

Effect of Homoeopathic treatment on Activity of Daily Living (ADL) in Knee Osteoarthritis: A prospective observational study

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Abstract

Objectives: To investigate the effect of individualized homoeopathic medicines in improving ADL by reducing pain, stiffness and limiting the disease progress. **Materials and Methods:** 131 consecutive patients with OA of knee were recruited and followed up for minimum period of twelve months. Two orthopaedic surgeons diagnosed the disease based on clinical examination of the patients. Three trained homoeopathic physicians prescribed individualized homoeopathic simillimum and the patients were evaluated for pain on WOMAC Osteoarthritis Index LK3.1 (IK) survey form measuring pain, stiffness and ADL. The pain was also measured on Numerical pain rating scale for confirmation. **Result:** Individualized homoeopathic medicines prescribed as per law of similia improved the mean ADL from 35.85 to 19.08 (p- 0.0001). Mean pain on WOMAC Osteoarthritis Index survey form improved from 10.50 to 5.48 (p-0.0001). The mean pain score on NRS improved from 6.34 to 3.77 (p-0.0001) and the mean morning stiffness also improved from 4.55 to 2.18 (p-0.0001). **Conclusion:** Homoeopathic medicines have potential to improve the ADL of OA patients by reducing pain and stiffness and limiting progress of the disease without any adverse systemic effects and can safely be employed as a comprehensive health care therapeutics.

Key words: Activity of daily living, Homoeopathy, Individualized Homoeopathic medicines, Osteoarthritis, Pain score

INTRODUCTION

Osteoarthritis (OA) is a slow, progressive, degenerative disease, affecting the articular cartilage of the joints and ultimately causing its destruction leading to disability. The most commonly affected joint is knee. Pain is a major complaint compelling patient to seek medical advice. Incidence of the joint being disabled is consistent with the period of individual's suffering. There is steady rise in the prevalence of the disease, and in the near future, it is projected to rank second for women and fourth for men, in terms of years lived with disability.^[1]

The exact incidence and prevalence of the disease are difficult to determine because the clinical syndrome of OA (pain and stiffness) does not always correspond to the structural change.^[2] The correlation between the radiological change and symptom is weak and is common for patients with radiological OA to have few or no symptoms, whereas classical symptoms of OA may occur in the absence of structural changes on radiograph.^[3]

The disease is associated with varying degree of functional limitation and reduced activity of daily living (ADL) and

accounts for more trouble with climbing stairs and walking than any other disorder. Eighty percent of people with the disease have some degree of limitation of movements and 25% cannot perform their major ADL.^[2] Nonadherence to the treatment is one of the major causes of increasing the disease burden which is driven by various factors such as illness stigma represented by increased pill loads, previous medication effectiveness, and fear of addiction or adverse reactions.^[4]

Besides the risks associated with pharmacological conservative care which include gastrointestinal bleeding, renal failure, and myocardial infarction, this regimen is successful in <50% of patients after 12 weeks and over 1 year, results in statistically significant but practically minor improvement in OA symptoms.^[5] The nonsteroidal anti-inflammatory drugs (NSAIDs) which are very frequently prescribed drugs for

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pain relief proved to be ineffective with no statistical difference detected between patients taking NSAIDs versus placebo.^[5] Thus, the conservative management of OA is neither clinically effective for pain nor cost-effective within the constraint of a patient. New treatment modalities for OA should be pursued.^[5] Homoeopathic medicines have been found effective in reducing pain and stiffness of the joints, with improvement in quality of life of a patient with rheumatoid arthritis (RA).^[6]

The primary objective of the study was to investigate the effect of individualized homoeopathic medicines in improving ADL by reducing pain, stiffness and limiting the disease progress.

MATERIALS AND METHODS

The prospective, observational study was carried out between February 2011 and February 2014 in the outpatient department of Motiwala Homoeopathic Medical College and Hospital, Nashik, Maharashtra, India. Ethical clearance was obtained from the Ethical Committee of Research Cell of Motiwala Homoeopathic Medical College. Two orthopedic physicians diagnosed the disease based on signs and symptoms and clinical examination. Three homoeopathic experts were assigned for prescribing homoeopathic medicines as per the Law of Similia.

