE					AFTER TREATMENT SCORE				
PATIENT	PAIN	STIFFNESS	DIFFICULTY	OUT (84	DF	PAIN	STIFFNESS	DIFFICUTY	OUT 84	OF
1	7	4	24	35		4	2	15	21	
2	5	4	29	38		2	2	15	19	
3	8	3	27	38		4	2	9	15	
4	7	3	23	33		3	2	16	21	
5	11	4	28	43		3	3	17	23	
6	9	4	31	44		4	2	19	25	
7	12	2	33	47		7	0	21	28	

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8	11	3	36	50	5	2	20	28
9	10	4	36	50	6	3	17	26
10	10	7	34	51	4	4	16	24
11	11	2	38	51	6	1	14	21
12	10	4	39	53	3	2	21	26
13	13	6	42	61	7	4	21	32
14	15	2	46	63	8	2	23	35
15	15	6	44	65	6	4	20	30

6.6. DISTRIBUTION OF CASES ACCORDING TO WOMAC SCALE IN GROUP II

Table 6:

	BEFORE	TREATMENT	SCORE	AFTER TREATMENT SCORE					
PATIENT	PAIN	STIFFNESS	DIFFICULTY	OUT OF 84	PAIN	STIFFNESS	DIFFICUTY	OUT 84	OF
1	10	2	37	49	6	2	15	23	
2	10	4	38	52	7	2	27	36	
3	11	5	42	58	5	3	21	29	
4	15	3	47	65	7	2	24	33	
5	14	5	41	60	6	3	21	29	
6	8	4	26	38	4	2	16	22	
7	7	4	27	38	4	2	14	18	
8	7	3	27	37	3	1	14	14	
9	8	2	24	34	3	2	15	20	
10	11	3	28	42	5	2	16	23	
11	10	3	30	43	4	1	17	22	
12	12	1	34	57	8	1	20	29	
13	13	1	35	49	6	1	21	28	
14	9	3	37	49	4	2	15	21	
15	10	5	32	47	6	3	18	27	

Scoring in WOMAC scale was done by using 3 main parameters namely pain, stiffness, and difficulty in performing activities. Among these parameters, pain has a total score of 20, stiffness score is out of 8 and the score for difficulty is out of 56. The total score is out of 84.

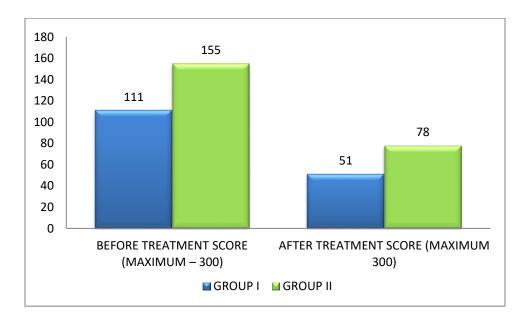
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6.7. COMPARING THE SCORES ACCORDING TO PAIN INTENSITY

Table 7:

	BEFORE TREATMENT SCORE (MAXIMUM – 300)	
GROUP I	111	51
GROUP II	155	78

Chart 5:



The maximum score for pain intensity is 300. In group I, before the treatment score was 111 which have reduced to 51 after the treatment. Similarly, in group II the score was 155 before treatment and came down to 78 after treatment.

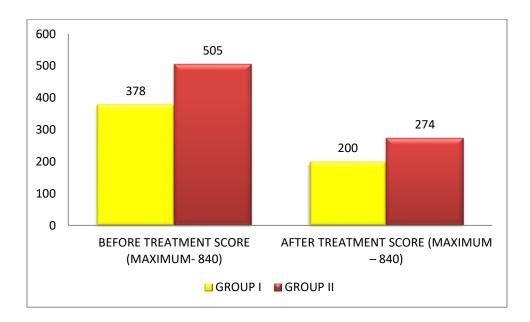
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6.8. COMPAING THE SCORES ACCORDING TO STIFFNESS

Table 8:

	BEFORE TREATMENT SCORE (MAXIMUM- 120)	AFTER TREATMENT SCORE (MAXIMUM – 120)
GROUP I	44	25
GROUP II	48	29

Chart 6:



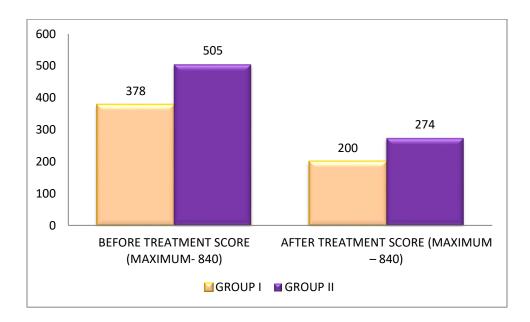
The maximum score for stiffness is 120. On comparing the before and after treatment scores for stiffness, in group I the score was 44 before treatment then came down to 25 after treatment. Similarly in group II the score was 48 before the treatment and reduced to 29 after the treatment.