Body mass index (BMI) was calculated by measuring individual's weight in kg and dividing his/her height in meter square (kg/m^2) to know the relation between incidence of disease and obesity.

BMI between 18.5 and 24.9 is classified as normal, between 25 and 29.9 as preobese/overweight, between 30 and 34.9 as obese Class I, between 35 and 39.9 as obese Class II, and more than 40 as obese Class III.

Inclusion Criteria

1. Patients aged 35 years or more
2. Patients diagnosed with OA clinically by two orthopedic physicians based on the symptoms of pain, stiffness, and swelling were recruited
3. Patients presenting with crepitus, osteophytes, restricted range of motion (ROM), joint line tenderness, and deformity (varus/valgus/fixed flexion deformity) on clinical examination were recruited for the study.

Exclusion Criteria

The patients with raised levels of serum uric acid, positive rheumatoid factor, and C-reactive protein (CRP) and with clinical evidence of psoriatic arthritis, i.e., presence or history of any psoriatic lesion were excluded from the study.

Participants

A total of 143 consecutive patients (35 years or above) from the outpatient department of Motiwala Homoeopathic Medical College and Hospital with complaints of pain, swelling of knee joint, and/or associated with the similar complaints in other big joint such as hip or shoulder and diagnosed as OA of the knee on clinical examination along with plain radiograph of

joints (if present) were recruited for the study. Informed consent was signed by patient himself/herself. A specific case record format (CRF) was filled for diagnosing the disease clinically and arriving at similitum. Symptoms such as persistent pain that is worse with use, morning stiffness lasting not more than half an hour, and gelling, i.e., inactivity pain were considered for clinical diagnosis. Examination of the joints for the presence of crepitus or osteophytes, restricted ROM, joint line tenderness, deformity (varus/valgus/fixed flexion deformity) was carried out. Complete blood count, erythrocyte sedimentation rate, RA, CRP, and serum uric acid were also performed to rule out inflammatory arthropathies such as RA, other connective tissue disorder, or Gout. Psoriatic arthritis was excluded with clinical evidence of skin lesion or history of the same. The presence or absence of radiological evidence of loss of joint space, osteophyte formation, subchondral bone thickening, or cyst formation was not considered much significant for diagnosis. Correlation between the radiological changes and symptoms is weak and follow-up radiographs were not taken as improvement in joint structure is rare once the condition has become established.^[7]

Therapy

Each individual patient was prescribed a single homoeopathic medicine (selected considering mental generals, physical generals, and particulars) at a time in one to three doses (one dose comprises four globules medicated with indicated medicine) depending upon the susceptibility of the patient and the nature of the medicine prescribed^[8] and documented in case recording format (CRF). The potency of the medicine was decided by individual susceptibility.^[8] Acutely, acting medicine for 2–3 days was prescribed when patient did not show any progress within next 2–3 days considering totality. Each individual patient was followed up at 1 month of interval or early if required. The conservative management (analgesics as required) was continued as it was.

Duration of Therapy

The consultations were made at 1 month of interval where the medicine selected as per the totality of symptoms was prescribed. During acute condition of pain, the medicine was selected considering the acute totality and having no inimical relation with the previously prescribed medicine. In case of acute condition, the consultations are made at 3–5 days of interval or early if required. Each patient was treated for minimum period of 12 months. The mean period of treatment was 27 months.

Assessment of the Progress

Each individual patient was assessed for pain, morning stiffness, and its impact on ADL. WOMAC survey form^[9] was used for the assessment of progress. The WOMAC OA Index LK3.1 (IK) survey form measures pain (0–16), stiffness of the joint (0–8), and ADL (0–68) based on questionnaires for each variable as mild, moderate, severe, and extreme. The changes in variable from one category to the subsequent lower one was considered as significant. The pain was also assessed on Numerical Rating Scale (NRS) (0–10).