6.9. COMPARING THE SCORES ACCORDING TO DIFFICULTY:

Table 9:

	BEFORE TREATMENT SCORE (MAXIMUM- 840)	AFTER TREATMENT SCORE (MAXIMUM – 840)
GROUP I	378	200
GROUP II	505	274

Chart 7:



The maximum score for difficulty is 840. In group I, before the treatment score was 378 that reduced to 200 after the treatment. In group II, the score was 505 before treatment that reduced to 274 after the treatment.

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6.10. DISTRIBUTION OF CASES ACCORDING TO PSQI SCALE IN GROUP I

TABLE 10:

Patients/	Before	Treatmen	t			After Treatment				
components	1	2	3	4	5	1	2	3	4	5
1	2	2	2	1	2	0	1	1	0	0
2	3	2	1	1	3	1	0	1	1	1
3	1	2	1	1	2	1	1	1	1	0
4	1	3	2	1	2	1	2	2	0	0
5	1	3	3	1	2	1	2	1	0	1
6	2	2	2	1	1	0	1	1	0	0
7	2	1	2	1	3	2	0	0	0	2
8	2	2	1	1	1	2	2	1	1	0
9	2	1	2	1	2	1	0	0	0	1
10	1	3	2	0	1	0	2	1	0	0
11	3	3	2	1	2	1	1	1	1	1
12	2	2	3	1	1	2	1	1	1	1
13	1	3	1	2	1	0	1	0	1	1
14	2	2	2	2	1	0	1	1	1	0
15	1	2	1	3	1	1	1	0	2	0

- Component 1: overall sleep quality
- Component 2: sleep latency
- Component 3: sleep duration
- Component 4: sleep disturbance
- Component 5: daytime dysfunction of activities

Each component is scored out of 3. All together for 5 components, the maximum score is out of 45.

TABLE 10.1:

COMPONENTS	BEFORE TREATMENT	AFTER TREATMENT
sleep quality	26	13
sleep latency	33	16
sleep duration	27	12
sleep disturbance	18	09
daytime dysfunction	25	09

6.11. DISTRIBUTION OF CASES ACCORDING TO PSQI SCALE IN GROUP II

TABLE 11:

Patients/	Before Treatment After			After Tr	reatment					
components	1	2	3	4	5	1	2	3	4	5
1	3	2	2	1	2	1	2	1	0	1
2	2	2	1	1	3	1	1	1	1	1
3	1	2	1	2	2	0	2	1	0	0
4	2	3	2	1	2	1	1	1	1	1
5	1	3	3	1	1	0	2	1	1	0
6	3	2	2	2	3	1	2	1	1	1
7	1	1	2	1	3	0	1	1	1	1
8	1	2	1	1	1	1	2	1	0	1
9	1	0	2	1	1	1	0	0	0	1
10	1	3	0	2	1	1	2	0	1	0
11	2	3	3	2	2	1	2	1	1	1
12	2	2	3	1	2	1	2	1	1	1
13	1	3	0	1	1	0	1	0	0	0
14	2	2	3	1	2	0	2	1	0	1
15	1	1	0	2	1	1	1	0	0	0

TABLE 11.1:

COMPONENTS	BEFORE TREATMENT SCORE	AFTER TREATMENT SCORE
sleep quality	24	10
sleep latency	31	23
sleep duration	25	11
sleep disturbance	20	8
daytime dysfunction	27	10

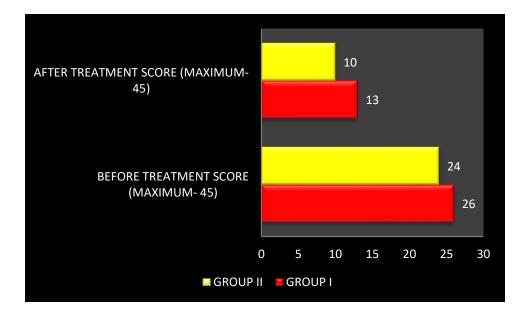
 ${}^{\rm Page}21$

6.12. COMPARING THE SCORE ACCORDING TO SLEEP QUALITY

Table 12:

	BEFORE TREATMENT SCORE (MAXIMUM- 45)	AFTER TREATMENT SCORE (MAXIMUM- 45)
GROUP I	26	13
GROUP II	24	10

<u>Chart 8:</u>



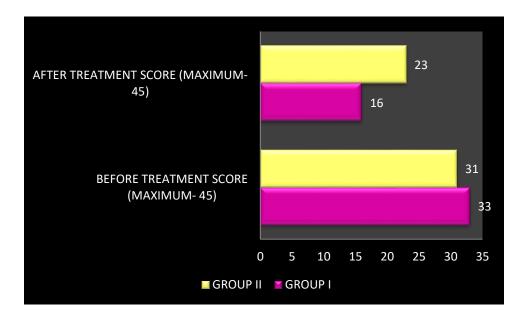
On comparing the scores for overall sleep quality out of 45, in group I before the treatment score was 26 and after the treatment score was 13. In group II before the treatment score was 24 and after the treatment score was 10.

6.13.COMPARING THE SCORE ACCORDING TO SLEEP LATENCY

Table 13:

	BEFORE TREATMENT SCORE (MAXIMUM- 45)	AFTER TREATMENT SCORE (MAXIMUM- 45)
GROUP I	33	16
GROUP II	31	23

Chart 9:



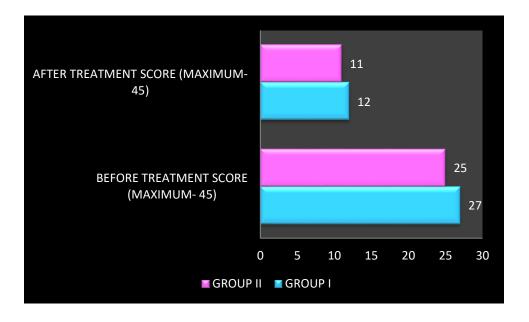
Out of maximum score of 45 for sleep latency, in group I before the treatment score was 33 which have reduced to 16 after the treatment. In group II the score obtained was 31 before the treatment that was reduced to 23 after the treatment.

6.14. COMPARING THE SCORE ACCORDING TO SLEEP DURATION

Table 14:

	BEFORE TREATMENT SCORE (MAXIMUM- 45)	AFTER TREATMENT SCORE (MAXIMUM- 45)
GROUP I	27	12
GROUP II	25	11

Chart 10:



The maximum score for sleep duration is 45. In group I the score obtained was 27 before the treatment that has come down to 12 after the treatment. Similarly in group II the score obtained was 25 before the treatment that has come down to 11 after the treatment.

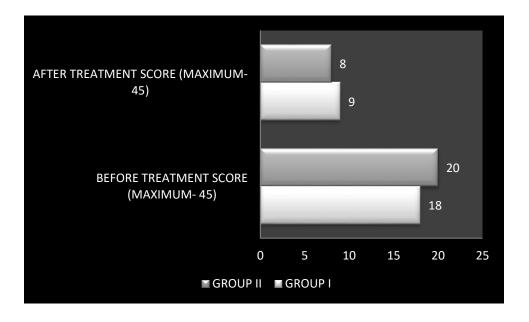
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6.15. COMPARING THE SCORE ACCORDING TO SLEEP DISTURBANCE

Table 15:

	BEFORE TREATMENT SCORE (MAXIMUM- 45)	AFTER TREATMENT SCORE (MAXIMUM- 45)
GROUP I	18	09
GROUP II	20	08

Chart 11:



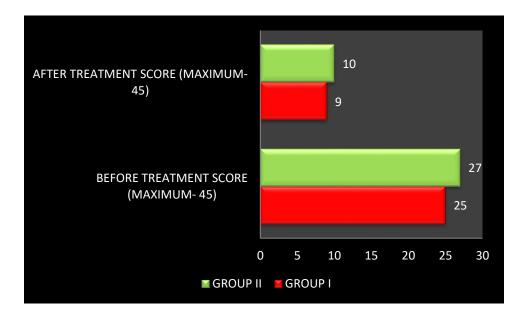
The maximum score for sleep disturbance is 45. In group I, score obtained before the treatment was 18 that reduced to 9 after the treatment. In group II, score obtained before the treatment was 20 that reduced to 8 after treatment.