Statistical Analysis

Student's *t*-test was employed for the statistical analysis of the data at 95% of confidence interval.

RESULTS

A total of 131 patients (107 females and 24 males) completed the study. Two percent of patients were found below the age of 40 years, 29% of patients found between 41 and 50 years, and maximum, i.e., 37% of patients found between 51 and 60 years whereas 21% of patients between the age group 61–70 years had the disease and 11% of patients age group between 71 and 80 years. Eighty-two percent of females were found to have the disease compared to males (18%).

Knee joint was observed to be commonly affected as 98.47% of patients had OA knee, of which 76.33% had bilateral knee OA and 22.13% had OA of any one side. 7.63% patients had hip OA and only 2.29% patients were observed to have shoulder OA.

Obesity was also found to be one of the factors responsible for aggravating joint destruction as only 16.03% of patients were found to have normal BMI. 5.34% of patients were overweight, 34.35% patients were preobese, 40.45% patients had Class I obesity, and 3.8% patients were observed to have Class II obesity [Table 1].

The mean pain score with WOMAC OA Index LK3.1 survey form improved from 10.50 to 5.48 and on NRS improved from 6.34 to 3.77. The mean stiffness improved from 4.55 to 2.18 and the mean ADL improved from 35.85 to 19.08 [Tables 2 and 3].

Table 1: Distribution of obesity among various age groups

Age group (in years)	Overweight	Preobese	Obesity Class I	Obesity Class II
≤40	-	1	-	-
41-50	3	24	11	-
51-60	2	11	22	1
61-70	-	6	15	3
71-80	2	1	3	1
In percentage	5.34	34.35	40.45	3.8

Table 2: Changes in pain score, morning stiffness, and activities of daily living before and after homoeopathic medicines

Pair	Paired sample	Mean	SD	SEM
Pair 1	Pain before (WOMAC pain scale)	10.50	3.39	0.30
	Pain after	5.48	2.67	0.23
Pair 2	Stiffness before	4.55	1.57	0.14
	Stiffness after	2.18	1.16	0.10
Pair 3	ADL before	35.85	9.42	0.82
	ADL after	19.08	8.86	0.77
Pair 4	NRS before	6.34	1.30	0.11
	NRS after	3.77	1.08	0.09

SD: Standard deviation; SEM: Standard error of mean; ADL: Activities of daily living; NRS: Numerical Rating Scale

Pulsatilla and *Lycopodium* were prescribed in 12 patients as a constitutional similimum; *Calcarea Flour* was prescribed in fifteen patients; *Calcarea Carb* and *Bryonia* each were prescribed at 11 occasions; *Rhus tox*, *Kali Carb*, and *Natrum Mur* were indicated in eight patients; *Kali Sulph*, *Mag Mur*, *Lachesis*, *Silicea*, *Sulfur*, and *Phosphorus* each were prescribed in four patients; *Staphysagria*, *Ignatia*, and *Graphitis* were prescribed at nine occasions; *Arsenic Album*, *Tuberculinum*, *Carcinocin*, *Calcarea Sulph*, *Natrum Phos*, *Sepia*, *Mag Carb*, *Ferrum Phos* and *Kali Bichromicum*, *Medorrhinum*, and *Belladonna* were indicated in one patient each as a constitutional similimum [Figure 1]. *Arnica Montana*, *Rhus tox*, *Bryonia alba*, *Ruta*, and *Belladonna* were prescribed during acute episodes if the condition did not improve within next 2 days of prescribing constitutional medicine. All the medicines were prescribed in 6C, 30C, and 200C raising potency to 1M as per the susceptibility of the individual patient. The medicine was changed when patient did not show improvement in the general or physical complaints on two successive follow-ups in spite of raising the potency, following Gibson Miller remedy relationship chart.^[10] Placebo was continued as long as improvement continued once constitutional similimum was prescribed.

DISCUSSION

OA, a destructive joint diseases causing limited mobility, is the most common cause of arthritis and one of the leading causes of disability worldwide. Each year, 2 million people visit their general practitioner for complaints of OA.^[11] People with OA experience varied degree of disability or limited motion as a consequence of their symptoms which further affect the daily activities of the patients. A holistic approach to care considers the global needs of an individual, taking into account social and psychological factors that have an effect on their ability to carry out ADL.^[7] Homoeopathic system of therapeutics considers an individual's emotional, psychological aspect along with its disease manifestations to arrive at similimum and hence can be employed in such condition to improve the ADL by reducing the disease symptoms. The present study is an attempt to investigate the effect of individualized homoeopathic medicines in reducing pain and stiffness and limiting the disease progress, thereby improving the ADL.

The most common joint found to be affected was knee joint which is considered as a major weight-bearing joint. The literature was confirmed by observing the increased prevalence of the disease among females (82%) than males (18%). Highest numbers of patients, i.e., 37% were found among the age group between 50 and 60 years, which is considered as the postmenopausal age of a female. This correlates the incidence of the disease with menopause or impaired calcium metabolism. The increased load or weight on these weight-bearing joints in terms of obesity is one of the contributing factors for the progress of joint destruction.^[1] It was found to be one of the contributing factors in joint

destruction as 34.35% of patients found to have condition of preobesity, 40.45% of patients found to belong to Class I obesity, and 3.8% of patients had Class II obesity, whereas 5.34% of patients were overweight. This shows the higher incidence of the disease in people having obesity. Moreover, only 16.03% of people had normal BMI.

OA predominantly affects older people and often coexists with other conditions associated with aging and obesity, such as cardiovascular diseases, diabetes, common sensory deficit (e.g., poor vision), and psychological problems such as anxiety, depression, and social isolation,^[7] and many pharmacological preparations are poorly tolerated. Homoeopathic medicines when employed as constitutional similimum, many symptoms associated with disease such as gastralgia (34 patients), sleeplessness (42 patients), cervical spondylitis (12 patients), hemorrhoids (26 patients), vertigo (6 patients), eczema (3 patients), frequency of urination (11 patients), constipation (20 patients), asthma (8 patients), dermoid cyst (1 patient) improved proving it to be holistic care therapeutics [Figure 2]. Diabetes and hypertension were also found to be present in majority of cases. These were revealed during interrogation with the patients and were not the primary complaint of the patients as the modern conventional medicines were being consumed by them. These diseases though not presented as chief complaints of the patients were observed to be under control on evaluation with individualized homoeopathic medicines as an adjunct to conventional therapy.

The present study elicited the potential of individualized homoeopathic medicines in improving ADL of patients

with OA by reducing pain and stiffness of the affected joint. However, the study could not find out the effect of homoeopathic medicines on progress of joint destruction as radiographic images of the affected joint were not taken.

The patients were followed up for 3 years which is a small period to assess the progress of disease as disease progression in OA is a slow process and occurs over years or decades. The rate of progression is variable between individual, and many patients with clinical evidence of OA may not suffer appreciable progression either by symptoms or radiographic changes.^[1] Patients with such chronic disease are subject to change the therapy very often on account of their sufferings. Although the period of therapy is small to assess the progress of the disease but in comparison to period of continuation of treatment with other therapies in general, mean period of treatment to a specific alternative therapy of 27 months is a satisfactory period of treatment. This long-term adherence to a therapy with substantial relief in pain and improvement in ADL signifies the clinical effect of homoeopathic medicines. Patient did not stop receiving conservative management (analgesics) if required; hence, the present study could not differentiate whether the results obtained are purely the effect of homoeopathic medicines. Hence, a controlled clinical trial comparing the effects analgesics or conventional therapy with that of Homoeopathic medicines over long period is warranted.