6.16. COMPARING THE SCORES ACCORDING TO DAYTIME DYSFUNCTION

Table 16:

	BEFORE TREATMENT SCORE (MAXIMUM- 45)	AFTER TREATMENT SCORE (MAXIMUM- 45)
GROUP I	25	09
GROUP II	27	10

Chart 12

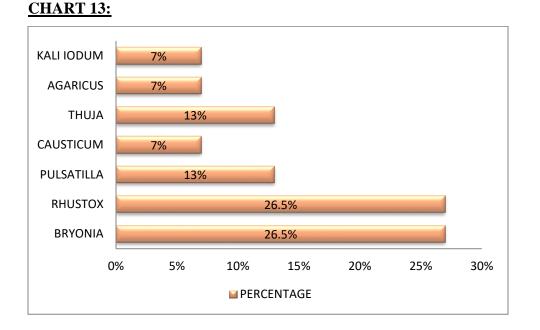


The maximum score for daytime dysfunction is 45. In group I, the score obtained before the treatment 25 that reduced to 9 after the treatment. In group II, the score obtained before the treatment was 27 that reduced to 10 after the treatment.

6.17. DISTRIBUTION OF CASES ACCORDING TO ADMINISTRATION OF MEDICINES IN GROUP II (SIMILLIMUM)

TABLE 17:

REMEDY	NO. OF CASES	%
BRYONIA	4	26.5
RHUSTOX	4	26.5
PULSATILLA	2	13
CAUSTICUM	1	7
THUJA	2	13
AGARICUS	1	7
KALI IODUM	1	7



In GROUP II, the 15 cases were given medicines according to symptom similarity. Among these 15 cases, for 4 cases (26.5%) were given Rhus tox, another 4 cases (26.5%) were given Bryonia. Thuja was given to 2 patients (13%) and so is Pulsatilla for 2 patients (13%). 1 patient (7%) was given Kali iodum, 1 patient (7%) was given Causticum and 1 patient (7%) was given Agaricus.

7<u>. STATISTICAL ANALYSIS</u> 8. DISSCUSSION

Osteoarthritis is one of the commonest diseases of the elderly people causing disabilities and difficulty in performing day to day activities of their life. OA being the comorbidity disease for sleep deprivation has made the patients to face problems in their night sleep. In this study, totally 30 cases were taken as the sample group where 45 - 55 age group (30%), and 56 - 65 age group (37%) were affected mostly. On analysis, the incidence of OA associated sleep disturbance was found to show female predominance females (60%).

There was a high incidence of OA of both knee joint (50%), and OA of left knee joint (20%) and right knee joint (17%) when the patients were grouped according to location of the affected joints. In both the groups 30CH potency (44%) has given more significant results compared to 200CH potency (40%).

In group II (simillimum), 7 medicines were used for 15 patients, among which Rhus tox (26.5%) and Bryonia (26.5%) showed equally good results.

9. CONCLUSION

10. <u>REFERENCES</u>

1. Colten HR, Altevogt BM. Sleep Physiology.

https://www.ncbi.nlm.nih.gov/books/NBK19956

2. Sleep disorders in the elderly: Diagnosis and management

Suzuki Keisuk, MD, PhD, Miyamoto Masayuki MD, PhD, and Hirata Koichi, MD, PhD

Journal of general and family medicine 2017 Apr; 18

3. McCurry M. Susan PhD,^{*} et al. Frequency of Co-Morbid Insomnia, Pain, and Depression in Older Adults with Osteoarthritis: Predictors of Enrollment in a Randomized Treatment Trial. Published online 2011 Jul 1.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3201756/

4. WHO Department of Chronic Diseases and Health Promotion. Available at: http://www.who.int/chp/topics/rheumatic/en/

5. Wittenauer Rachel, Smith Lily, and Aden Kamal. Osteoarthritis - World Health Organization. Priority Medicines for Europe and the World. "A Public Health Approach to Innovation". January 28 2013. <u>https://www.who.int/medicines/areas/priority_medicines/Ch6_12Osteo.pdf</u>

6. Davidson's Principles and practice of medicine. International edition, 20th edition. Churchill Livingstone Elsevier. Chapter: Musculoskeletal Disorders. Page no: 1096.