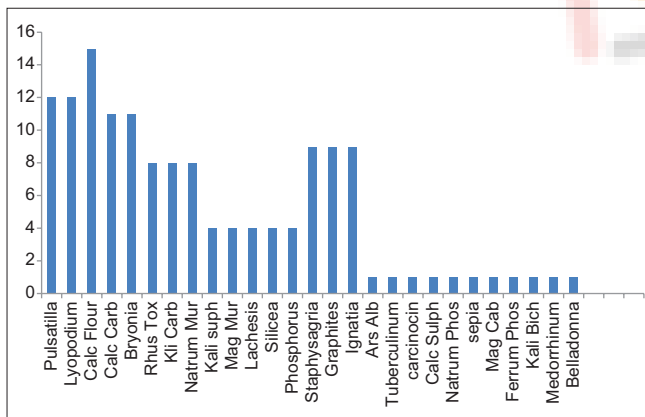


Figure 1: Medicine used in 131 patients with osteoarthritis

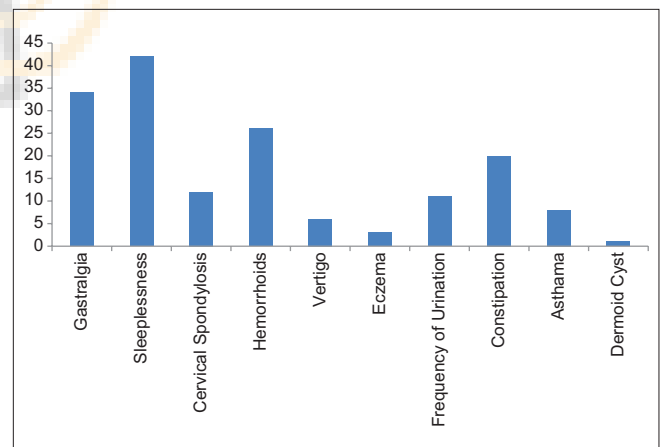


Figure 2: Distribution of associated complaints in 131 patients with osteoarthritis

Table 3: Student's t-test: Analysis of paired differences

Pair	Paired difference	Descriptive statistics of paired difference			95% CI of the difference		Paired samples t-test		
		Mean	SD	SEM	Lower	Upper	t-test value	df	P
Pair 1	Pain (before-after) WOMAC scale	5.023	2.561	0.224	4.58	5.466	22.44	130	0.0001
Pair 2	Stiffness (before-after)	2.366	1.437	0.126	2.118	2.615	18.85	130	0.0001
Pair 3	ADL (before-after)	16.771	8.407	0.734	15.318	18.224	22.83	130	0.0001
Pair 4	NRS (before-after)	2.565	1.171	0.102	2.363	2.767	25.07	130	0.0001

SD: Standard deviation; SEM: Standard error of mean; ADL: Activities of daily living; NRS: Numerical Rating Scale; CI: Confidence interval

CONCLUSION

Homoeopathic medicines are potential enough to improve the ADL of patients, by reducing pain and stiffness and limiting progress of the disease without any adverse, systemic effect and can safely be employed as a comprehensive health-care therapeutic.

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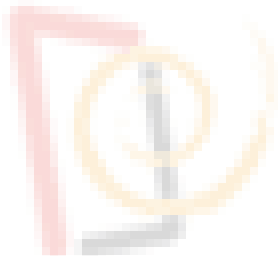
Nil.

Conflicts of Interest

There are no conflicts of interest.

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होम्योपैथी की औषधियों द्वारा घुटने के अस्थिसंधिशोध (ओस्टियोआर्थराइटिस) रोगियों की दैनिक जीवन गतिविधियों (एडीएल) में सुधार: एक पर्यवेक्षणीय अध्ययन

उद्देश्य: दर्द, जकड़न को कम करने और रोग की प्रगति को सीमित करने के द्वारा दैनिक जीवन गतिविधियों (एडीएल) को सुधारने में व्यक्ति-अनुसार होम्योपैथी औषधियों के प्रभाव की जांच करना।

सामग्री और विधि: घुटने के अस्थिसंधिशोध से पीड़ित 131 सिलसिलेवार रोगियों को नामांकित किया गया और कम से कम बारह माह की अवधि के लिए निरीक्षण में रखा गया। रोगियों के लाक्षणिक परीक्षण के आधार पर हड्डियों के दो शल्य-चिकित्सकों द्वारा रोग का निरूपण किया गया। तीन प्रशिक्षित होम्योपैथिक-चिकित्सकों द्वारा व्यक्ति-अनुसार होम्योपैथिक सिमिलिमम लेने की सलाह दी गयी और रोगियों का दर्द, जकड़न और एडीएल को मापने वाले वोमैक अस्थिसंधिशोध सूचकांक एलके 3.1 (आईके) सर्वेक्षण फॉर्म के आधार पर दर्द के लिए आंकलन किया गया। पुष्टि के लिए दर्द को संख्यात्मक दर्द निर्धारण स्तर पर भी मापा गया।

परिणाम: सिमिलिया के नियम के अनुसार दी गयी व्यक्ति-अनुसार होम्योपैथिक औषधियों से औसत एडीएल में 35.85 से 19.08 (पी=0.0001) का सुधार हुआ। वोमैक अस्थिसंधिशोध सूचकांक सर्वेक्षण फॉर्म पर औसत दर्द में 10.50 से 5.48 (पी=0.0001) का सुधार हुआ। एनआरएस पर औसत दर्द अंक में 6.34 से 3.77 (पी=0.0001) का सुधार हुआ और सुबह को होने वाली जकड़न में भी 4.55 से 2.18 (पी=0.0001) का सुधार हुआ।

निष्कर्ष: होम्योपैथिक औषधियों में दर्द और जकड़न को कम करने और बिना किसी हानिकर प्रणालीगत प्रभावों के रोग की प्रगति को सीमित करने के द्वारा रोगियों के एडीएल में सुधार करने की पर्याप्त क्षमता है और उन्हें व्यापक स्वास्थ्य देखभाल चिकित्सा के रूप में सुरक्षित रूप से प्रयोग में लाया जा सकता है।

Mejoramiento la capacidad de realizar las actividades cotidianas (CAC) en los pacientes de osteoartritis de rodilla con medicamentos homeopáticos: estudio prospectivo observacional

RESUMEN

Objetivos: Investigar el efecto de los medicamentos homeopáticos individualizados en mejorar la CAC al reducir el dolor y la rigidez, así como limitar la progresión de la enfermedad.

Materiales y métodos: Se incluyeron 131 pacientes consecutivos con una OA de rodilla y se efectuó un seguimiento durante un periodo mínimo de 12 meses. Dos cirujanos ortopedas diagnosticaron la enfermedad a partir de la exploración clínica de los pacientes. Tres homeópatas capacitados prescribieron el similimum homeopático individualizado. Los pacientes fueron evaluados en cuanto al dolor con el cuestionario del Índice de Artrosis WOMAC LK3.1 (IK) que mide el dolor, la rigidez y la CAC. A modo de confirmación, también se midió el dolor con la escala numérica de valoración del dolor (*NRS, Numerical pain rating scale*).

Resultado: Medicinas homeopáticas individualizadas fueron prescritos de acuerdo con la ley de similia que mejoró la media ADL 35,85-19,08 ($p < 0,0001$). El dolor medio en el cuestionario del Índice de Artrosis WOMAC mejoró de 10,50 a 5,48 ($p < 0,0001$). La puntuación media del dolor en la NRS mejoró de 6,34 a 3,77 ($p < 0,0001$) y la rigidez matutina media también mejoró de 4,55 a 2,18 ($p < 0,0001$)

Conclusiones: Los medicamentos homeopáticos tienen la suficiente potencia como para mejorar la CAC de los pacientes reduciendo el dolor y la rigidez, así como limitando la progresión de la enfermedad sin ningún efecto sistémico adverso. Pueden administrarse con seguridad en el tratamiento integral de la salud.