7. Oliveria SA, Felson DT, Reed JI, Cirillo PA, Walker AM. Incidence of symptomatic hand, hip, and knee osteoarthritis among patients in a health maintenance organization. Arthritis Rheum. 1995; 38:1134-41

8. Basker Tabitha, and S. Krishnamohan. "CARDIOSPERMUM HALICACABUM LINN. - A REVIEW". *Asian Journal of Pharmaceutical and Clinical Research*, Vol. 10, no. 10, Sept. 2017, pp. 23-26, doi:10.22159/ajpcr.2017.v10i10.20261

9. Ken Fern. Useful tropical plants database. Cardiospermum halicacabum L. <u>http://tropical.theferns.info/viewtropical.php?id=Cardiospermum+halicacabum</u>

10. Cardiospermum halicacabum. Schwabe News Volume 3 | Issue 2 | April 2012

https://www.schwabeindia.com/content/148-cardiospermum-halicacabum

11. Riley D.S. (2012) Cardiospermum halicacabum. In: Materia Medica of New and Old Homeopathic Medicines. Springer, Berlin, Heidelberg. DOI:

https://doi.org/10.1007/978-3-642-25292-1_18

12. Hahnemann S. Organon of medicine. New delhi: B. jain Publishers (P) Ltd; 2016.

13.Wilson Eugene, Rajamanickam GV, Vyas Neera, et al. Herbs used in Siddha medicine for arthritis- A Review. *Indian Journal of Traditional Knowledge*. Vol 7(1)-October 2007 pp687-686

14. Pal Prakash Chandra, Singh Pulkesh, Chaturvedi Sanjay, Pruthi Kumar Kaushal, and Vij Ashok, Epidemiology of knee osteoarthritis in India and related factors

Indian journal of Orthopaedics 2016 Sep; 50(5): 518–522 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5017174/

15.Motiwala FF, Kundu T, Bagmar K et al, Effect of Homoeopathic treatment on Activity of Daily Living (ADL) in Knee Osteoarthritis: A prospective observational study, *Indian Journal of Research in Homoeopathy* 2016; 10:182-7.

16. Allen D. Kelli and Golightly M. Yvonne, Epidemiology of osteoarthritis: state of the evidence, 2015 May

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4405030/

17. Harrison's principles of international medicine, 20th edition, Mc Graw Hill Education, Chapter-Disorders of joints and adjacent tissues - Osteoarthritis, page no. 2624 to 2628.

18. https://emedicine.medscape.com/article/330487-clinical

19. https://link.springer.com/article/10.1007/BF03327358

20. Parmelee, P. A., Tighe, C. A., & Dautovich, N. D. (2015). Sleep disturbance in osteoarthritis: linkages with pain, disability, and depressive symptoms. *Arthritis Care & Research* (Hoboken), 67(3), 358-365.

21. Kuralay Cigdem, Kayak Emine. Sleep Quality and Factors Affecting Patients with Knee Osteoarthritis. *International journal of caring science*. May-August 2018 Volume 2| Issue 2| Page 1141.

22. Fishbain DA, Cole B, Lewis JE, Gao J. What is the evidence for chronic pain being etiologically associated with the DSM-IV category of sleep disorder due to a general medical condition? A structured evidence-based review. *Pain Medicine*. 2010 Feb; 11(2):158-79.

23. Wilcox S, Brenes GA, Levine D, et al. Factors related to sleep disturbance in older adults experiencing knee pain or knee pain with radiographic evidence of knee osteoarthritis. *Journal of the American Geriatrics Society*. 2000 Oct; 48(10):1241-51.

24. Cheatle D. Martin et al. Assessing and Managing Sleep Disturbance in Patients with Chronic Pain. *Anesthesiology clinics*, ISSN: 1932-2275, Vol: 34, Issue: 2, Page: 379-393. Publication Year2016.

25. Osteoarthritis and sleep disruption. *Arthritis Foundation*. https://www.arthritis.org/living-with-arthritis/comorbidities/sleep-insomnia/osteoarthritis-and-sleep.php

26. Hahnemann S. The Chronic Diseases their peculiar nature and their Homoeopathic cure. New Delhi: B. Jain Publisher; 2017.

27. Roberts A. Herbert, The Principles and Art of Cure by Homoeopathy, B. Jain Publisers Pvt. Ltd.; 2017